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Obesity Prevention

Designing and implementing a kindergarten-based, family-involved intervention to prevent obesity in early childhood: the ToyBox-study

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Summary

The development of the ToyBox-intervention was based on the outcomes of the preliminary phase of the ToyBox-study, aiming to identify young children's key behaviours and their determinants related to early childhood obesity. The ToyBox-intervention is a multi-component, kindergarten-based, family-involved intervention with a cluster-randomized design, focusing on the promotion of water consumption, healthy snacking, physical activity and the reduction/ breaking up of sedentary time in preschool children and their families. The intervention was implemented during the academic year 2012–2013 in six European countries: Belgium, Bulgaria, Germany, Greece, Poland and Spain. Standardized protocols, methods, tools and material were used in all countries for the implementation of the intervention, as well as for the process, impact, outcome evaluation and the assessment of its cost-effectiveness. A total sample of 7,056 preschool children and their parents/ caregivers, stratified by socioeconomic level, provided data during baseline measurements and participated in the intervention. The results of the ToyBox-study are expected to provide a better insight on behaviours associated with early childhood obesity and their determinants and identify effective strategies for its prevention. The aim of the current paper is to describe the design of the ToyBox-intervention and present the characteristics of the study sample as assessed at baseline, prior to the implementation of the intervention.

Keywords: Design, kindergarten, obesity prevention, preschool children.

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Introduction

Childhood obesity is a major public health problem, with its prevalence increasing in most regions of the world (1–4). Recent studies suggest that these trends seem to gradually stabilize or even have already reached a plateau in some countries (5–8); however, the problem remains significant (2). The development of obesity is largely driven by lifestyle behaviours that positively or negatively affect energy balance (9,10) and are referred to as energy balance-related behaviours (EBRBs).

Early childhood is a critical period for addressing obesity prevention since EBRBs, psychological traits and physiological processes are largely formed and adopted at this age (11–13). As preschool children are still open for imprinting experiences, this age constitutes an optimal time point to intervene and sustainably influence EBRBs, thus setting the course for a healthy lifestyle. Kindergartens are ideal and potentially cost-effective settings for implementing obesity prevention interventions, since education and health promotion can be combined to encourage behavioural change and large populations of preschool children and their families can be approached at the same time (14).

The first step in developing such an intervention is to identify age-specific EBRBs that need to be targeted and their determinants, as well as the most appropriate policy, environmental, role modelling, behavioural and educational strategies to support the intervention (15). The early phases of the ToyBox-study aimed to (i) identify key EBRBs and their determinants at preschool age; (ii) evaluate existing behavioural models and educational strategies that best support behavioural change at this age group; (iii) assess environments, policies and legislation affecting the implementation of preschool age health promotion activities (14). Based on these preliminary outcomes, the ToyBox-intervention was designed and implemented in six countries across Europe.

The aim of the current paper is to describe the design of the ToyBox-intervention and present the characteristics of the study sample as assessed at baseline, prior to the implementation of the ToyBox-intervention.

Methods

The ToyBox-intervention is a multi-component, kindergarten-based, family-involved intervention, aiming to prevent obesity and ensure preschool children's optimum growth and development. It has a randomized cluster design and it was implemented in six European countries: Belgium, Bulgaria, Germany, Greece, Poland and Spain (Fig. 1). The ToyBox-study is registered with the clinical trials registry clinicaltrials.gov, ID: NCT02116296.

Figure 1 Dark grey: countries participating in the ToyBox-intervention; light grey: countries participating in the ToyBox-study.

Timeline

The baseline measurements of the ToyBox-intervention were conducted on children born between January 2007 and December 2008 (i.e. the age range was from 3.5 to 5.5). These children and their families were recruited mainly at kindergartens, but also at day care centres or preschool settings, depending on the country regulations and legislation. Precisely, in Germany, Bulgaria, Spain and Poland children/families were recruited from kindergartens, in Greece from kindergartens and day care centres and in Belgium from preschool settings. In order to avoid confusion for the reader, all these settings (kindergartens, day care centres, preschool settings) will be referred to as 'kindergartens' in this paper.

The timeplan of the ToyBox-intervention was designed so as to account for country-specific differences with regard to the opening and closing dates of the kindergartens and the duration and timing of national holidays. Recruitment of participants started in February 2012 and baseline data was collected between May and June 2012. The intervention was implemented within the academic year 2012–2013 from September 2012 to June 2013. Follow-up evaluation was performed between May and June 2013. In order to have comparable data, we had to ensure that baseline and follow-up measurements for all children were executed 12-months apart. For this reason, a limit of deviation of maximum 2 weeks between baseline and follow-up measurements dates per kindergarten was allowed. Process evaluation and assessment of cost-effectiveness were conducted during the teachers' training sessions and the implementation phase of the intervention. A detailed description of the ToyBox-intervention timeline is presented in Fig. 2.

