

# Positive Effects of Practical Nutrition Lessons in a Primary School Setting with a High Proportion of Migrant School Children

## Authors

Katharina S. Weber<sup>1, 2</sup>, Jessica Eitner<sup>1, 2, 3</sup>, Laura Dauben<sup>1, 2</sup>, Olaf Spörkel<sup>1, 2</sup>, Klaus Strassburger<sup>2, 4</sup>, Jörn Sommer<sup>5</sup>, Barbara Kaiser<sup>6</sup>, Anette E. Buyken<sup>7</sup>, Peter Kronsbein<sup>3</sup>, Karsten Müssig<sup>1, 2, 8</sup>

## Affiliations

- 1 Institute for Clinical Diabetology, German Diabetes Center at Heinrich Heine University, Leibniz Institute for Diabetes Research, Düsseldorf, Germany
- 2 German Center for Diabetes Research (DZD), München-Neuherberg, Germany
- 3 Department of Nutritional Science and Home Economics, Faculty of Food, Nutrition and Hospitality Sciences, Hochschule Niederrhein, University of Applied Sciences, Mönchengladbach, Germany
- 4 Institute for Biometrics and Epidemiology, German Diabetes Center at Heinrich Heine University, Leibniz Institute for Diabetes Research, Düsseldorf, Germany
- 5 InterVal GmbH, Berlin, Germany
- 6 Federal Centre for Nutrition (BZfE), Bonn, Germany
- 7 Institute of Nutrition, Consumption and Health, Faculty of Natural Sciences, University Paderborn, Germany
- 8 Division of Endocrinology and Diabetology, Medical Faculty, Heinrich Heine University, Düsseldorf, Germany


c/o Auf'm Hennekamp 65

D-40225 Düsseldorf

Germany

Tel.: +49/211/3382 218, Fax: +49/211/3382 690

karsten.muessig@ddz.uni-duesseldorf.de

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## ABSTRACT

**Background** Children with migration background are at increased risk for overweight, partly due to less favorable dietary habits compared to their German counterparts. We examined the effects of practical nutrition lessons among children with a high proportion of migration background in a primary school setting.

**Methods** Ten 3<sup>rd</sup> and 4<sup>th</sup> grade classes (n = 166 children, 73 % with migration background) received the intervention and nine school classes (n = 139 children, 76 % with migration background) served as control. Before, shortly after (only among the intervention group) and three months after the three-day practical nutrition lessons, the nutrition-related skills, behavior, attitudes, and knowledge of the children were assessed using a questionnaire. Changes between baseline and 1<sup>st</sup> follow-up among children of the intervention group were calculated using linear mixed models. Differences between the two groups for changes between baseline and 2<sup>nd</sup> follow-up were tested using linear regression analyses. Models were adjusted for potential confounders.

**Results** Shortly after the practical nutrition lessons, the children of the intervention group had improved their knowledge ( $\beta = 1.7$ ; 95 % CI: 1.0; 2.4,  $P < 0.001$ ) and skills ( $\beta = 1.8$ ; 95 % CI: 1.4; 2.2,  $P < 0.001$ ). These changes were sustainable and larger in the intervention compared to the control group (knowledge:  $\beta = 1.6$ ; 95 % CI: 0.7; 2.5,  $P < 0.001$ ; skills:  $\beta = 1.3$ ; 95 % CI: 0.7; 1.9,  $P < 0.001$ ). Changes in nutrition-related behavior and attitudes did not differ between the groups.

**Conclusions** Providing practical nutrition lessons in a primary school setting with a high proportion of children with immigrational background improved the children's nutrition-related knowledge and skills.