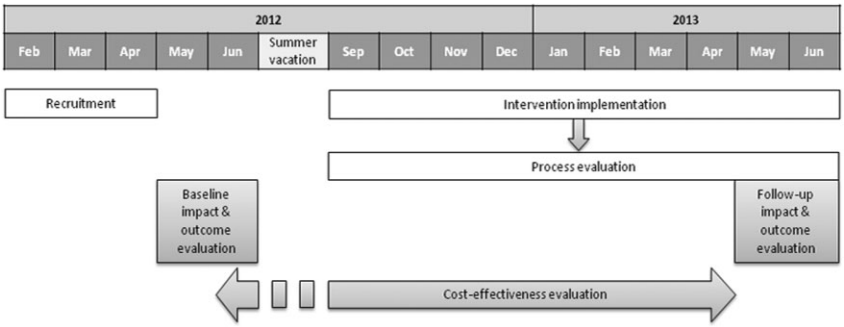

Figure 2 Timeplan of the ToyBox-intervention.

Sampling

Kindergartens were recruited from the provinces of Oost-Vlaanderen and West-Vlaanderen (Belgium), Varna (Bulgaria), Bavaria (Germany), Attica (Greece), Mazowieckie (Poland) and Zaragoza (Spain). A maximum radius of 50 km from the local Institutes was considered for kindergarten recruitment. A minimum sample of 800 children and their families and 20 kindergartens per country, resulting in a total sample of 4,800 children and their families and 120 kindergartens, was initially targeted. However, in order to account for an estimated dropout rate of about 30%, a minimum total number of about 6,500 children and their families were aimed to be recruited in the six participating countries. The software http://www.statisticalsolutions.net was used for implementing the power calculations. Based on current literature (16) a baseline value for children's body mass index (BMI) = 16.35 kg m^{-2}, an expected follow-up value of children's BMI = 16.17 kg m^{-2}, a standard deviation = 1.73, an α-value = 0.05 and a power of test = 0.8 were used, resulting in a minimum sample of 726 children, which should be achieved. For this reason, a minimum number of 800 children with complete data (anthropometric data and core questionnaire) at baseline and at follow-up were aimed for each intervention country, since it was considered more than adequate to achieve statistical power for evaluating the impact and outcome of the ToyBox-intervention.

Recruitment procedures

Ethical approvals and consent forms

The ToyBox-study adhered to the Declaration of Helsinki and the conventions of the Council of Europe on human rights and biomedicine. Prior to initiating the intervention, all participating countries obtained ethical clearance for the baseline and follow-up examinations and for the implementation of the intervention from the relevant ethical committees and local authorities. More specifically, approval for the study was obtained by the following entities: in Belgium by the Medical Ethics Committee of the Ghent University Hospital; in Bulgaria by the Ethics Committee of the Medical University of Varna; in Germany by the Ethics Committee of the Ludwig Maximilian University of Munich; in Greece by the Bioethics Committee of Harokopio University and the Greek Ministry of Education; in Poland by the Bioethics Committee of the Children's Memorial Health Institute and the Department of Information and Publicity of the Polish Ministry of Education; and in Spain by the Clinical Research Ethics Committee and the Department of Consumers' Health of the Government of Aragón. All headmasters/teachers and parents/caregivers provided a signed consent form before being enrolled in the study.

Recruitment methodology

A standardized, multistage sampling approach was applied for the recruitment of kindergartens and teachers as well as for families and children in all countries, which was composed of the following five sampling steps. Sampling step 1: a list of all the municipalities located in the selected provinces in each intervention country, within a radius of 50 km around the local institutes was created; sampling step 2: each country provided the coordinating centre with information on selected socioeconomic status (SES) variables (i.e. mean years of education of the population aged between 25 and 55 years or mean annual household income) for these municipalities; sampling step 3: the coordinating centre created tertiles of the municipalities for each country (based on the mean values of the selected SES variables) and municipalities were divided in three SES groups (i.e. low SES, medium SES and high SES); sampling step 4: from each of these SES groups, approximately five municipalities were randomly selected in each country; sampling step 5: lists of all the kindergartens located within each of these randomly chosen municipalities were created. Within each randomly selected municipality, the kindergartens were ranked in a descending order, based on the number of registered children in each kindergarten. Recruitment of kindergartens started from the top of the