## Key words

lifestyle intervention, prevention, migration background

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## Correspondence

Prof. Dr. Karsten Müssig

Institute for Clinical Diabetology

German Diabetes Center

Division of Endocrinology and Diabetology

Medical Faculty, Heinrich Heine University

Düsseldorf

## Introduction

Based on data of a German health survey, the prevalence of overweight and obesity not only doubles during primary school time, but is even higher among children with migration background in comparison to their German counterparts [1]. This might be in part explainable by a less favorable dietary behavior, i. e. higher consumption of foods rich in sugar and fat, of these children [2]. National and European Union (EU)-wide school-based intervention programs with the aim to promote healthy lifestyles and to prevent overweight and obesity among primary school children revealed a divergent responsiveness of the children depending on their origin and the socio-economic status (SES) of their family [3–5]. While a school-based health promotion program only reduced the prevalence and four-year incidence of overweight among children from families with a high SES [5] and a school-based prevention program promoting water consumption was only effective in children without migration background [4], the EU-wide school-based fruits and vegetables program increased the consumption and knowledge on these foods specifically among children living in difficult social conditions [3].

We have previously shown that a school-based intervention offering weekly guided physical activity lessons for 3<sup>rd</sup> and 4<sup>th</sup> grade primary school children with a high proportion of migration background improved the children's fitness and motor skills [6]. However, ten lessons of nutritional education per school year, provided by the teachers and conducted based on child-oriented paper-based material specifically developed for this intervention did not change the children's self-reported food consumption frequencies or dietary knowledge when compared to children not receiving the intervention [6]. Thus, the dietary intervention was modified, now comprising an evaluated three-day curriculum of practical nutrition lessons [7] conducted by dietician trainees.

The aim of the present study was to evaluate the effects of a school-based intervention providing practical nutrition lessons for 3<sup>rd</sup> and 4<sup>th</sup> grade primary school children with a high proportion of migration background. We hypothesized that this education improves the self-reported nutrition-related skills, behavior, attitudes, and knowledge of the children participating in the intervention in comparison to 3<sup>rd</sup> and 4<sup>th</sup> graders not receiving the intervention, but with a comparable percentage of migration background.

## Materials and Methods

### Study population

The newly implemented nutrition lessons within the initiative 'SMS. Sei schlau. Mach mit. Sei fit.' ['Be smart. Join in. Be fit.'] (<http://www.sms-mach-mit.de/>) were evaluated within a controlled, non-randomized intervention trial in a primary school-based setting (German Clinical Trials Register: DRKS00005119). The evaluation was approved by the ethics committee of Heinrich Heine University Düsseldorf and performed according to the Declaration of Helsinki. The parents gave written informed consent prior to the participation of their children. The evaluation was performed between 02/2016 and 06/2016 in the ten 3<sup>rd</sup> and 4<sup>th</sup> grade primary school classes from eight schools participating in the SMS initiative during that school year. For each of these intervention classes, one 3<sup>rd</sup>

or 4<sup>th</sup> grade class of the same school was chosen as control class (► **Fig. 1**). Of note, for one intervention class, no suitable control class was available so that only nine classes from seven schools were assigned to the control group (► **Fig. 1**, ► **Table 1**). The target group of the SMS initiative comprises children with an increased need for support for a balanced lifestyle and the prevention of lifestyle-related diseases [6]. This is reflected by the high proportion of children with migrant background in the present study cohort (► **Table 1**).

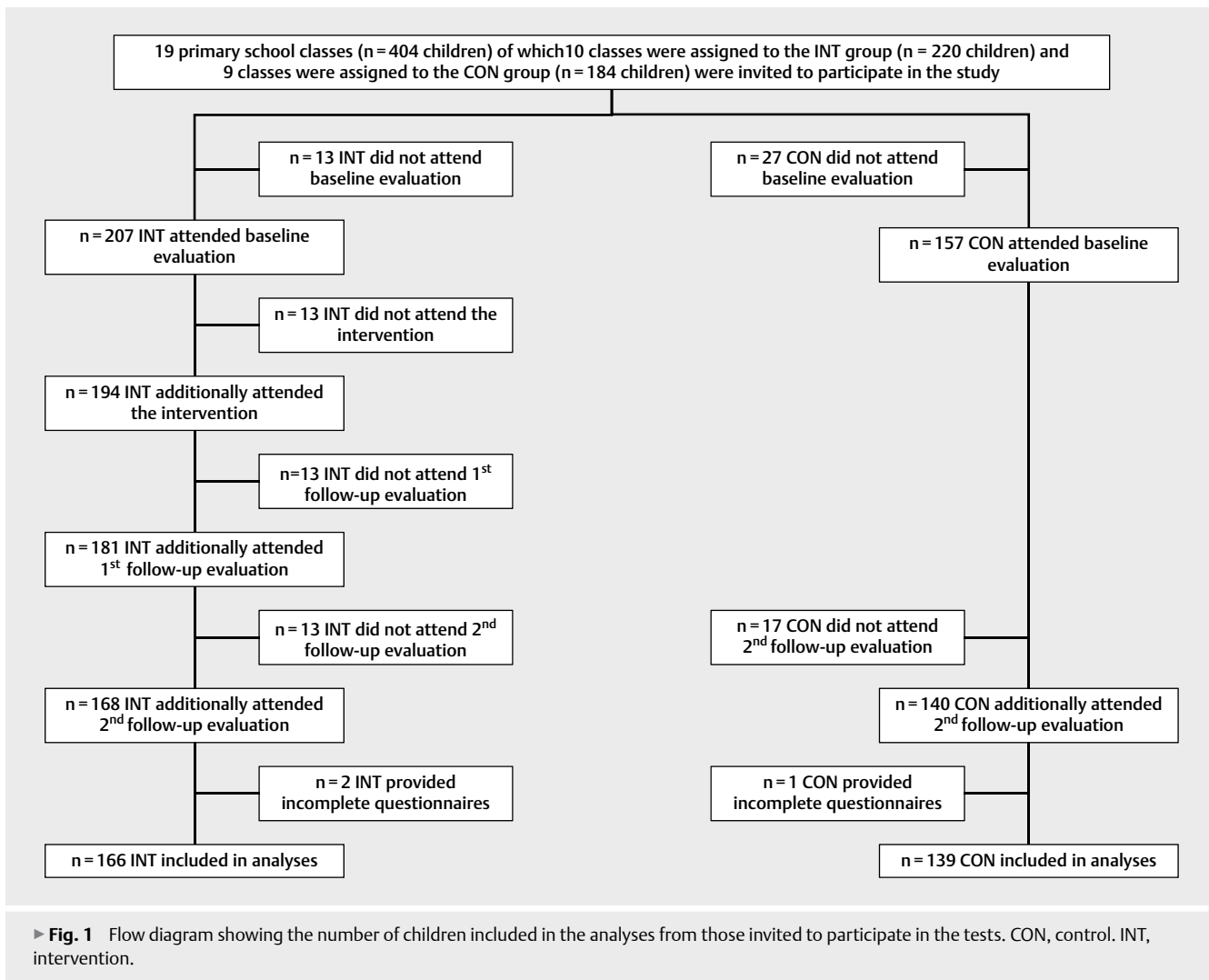
### Practical nutrition lessons

During three consecutive days, the children of the intervention group received practical nutrition lessons, i. e. the 'aid Ernährungsführerschein', a nutrition certificate developed by the aid info service e.V. for school-based nutrition education in primary schools [7]. The intervention was conducted by dietician trainees. It is worth noting that didactic training plays a central role in the education of the dietician trainees. In addition, their curricula comprises a separate module in which the students specifically prepared for the practical nutrition lessons. In 90 % of the participating schools, the classroom teachers assisted the dietician trainees in supervising the children, specifically while practically working in groups on the contents of the nutrition lessons. It comprises six modules, which cover the following learning objectives and expertise: (1) the children train the practical handling of foods and kitchen utensils, (2) they get to know the food groups of the aid food pyramid, (3) they are able to prepare small dishes by themselves, (4) they apply hygiene regulations and are able to set up their kitchen workplace, and (5) they are able to create a pleasant eating atmosphere [7, 8]. The nutrition certificate of the aid info service e.V. has been evaluated and is also suitable for children with migrant background [8, 9].