lists for each one of the selected municipalities. After each kindergarten was recruited, children's participation rate was calculated and if it was lower than 50%, the kindergarten was excluded from the study and recruitment continued with the next kindergarten in each list. Recruitment of kindergartens and children lasted until a minimum sample of 1,100 signed consent forms by the parents/caregivers was obtained in each country. The parental consent forms were obtained in order to proceed with the baseline and follow-up measurements for the children and with the completion of the questionnaires by the parents/caregivers. Regarding the implementation of the ToyBox-study, beyond local entities teachers' and headmasters' approval was also prerequisite in order to include each kindergarten in the study. No consent forms were requested by the parents/caregivers since all children in each intervention class were participating in the kindergarten-based ToyBox activities and all parents/caregivers received newsletters, tip cards and posters.

Eligibility criteria

Kindergartens were considered eligible for inclusion in the intervention if (i) they were located within a radius of 50 km around the local institutes; (ii) headmasters and teachers provided signed consent form and (iii) families'/children's participation rate was at least 50%.

Children within recruited kindergartens were eligible if (i) they were aged between 3.5 and 5.5 years at the time of recruitment (i.e. born between January 2007 and December 2008); (ii) their parents/caregivers provided a signed consent form and (iii) were not participating in any other clinical trial or other health-oriented project during the academic years 2012–2013 and 2013–2014.

Randomization

Randomization of the recruited municipalities to intervention and control group was conducted centrally by the coordinating centre, after the completion of baseline measurements. The municipalities were assigned to the intervention or control group in a 2 : 1 ratio within each SES group. Since the randomization was conducted at a municipality level, the kindergartens within each municipality were automatically allocated to the intervention or control group.

Implementation of the ToyBox-intervention

The four EBRBs which were found to be associated with early childhood obesity in the preliminary phases of the ToyBox-study (17,18), i.e. water consumption, snacking, physical activity and sedentary behaviours (17,18), were targeted in the ToyBox-intervention. The ToyBox-intervention was implemented within the academic year 2012–2013, following a predefined timeplan of implementation. All material used during the intervention was the same across participating countries, allowing for some small cultural adaptations at a local level. The development of the intervention material was based on the intervention mapping protocol and the PRECEDE-PROCEED model, as described elsewhere (19). Furthermore, the intervention was developed based on the findings of preparatory studies conducted during the early phases of the ToyBox-study (PRECEDE phase) (20–24).

The teachers from recruited kindergartens assigned to the intervention group, participated in three training sessions, where the local research teams presented the intervention material and provided detailed information on how to implement the intervention (25). Kindergarten teachers' training sessions were conducted based on a standardized teachers' training protocol and using standard training modules. In order to limit contamination between the intervention and the control kindergartens, no access to any intervention material or teachers' trainings was provided to the control group during the implementation phase and control kindergartens were asked to continue with the standard curriculum.

The implementation of the ToyBox-intervention was conducted at four levels. The first three levels were implemented in the kindergarten setting, while the fourth level addressed parents/caregivers aiming to induce certain changes at children's social and physical environment at home in order to promote the four targeted EBRBs. More specifically:

Level 1. Teachers conducted permanent environmental changes in the classroom/kindergarten, in order to create a classroom and kindergarten environment supportive to the execution of the four targeted EBRBs (i.e. installations of water stations and the 'magic snack plate' to assist water and healthy snack consumption and rearrangements of the classroom/kindergarten to create some free space to assist children's movement).

Level 2. Teachers promoted the four targeted EBRBs on regular basis and predefined time within each day, in the classroom/kindergarten, aiming at total class participation (i.e. reminding every day children to drink water regularly and do short movement breaks twice in the morning and twice in the afternoon, arranging a daily break for the whole class to eat healthy snacks and performing two physical education sessions per week with a duration of 45 min each).

Level 3. Teachers implemented interactive classroom activities, aiming at total class participation, minimum for 1 h per week (e.g. children's participation in experiments, kangaroo stories with children following the movements described in the stories, etc.). Teachers were also instructed

to use the kangaroo handpuppet and perform these four EBRBs themselves, so as to enhance the effects of the intervention via role modelling.

Level 4. Parents/caregivers were encouraged and advised via simple and friendly to read material (nine newsletters and eight tip cards, as well as four posters which were coloured by their child) to apply relevant environmental changes at home, act as role models and implement these lifestyle behaviours together with their children.