### Evaluation of the practical nutrition lessons

The effects of the practical nutrition lessons within the SMS initiative were assessed by applying the questionnaires developed for the evaluation of the nutrition certificate by the aid info service e.V. [9]. The evaluation comprised self-administered questionnaires at three time points, i. e. the baseline evaluation prior to the intervention, the 1<sup>st</sup> follow-up evaluation shortly after the intervention to assess the short-term effects, and the 2<sup>nd</sup> follow-up evaluation three months after the intervention to assess the longer-term effects of the intervention. At all three time points, the children of the intervention group were questioned, whereas the children of the control group, the parents of both the children of the intervention and the control group, the dieticians, and the classroom teachers of the children were only surveyed at single time points (Supplementary **Fig. 1S**). The children of the intervention and control group filled in their questionnaires in the classroom. The parents, dieticians, and classroom teachers were provided the questionnaires at the respective evaluation time point and were asked to return the completed questionnaire within one week by mail. The dieticians filled in one questionnaire per intervention class. Of note, due to the high proportion of children with migration background, the parents' questionnaires were provided in Turkish and Russian language in addition to the German version.

The children's questionnaires comprised their knowledge development as well as their self-perceived changes in attitudes, be-



havioral development, and skills development. The skills development was assessed by asking the children to specify their level of agreement to the statement “I can already prepare fruit quark by myself without any help.” using a Likert scale. The behavioral development was also assessed using Likert scales asking for the level of agreement on aspects of which the children pay attention to during a meal. The level of agreement on what the children enjoy or would enjoy with respect to meal preparation and eating atmosphere covered the children’s change in attitudes. For all these three areas, a higher score on the Likert scale indicated stronger agreement. The children’s knowledge development was assessed by the following parts of the questionnaire: the children were asked to put together a balanced school breakfast by choosing foods from a graphical selection list, they were questioned on recommended daily quantities of foods and beverages, and they were asked for the correct answer of ten food-related statements. The evaluation criteria of the knowledge-related parts of the questionnaire has been described previously [9]. Of note, differently to the aid info service e.V. [9], we additionally considered as correct answers a ‘moderate’ daily recommended quantity of bread, potatoes, rice, pasta (correct answer according to the aid info service e.V.: ‘ample’)

and ‘eat more meat instead of vegetables to grow up fit and strong’ (correct answer according to the aid info service e.V.: ‘eat more vegetables instead of meat to grow up fit and strong’).

The questionnaire of the dieticians and classroom teachers covered aspects of the implementation of the intervention. The classroom teachers additionally filled in a questionnaire asking for the language skills, the motivation in “social studies and science” and the team-working ability of the children. The parents were surveyed with the aim to complement their children’s perceptions on the effects of the intervention. As only 35% and 27% of the parents of the intervention and control group, respectively, provided completed questionnaires, these results are not reported due to an insufficient representativeness with the exception of the information on the socio-economic status of the families, which are presented in Supplementary **Table 15**.

### Statistical analyses

Differences between the intervention and control group as well as between participators and non-participators were calculated using Fisher’s exact test or Chi-square test for categorical variables and unpaired t-Test for normally distributed continuous variables. Changes in nu-

► **Table 1** Baseline characteristics of the children of the intervention and control group.

	Intervention	Control	P *
N (% males)	166 (47.6%)	139 (49.6%)	0.732
Age at baseline [years]	9.3 ± 0.7	9.9 ± 0.8	<b>&lt;0.001</b>
Migration background [n (%)]	120 (72.3%)	105 (75.5%)	0.601
Schools [n (%)]			<b>0.011</b>
School 1 (2 INT classes, 2 CON classes)	30 (18.0%)	33 (23.8%)	
School 2 (1 INT class, 1 CON class)	19 (11.5%)	14 (10.1%)	
School 3 (1 INT class, 1 CON class)	20 (12.0%)	12 (8.6%)	
School 4 (2 INT classes, 2 CON classes)	27 (16.2%)	32 (23.0%)	
School 5 (1 INT class, 1 CON class)	25 (15.2%)	15 (10.8%)	
School 6 (1 INT class, 1 CON class)	18 (10.8%)	16 (11.5%)	
School 7 (1 INT class, 1 CON class)	13 (7.8%)	17 (12.2%)	
School 8 (1 INT class, 0 CON classes)	14 (8.5%)	-	
Language skills [n (%)]			
Rather good	77 (46.4%)	73 (52.5%)	0.213
Rather good – satisfying	5 (3.0%)	1 (0.6%)	
Satisfying	62 (37.3%)	39 (28.0%)	
Satisfying – rather problematic	5 (3.0%)	5 (3.6%)	
Rather problematic	17 (10.3%)	20 (14.4%)	
Educational needs	0 (0.0%)	1 (0.6%)	
Motivation in “social studies and science” [n (%)]			0.199
Rather good	92 (55.4%)	68 (48.9%)	
Rather good – satisfying	7 (4.3%)	5 (3.6%)	
Satisfying	62 (37.2%)	52 (37.5%)	
Satisfying – rather problematic	0 (0.0%)	1 (0.7%)	
Rather problematic	5 (3.1%)	11 (7.9%)	
Educational needs	0 (0.0%)	1 (0.7%)	
Not classifiable	0 (0.0%)	1 (0.7%)	
Team-working ability [n (%)]			<b>0.002</b>
Rather good	125 (75.3%)	83 (59.7%)	
Rather good – satisfying	4 (2.4%)	0 (0.0%)	
Satisfying	29 (17.5%)	39 (28.1%)	
Satisfying – rather problematic	0 (0.0%)	1 (0.7%)	
Rather problematic	8 (4.8%)	15 (10.8%)	
Educational needs	0 (0.0%)	1 (0.7%)	

Data are n (%) or mean ± SD. \* P-values for differences between intervention and control (Fisher's exact test or Chi-square test for categorical variables and unpaired t-Test for normally distributed continuous variables). **Bold** indicates significant changes (P<0.05).

trition-related skills, behavior, attitudes, and knowledge (dependent variables) between baseline and 1<sup>st</sup> follow-up among children of the intervention group were tested using linear mixed model analyses. Multivariable linear regression analyses (ANCOVA) were applied to analyze differences between the intervention and control group for changes in nutrition-related skills, behavior, attitudes, and knowledge (dependent variables) between baseline and 2<sup>nd</sup> follow-up. As a non-randomized study design was applied, linear mixed model and multivariable linear regression analyses were adjusted for potential confounders. Model 1 was adjusted for the baseline value of the respective dependent variable. Model 2 was additionally adjusted for age at baseline, sex, school [school 1/school 2/school 3/school 4/school 5/school 6/school 7/school 8], and migrant background [yes/no]. P<0.05 was considered statistically significant. The problem of multiple testing was accounted for by additionally applying Bonferroni

correction individually for each category of the questionnaire using P<0.05/m as significance level, with m equaling the number of questions per category. Statistical analyses were performed using SAS (version 9.4; SAS Institute, Cary, NC).

## Results

Of the 19 primary school classes from eight schools comprising 404 school children, ten classes (equaling 220 children) were assigned to the intervention group and nine classes (equaling 184 children) to the control group. Among the intervention group, 166 children participated in the intervention and attended baseline, 1<sup>st</sup> and 2<sup>nd</sup> follow-up evaluation. Among the control group, 139 children attended baseline and 2<sup>nd</sup> follow-up evaluation (► **Fig. 1**). Participants and non-participants had comparable age at baseline and

prevalence of migration background (Supplementary Table 2S). Children of the intervention compared to the control group were younger and differed in their team-working ability, but were similar regarding migration background, language skills, and motivation in “social studies and science” (► Table 1). According to the subgroup of families who provided information on their socio-economic status, children of the intervention and control group did not differ in these parameters, e. g. the number of children living in the household, the percentage of single parenthood and the employment status, the school-leaving qualification as well as the vocational training of the parents (Supplementary Table 1S).