Across the ToyBox-intervention countries, standardized protocols, methods, tools and material were used for the implementation of the intervention, as well as for the process, impact, outcome evaluation and the assessment of its cost-effectiveness. More information on the methods and tools used for this purpose are provided in the current supplement of *Obesity Reviews* (25–32).

Results

The mean participation rate per kindergarten in the total study sample was 63.3%. In total, 7,056 of the recruited preschool children and their parents/caregivers provided complete data at baseline measurements (Fig. 3). Children with complete data were considered those with (i) weight, height and waist circumference measurements and (ii) at least 75% of the parental/caregivers' core questionnaire completed. Participants were recruited from municipalities grouped in three socioeconomic levels (Table 1). The socioeconomic level of the kindergartens and the family at the baseline measurements was defined based on the SES level of the municipality they belonged to. Table 2 shows the number of children with specific available data per country. Besides anthropometric measurements and parental/caregivers' core questionnaire, a medical history questionnaire, a food frequency questionnaire and pedometer data were collected.

Socio-demographic characteristics of the families participating in the ToyBox-intervention

The socio-demographic characteristics of the study participants (both intervention and control groups) are displayed in Table 3. Mean age of children was 4.7 years, with 48.1% being females. Mean parental age was 35.3 and 38.0 years for mothers and fathers, respectively. The majority of participating children were found to live in two-parent families, while the mean household size was 3.9. Overall, participating families were found to have on average 1.8 children under the age of 18 years.

The proportion of children having one parent born abroad varied across countries, ranging from 1.9% in Bulgaria to 14.7% in Germany. The percentage of children with at least one parent being unemployed varied from 1.0% in Germany to 12.0% in Spain. No significant differences were found for these variables, between the intervention and control group, in all countries (data not presented).

Discussion

Key learnings from previous school-based obesity prevention programmes were considered in the development of the ToyBox-intervention. Specifically, the ToyBox-intervention

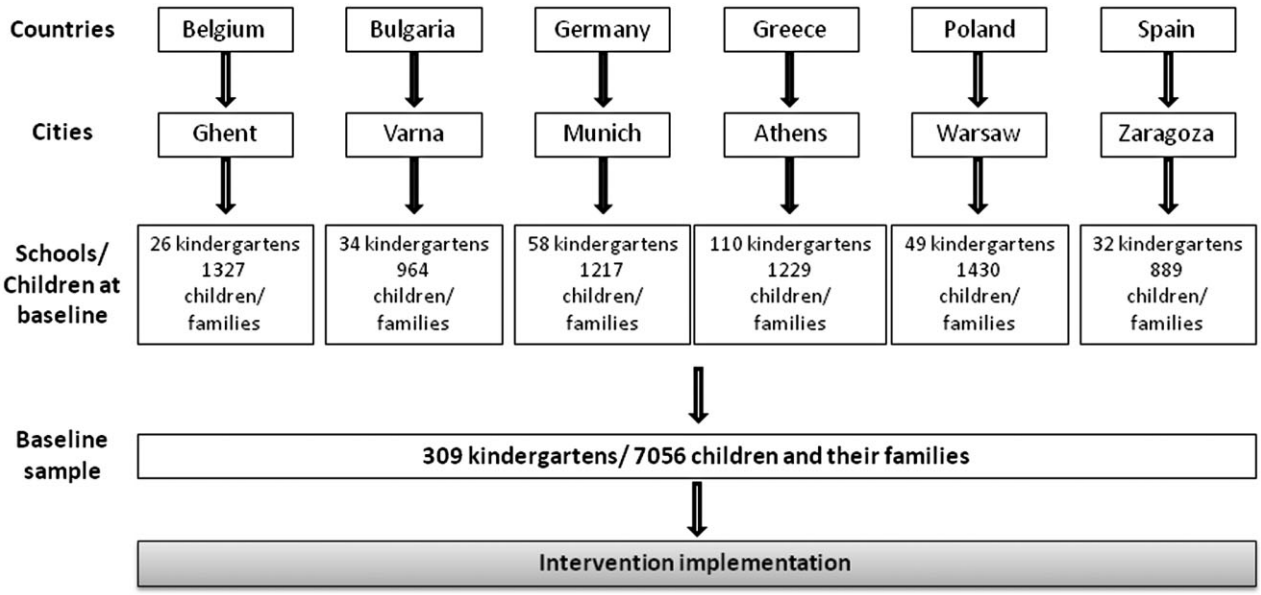

Figure 3 Number of children with complete data at baseline, by country: the ToyBox-intervention.