## Evaluation of the implementation of the practical nutrition lessons by the dieticians and classroom teachers

The intervention was carried out by 20 dieticians, with two dieticians supervising one of the intervention school classes. The given contents of the six modules of the practical nutrition lessons were performed between 10% and 90% and the methodological and didactical approaches were followed completely (40%) to largely (60%) by the dieticians. The motivation and mood of the participating children were evaluated as very positive by 80% of the dieticians. In 90%, the children developed a routine with respect to the different aspects of meal preparation. None of the dieticians reported problems with delivering the contents and only 30% stated minor problems with the participation of the children, whereas 70% reported minor to major problems with the involvement of the parents with respect to homework assistance and supply of materials for their children. The materials for implementation of the practical nutrition lessons provided by the aid info service e.V. were evaluated by the dieticians as follows: 80% rated the application of the materials as very positive, 100% described the design and layout of the materials as very appropriate for children, 70% ranked the level clarity of the tasks as very to rather positive for the children, and 70% rated the overall teaching concept as very positive.

According to the classroom teachers, the children had previously worked on the topic food preparation (57%, n = 7), school breakfast (90%, n = 10), and other nutrition-related topics (88%, n = 8).

The teachers reported to have experiences with thematically (70%, n = 10) and methodologically (20%, n = 10) comparable school lessons. The majority of the teachers rated the collaboration with the dieticians as fully to largely pleasant and productive (89%, n = 9). 89% (n = 9) and 78% (n = 9) of the teachers fully to largely agreed that the dieticians provided relevant expertise and practical experiences, respectively.

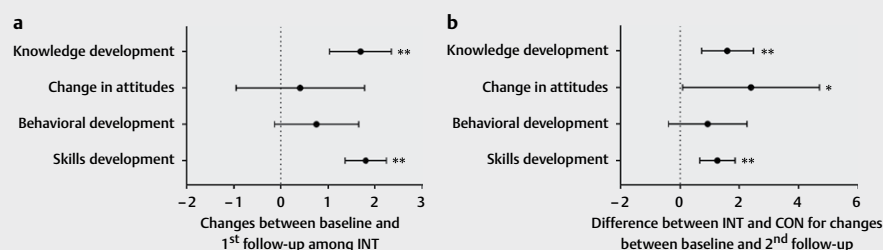
The presence of the dieticians during the practical nutrition lessons was evaluated as positive by 86% (n = 161) of the children of the intervention group. More than 90% (n = 165) of the children of the intervention group indicated that they enjoyed the practical nutrition lessons.

## Acute effects of the practical nutrition lessons in the intervention group

After participation in the practical nutrition lessons, children of the intervention group showed acute improvements in their skills and knowledge (► Fig. 2a). The change in the children’s skills was evaluated based on their self-report whether they are able to prepare fruit quark by themselves without any help. The improved knowledge was mainly driven by higher scores in the recommended daily quantities of milk and cheese, fruits and vegetables, bread, potatoes, rice, and pasta, water and unsweetened tea, as well as sweets, chips, and lemonade. Furthermore, the children more often correctly answered that juice should be mixed with water, that “1 tsp.” sugar means 1 teaspoon, that milk is good because it makes the bones and teeth strong, that bread made from whole grains is better than from refined grains, that ‘kids yoghurts’ and ‘Kinder Milk Slice’ are sweets, and that everyone is allowed to eat a handful of sweets per day. In addition to the improvements in skills and knowledge, the children of the intervention group stronger agreed that they help with preparing the food and that they take care of washing their hands before a meal after the intervention compared to before (Supplementary Table 3S).

## Longer-term effects of the practical nutrition lessons in the intervention compared to the control group

Between baseline and 2<sup>nd</sup> follow-up, i. e. three months after the intervention, children of the intervention compared to the control



► **Fig. 2** Changes between baseline and 1<sup>st</sup> follow-up among children of the intervention group (a) and differences between the intervention and control group (intervention minus control group) for changes between baseline and 2<sup>nd</sup> follow-up (b) in knowledge development, change in attitudes, behavioral development, and skills development. Data are regression coefficients (β), 95% confidence intervals (95% CI), and P-values from linear regression analyses adjusted for the dependent variable at baseline, age at baseline, sex, school [school 1/school 2/school 3/ school 4/school 5/ school 6/school 7/school 8], and migrant background [yes/no]. \* P < 0.05. \*\* P < 0.001, findings still significant after Bonferroni correction (significance level P < 0.05/4 = P < 0.013). CON, control. INT, intervention.