Table 1 Number of preschool children by country and socioeconomic status (SES) at baseline: the ToyBox-intervention

Country	Low SES municipalities, *N* (%)	Medium SES municipalities, *N* (%)	High SES municipalities, *N* (%)	Total *N*
Belgium	534 (40.2)	397 (29.9)	396 (29.8)	1,327
Bulgaria	137 (14.2)	336 (34.9)	491 (50.9)	964
Germany	276 (22.7)	422 (34.7)	519 (42.6)	1,217
Greece	643 (52.3)	374 (30.4)	212 (17.2)	1,229
Poland	482 (33.7)	422 (29.5)	526 (36.8)	1,430
Spain	359 (40.4)	309 (34.8)	221 (24.9)	889
Total	2,431 (34.5)	2,260 (32.0)	2,365 (33.5)	7,056

Table 2 Number and proportion of preschool children with specific available data at baseline, by country: the ToyBox-intervention

Country	Body mass index	Waist circumference	Parental core questionnaire	Medical history questionnaire	Food frequency questionnaire	Pedometer data
Belgium	1,327	1,322	1,327	1,327	956	928
Bulgaria	964	963	964	964	795	562
Germany	1,216	1,211	1,217	1,217	1,217	497
Greece	1,229	1,228	1,229	1,229	1,229	620
Poland	1,430	1,429	1,430	1,430	1,391	1,228
Spain	889	889	889	889	878	629
Total	7,055	7,042	7,056	7,056	6,534	4,464

was based on behavioural models (19), involved role models (parents/caregivers, teachers, kangaroo), aimed to improve children's social and physical environment both at home and at kindergarten, had a multi-component design focusing both on nutrition and physical activity-related behaviours and was implemented for a period for more than 6 months with daily intensity (33–36).

The ToyBox sample was carefully recruited, using a standardized, multistage sampling procedure, to ensure sufficient representativeness in the participating regions, aiming for the inclusion of low, medium and high SES groups in six European countries. Previous studies showed that families from the high SES group, are more likely to actively participate in any initiative aiming to prevent or treat childhood obesity (37), while the relationship between socioeconomic level and childhood obesity may vary across countries of different socioeconomic development (38). The stratified sampling conducted in the ToyBox-intervention limited the possibility of selection bias and ensured representation of different SES groups within each country, allowing the ToyBox-intervention to address and explore the diversity of childhood obesity, evaluate its effectiveness and identify potential differences in the active involvement of teachers and parents/caregivers in the intervention across the different European regions and SES-groups. Moreover, using municipalities as the sampling unit limited contamination among neighbouring kindergartens and allowed ToyBox-intervention to control for diversities among families'/children's physical environment in the neighbourhood (e.g. playgrounds, restaurants), which may influence their lifestyle habits (39). On the other hand, the ToyBox-intervention was implemented at a kindergarten level, with the participation of the whole class, aiming to increase acceptability and avoid stigmatization since everyone received the same intervention, as well as to maximize generalizability by reducing participant self-selection.

The effectiveness of the ToyBox-intervention will be tested at different levels, by assessing its impact and outcome. As such, beyond children's BMI changes and changes in their weight status, potential changes in children's water consumption, snacking, physical activity and sedentary behaviours and their determinants will be also examined before and after the intervention (40). All measurements and data collection for impact and outcome evaluation were performed during the same time period at baseline and follow-up (i.e. May–June 2012 and May–June 2013, respectively), in order to avoid potential seasonality effects. Overall, standardized written protocols, material and tools during all phases of the intervention (recruitment, teachers' training, intervention implementation, impact and outcome evaluation) have been used, combining both objective and self-reported methods of assessment (28–30). Multi-level analyses (four levels: 'time', 'preschool child', 'class', 'kindergarten') will be performed to examine the

Table 3 Socio-demographic characteristics of preschool children* and their families ($N = 7,056$) by country at baseline: the ToyBox-intervention