group yielded a higher improvement in their skills and knowledge (► Fig. 2b). The improved skills were again evaluated based on the children's self-report on the ability to prepare fruit quark. The children of the intervention compared to the control group showed a larger improvement in their knowledge mainly by yielding higher scores in the recommended daily quantities of fruits and vegetables, water and unsweetened tea, and sweets, chips, and lemonade and by correctly knowing that bread made from whole grains is better than from refined grains, that 'kids yoghurts' and 'Kinder Milk Slice' are sweets, and that everyone is allowed to eat a handful of sweets per day. In addition, children of the intervention group showed a stronger increase in agreeing that their school breakfast includes fruits and vegetables three months after the intervention compared to before than children of the control group (Supplementary Table 4S).

## Discussion and conclusions

A school-based intervention offering practical nutrition lessons for primary school children with a high proportion of migration background increased the short-term nutrition-related knowledge and skills of the children in the intervention group. These improvements in knowledge and skills were sustainable and larger in the intervention compared to the control group.

These findings of improved nutrition-related knowledge and skills are comparable to the results obtained by the aid info service e.V., who previously evaluated the practical nutrition sessions and observed desirable and sustainable developments with respect to the skills, the knowledge, and additionally the attitudes of the children [9]. Of note, this previous evaluation only included children receiving the intervention and did not comprise a control group. The present results are specifically mirrored when comparing the effects of the intervention among children with (21 %) and without (89 %) immigrational background in the previous evaluation: The improvements in skills were larger ( $P=0.017$ ) and the improvements in knowledge tended to be larger ( $P=0.052$ ) among children with migration background, whereas there were no differences for changes in attitudes and behavior between these two groups [9].

In Israel, a school-based intervention was conducted providing nutrition lessons and examining their effects on nutrition knowledge, eating habits, and eating behaviors among children of the intervention compared to a control group. This program did not focus on children with migration background, but targeted pupils and their parents from low SES [10]. Although low SES cannot be equated with migration background, children with migration background belong disproportionately often to a lower SES than children without migration background [2]. In line with our findings, the Israeli intervention program revealed improved nutrition knowledge directly and 3 months after the intervention among children of the intervention compared to the control group. In addition, parental-reported eating habits of the children and the quality of the children's packed school lunches greater improved in the intervention compared to the control group [10]. This indicates that the school-based setting is suitable to beneficially affect nutrition-related determinants among children with migration background or low SES, i. e. target groups which are hard to reach [11], showed lower re-

sponsiveness to health-related interventions [4, 5], and presented with less favorable dietary habits [2] compared to children without immigrational background or higher SES.

Of note, the present intervention beneficially changed nutrition-related knowledge and skills, but did not affect self-reported attitudes or behavior. Although changing knowledge alone is unlikely to automatically result in behavioral changes [12], previous school-based intervention programs lasting between nine weeks to six years reported increased knowledge in addition to improvements in self-reported behaviors, nutrient intakes, and attitudes to healthy eating [10, 12–14]. Thus, the following measures might be helpful to additionally provoke improvements in the children's behavior: first, prolonging the duration of the practical nutrition lessons and, second, stronger involving of the children's parents as parental involvement has been previously shown to positively affect the success of school-based interventions [15]. However, the three-day practical nutrition lessons of the aid info service e.V. have been chosen as they provide an evaluated program for primary school children and have been described to be suitable for children with migration background [8, 9]. Concerning the involvement of the parents, the low response rate of the parental questionnaires clearly indicated the poor accessibility of this target group. All in all, the present results additionally show the importance of nutrition-related content in theory as well as in practice in primary school curricula within formal education. Just recently, dietetics as a subject has gained in importance not only at primary school, but also at secondary school and a program for the training of students of teaching in dietetics has been newly established at the University of Paderborn, Germany [16].