Country	Children's mean age (SE)	Children's female gender, *N* (%)	Mean age of mother (SE)	Mean age of father (SE)	Two-parent family, *N* (%)	Mean household size†	Mean no of children <18 years/ household (SE)	One parent born abroad, *N* (%)	Both parents born abroad, *N* (%)	One parent unemployed, *N* (%)	Both parents unemployed, *N* (%)
Belgium	4.4 (0.02)	629 (47.4)	33.7 (0.13)	36.4 (0.16)	1,143 (86.1)	4.1 (0.03)	2.1 (0.03)	109 (8.2)	65 (4.9)	35 (2.6)	3 (0.2)
Bulgaria	4.9 (0.01)	487 (50.5)	33.9 (0.14)	37.2 (0.17)	802 (83.2)	3.7 (0.04)	1.5 (0.03)	18 (1.9)	1 (0.1)	62 (6.4)	1 (0.1)
Germany	4.6 (0.02)	594 (48.8)	35.7 (0.15)	38.6 (0.18)	1,094 (89.9)	4.0 (0.03)	2.0 (0.02)	179 (14.7)	147 (12.1)	12 (1.0)	2 (0.2)
Greece	4.9 (0.01)	601 (48.9)	37.0 (0.13)	40.7 (0.16)	1,060 (86.2)	3.8 (0.04)	1.8 (0.03)	154 (12.5)	87 (7.1)	145 (11.8)	12 (1.0)
Poland	4.9 (0.01)	675 (47.2)	34.6 (0.12)	36.6 (0.14)	1,291 (90.3)	3.9 (0.03)	1.8 (0.02)	29 (2.0)	4 (0.3)	23 (1.6)	0 (0.0)
Spain	4.9 (0.01)	407 (45.8)	37.8 (0.15)	39.2 (0.17)	794 (89.3)	3.6 (0.03)	1.6 (0.02)	57 (6.4)	65 (7.3)	107 (12.0)	5 (0.6)
Total	4.7 (0.01)	3,393 (48.1)	35.3 (0.06)	38.0 (0.07)	6,184 (87.6)	3.9 (0.01)	1.8 (0.01)	546 (7.7)	369 (5.2)	384 (5.4)	23 (0.3)

*Children with complete data for the respective variable.
†Number of adults and children living in the same house.

impact and outcome evaluation of the ToyBox-intervention, taking clustering of two measurements (baseline and follow-up) of preschool children in classes in kindergartens into account.

Apart from the impact and outcome evaluation, process evaluation and cost-effectiveness were also assessed in the ToyBox-intervention (31,32). Process evaluation was used to record the level and the fidelity of implementation of the intervention at kindergarten level and is expected to further guide our understanding on the outcomes of the intervention at kindergarten, municipality and country level. Moreover, reporting of potential differences in contextual factors, infrastructure, settings and resources across participating countries, within the framework of process evaluation, will provide feedback on potential further local adaptations that might be needed. Last but not least, the process evaluation data will guide the revision and improvement of the intervention material, which will be uploaded on the ToyBox website (www.toybox-study.eu) after the completion of the project aiming to assist the research community or any public health initiatives focusing on the prevention childhood obesity.

Regarding cost-effectiveness, it is notable that most studies do not report cost estimates or cost-effectiveness, which should be an important information for public health policy makers (41). In the ToyBox-intervention, health economic modelling was used to estimate the cost-effectiveness of the intervention. The holistic assessment of the impact, outcome, process and cost-effectiveness of the ToyBox-intervention is expected to provide analytical information on its results and according to these results it may support decision-making for public health policy regarding the potential expansion of the ToyBox-study on a pan-European scale.

The ToyBox-intervention has certain strengths and limitations. The standardized material, teachers' training sessions and protocols for the implementation and evaluation of the ToyBox-intervention, which have been followed across the six participating countries, comprise some of its strengths. Although these strengths of the programme allows comparisons among participating countries, at the same time, they provide limited flexibility with respect to the local needs and priorities. The approach of 'one size fits all' might not be the best approach for the diversity of cultures, local systems and needs across Europe. Despite the fact that objective measurements were performed, still, many of the collected data were self-reported by teachers and parents/caregivers. Self-reported data may be prone to recall bias and social desirability. Furthermore, only one follow-up examination was conducted at the end of the intervention, while more follow-up assessments in the following years would potentially provide further insights on the longer-term impact and outcome of this intervention.

In conclusion, the ToyBox-study used a multidisciplinary approach by a multidisciplinary team, in developing, implementing and evaluating a multi-component, kindergarten-based, family-involved intervention. More than 7,000 preschool children, their teachers and their families from six European countries participated in the ToyBox-intervention. The impact, outcome, process evaluation and cost-effectiveness of the ToyBox-intervention will be assessed and will guide the potential expansion of ToyBox or other similar initiatives for the prevention of early childhood obesity in Europe.

Conflict of interest statement

No conflict of interest was declared.

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