## Strengths and limitations

Strengths of this study are the inclusion of schools with a high proportion of children with immigrational background and the comparison of the intervention effects with a control group. In addition, evaluated materials were used for the intervention and the evaluation [8, 9] and the practical nutrition lessons were conducted by trained personnel, i. e. dietician trainees. Limitations comprise, firstly, that the children could not be matched for migration background and age due to the school-based setting. However, these variables were included as confounders in the mixed models and regression analyses to minimize possible effects on the results [6]. Second, the participating school classes could not be randomly allocated to the intervention and control group as the practical nutrition lessons are part of the SMS initiative. Also, for one intervention class, no suitable control class of the same school was available, resulting in the inclusion of ten intervention and nine control classes. Third, to ensure a comparable socio-economic and migration background of the children of the intervention and control group, the control classes were chosen from the same schools as the intervention classes. This, however, implies that a knowledge exchange between the two groups might have happened, e. g. on the schoolyard. Of note, the children of the control classes did not receive the intervention within the same school year. Fourth, the evaluation only assessed the nutrition-related effects of the intervention based on self-reports of the children instead of additionally applying objective measures or practical tasks such as the quality of packed school lunches [10] or, for instance, the preparation

of a fruit quark. A further approach to objectively evaluate the contents of the nutrition lessons with respect to the preparation of a fruit quark is to provide the children with several pictures or photographs showing the preparation steps and asking them to arrange these pictures in the right order by numbering them. Of note, at 1<sup>st</sup> follow-up, up to 50 % of the children of the intervention group reported that they have already prepared at least one of the dishes of the practical nutrition lessons at home.

With regard to the evaluation materials provided by the aid info service e.V., the following limitations need to be additionally considered: the balanced school breakfast did not consider added fats, so that the total score of the balanced school breakfast only comprised protein-rich foods, beverages, grain products, fruits and vegetables, and sugar without including a fat component. Furthermore, the answers of two of the knowledge-related questions, i. e. the recommendation for an ample daily consumption of bread, potatoes, rice, and pasta as well as the statement that children should eat more vegetables instead of meat to grow up fit and strong need careful consideration. As only the quantity and not the quality of the carbohydrate-rich side dishes is evaluated and as the current evidence on both, the carbohydrate proportion and quality for the prevention of nutrition-related diseases among children and adolescents is limited [17], we additionally considered a moderate daily consumption of these foods as correct answer. Concerning the second question, we again rated two answers as correct, i. e., eating more vegetables instead of meat as well as eating more meat instead of vegetables to grow up fit and strong. We do agree that vegetables are a very nutritious food group, which provide high amounts of vitamins, minerals, antioxidants, and phytochemicals [18]. It is, however, questionable, whether these nutrients are essential for child growth or whether this characteristic should rather be allocated to meat as an important source of protein [19].

In conclusion, a school-based intervention providing practical nutrition lessons in 3<sup>rd</sup> and 4<sup>th</sup> graders with a high proportion of migration background resulted in sustainable increases in the nutrition-related knowledge and skills of the children of the intervention compared to the control classes. Thus, this dietary education appears to be a successful means of promoting the nutrition expertise of these children. Measures complementing the practical nutrition sessions might be necessary to directly target the children's behavior and attitudes.

## Declarations

**Ethics approval and consent to participate.** The evaluation was performed according to the Declaration of Helsinki and approved by the ethics committee of Heinrich-Heine-University Düsseldorf (study reference number: 3963). The parents gave written informed consent prior to the participation of their children.

Consent for publication. Not applicable.

**Availability of data and material.** Due to restrictions imposed by the ethics committee of Heinrich-Heine-University Düsseldorf regarding patient consent, data are available upon request. Requests for data may be sent to the corresponding author Prof. Dr. Karsten Müssig (karsten.muessig@ddz.uni-duesseldorf.de).

## Authors' contributions

KSW wrote the manuscript and researched data; JE researched data; KSW, JE, and KS performed the statistical analysis; LD, OS, AEB, PK contributed to discussion and reviewed/edited the manuscript; JS and BK provided the questionnaires and support for data analyses; KM designed the study, contributed to discussion and reviewed/edited the manuscript. All authors critically reviewed the manuscript. KM is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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**Trial registration:** German Clinical Trials Register, DRKS-ID: DRKS00005119. Registered 10 July 2013 (retrospectively registered).

## Conflict of Interest

The authors declare that they have no conflict of interest.

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