

A systematic approach for the development of a kindergarten-based intervention for the prevention of obesity in preschool age children: the ToyBox-study

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Summary

The increasing childhood obesity epidemic calls for appropriate measures and effective policies to be applied early in life. Large-scale socioecological frameworks providing a holistic multifactorial and cost-effective approach necessary to support obesity prevention initiatives in this age are however currently missing. To address this missing link, ToyBox-study aims to build and evaluate a cost-effective kindergarten-based, family-involved intervention scheme to prevent obesity in early childhood, which could potentially be expanded on a pan-European scale. A multidisciplinary team of researchers from 10 countries have joined forces and will work to realize this according to a systematic step-wise approach that combines the use of the PRECEDE-PROCEED model and intervention mapping protocol. ToyBox-study will conduct systematic and narrative reviews, secondary data analyses, focus group research and societal assessment to design, implement and evaluate outcome, impact, process and cost effectiveness of the intervention. This is the first time that such a holistic approach has been used on a pan-European scale to promote healthy weight and healthy energy balance-related behaviours for the prevention of early childhood obesity. The results of ToyBox-study will be disseminated among key stakeholders including researchers, policy makers, practitioners and the general population.

Keywords: Intervention mapping, obesity prevention, PRECEDE-PROCEED, preschool children.

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Introduction

The prevalence of obesity has reached epidemic proportions in adult populations showing a steep increase over the last decades while childhood and adolescent overweight and obesity has increased markedly across Europe, even though in a few countries the speed of increase seems to have levelled off (1–7). Overweight in early childhood has been shown to increase the likelihood of being obese in later childhood (8,9) but also tracks to adulthood in one-third to one-half of cases (10), where it becomes associated with an increased prevalence of chronic disease (11–13). The challenge arising from childhood-onset overweight and obesity calls for appropriate preventive measures and effective policies to be taken early in life. Early prevention seems therefore to be an emerging and effective approach to decrease obesity and obesity-related chronic disease in adulthood (4,14–18).

To date, most efforts to prevent obesity in children by promoting energy balance-related behaviours have reached inconsistent results regarding the desired outcomes (reported either as body mass index [BMI], percent fat content or skin-fold thickness), while some studies found improvements in health behaviour knowledge, diet and/or physical activity (19–21). The results of several systematic reviews have revealed that most of the studies addressing obesity prevention are of low methodological rigor (22). Their ineffectiveness can be partly attributed to the fact that they were not guided by a careful enough systematic evidence-based development process (too general, not well informed by evidence from earlier research and not rooted in behaviour change theory) and they have failed to include intervention strategies tailored to the most important and modifiable determinants of the key health behaviours (19,23). In addition, sustainable school and family environmental factors have not been addressed properly, and the stakeholders' views, the contextual factors and policy framework were not taken into account (19,23). There are also problems regarding sample selection and size, intensiveness of implementation or even the description of the intervention as such, short intervention period and largely lacking evaluation of process, impact and outcomes as well as a proper choice of assessment tools (19,23,24).

In spite of the limited good quality data on which to draw conclusions about obesity prevention in children and adolescents, there seems to be enough evidence to suggest that school-based interventions may be more promising than solely family-based trials (25). Schools are potentially important channels of intervention because they offer access to large populations of children, often with mixed socioeconomic background, and provide the opportunity to institutionalize programs in communities. Recent findings from school-based intervention programs have delivered some encouraging findings regarding obesity indices in

primary schoolchildren indicating the potentiality of such programs (17,18,26–29); however, limited research exists on reducing obesity in the preschool setting (30).

To be successful in addressing childhood obesity, it is important to adopt a holistic multifactorial and cost-effective approach guided by an appropriate socioecological framework. This should not only combine the most effective aspects of behavioural models and strategies but also consider existing policies and regulations and engage relevant stakeholders for the design, implementation and evaluation of the health promotion program. The European Commission's Directorate General for Research funded the ToyBox-study, with a starting date of 1 March 2010, within its seventh framework program. ToyBox stands for 'Multifactorial evidence based approach using behavioural models in understanding and promoting fun, healthy food, play and policy for the prevention of obesity in early childhood' (www.toybox-study.eu). The overall aim of the ToyBox-study is to build and evaluate a cost-effective kindergarten-based, family-involved intervention scheme aiming to prevent obesity in childhood, which could potentially be expanded on a pan-European scale. This paper describes the systematic approach, methodologies and intended deliverables of the different parts of the ToyBox-study and the advances that the project is expected to bring.

The ToyBox systematic approach

A conceptual model ideally serving the needs of the current project is the PRECEDE-PROCEED (P-P) model (31–33), an educational and ecological approach in health program planning (Fig. 1). P-P model has been considered to be the best among 10 planning models on usefulness for research and usefulness for practice (32) and its use could potentially increase the sustainability of an intervention programme. The salient features of this model of program planning and evaluation are found in the phases and procedures that follow a sequence of steps aligned with a generic logic model or systems model of causes and effects. Although the P-P model provides a detailed and well-structured approach for the assessment (PRECEDE) and the implementation and evaluation (PROCEED) procedures, it lacks a stepwise practical guide for the development of the intervention. Such a guide can lead intervention developers in extracting and blending together the results of the PRECEDE phases to come up with a detailed intervention plan with specific goals, practical approaches and guidance on how to develop and implement the intervention. In the current project, intervention mapping (IM) (34) will provide this stepwise guiding plan and will therefore be incorporated as an intermediary step between the PRECEDE and PROCEED components of the P-P model. The inclusion of the IM within the P-P model has been considered as an important theoretical development in

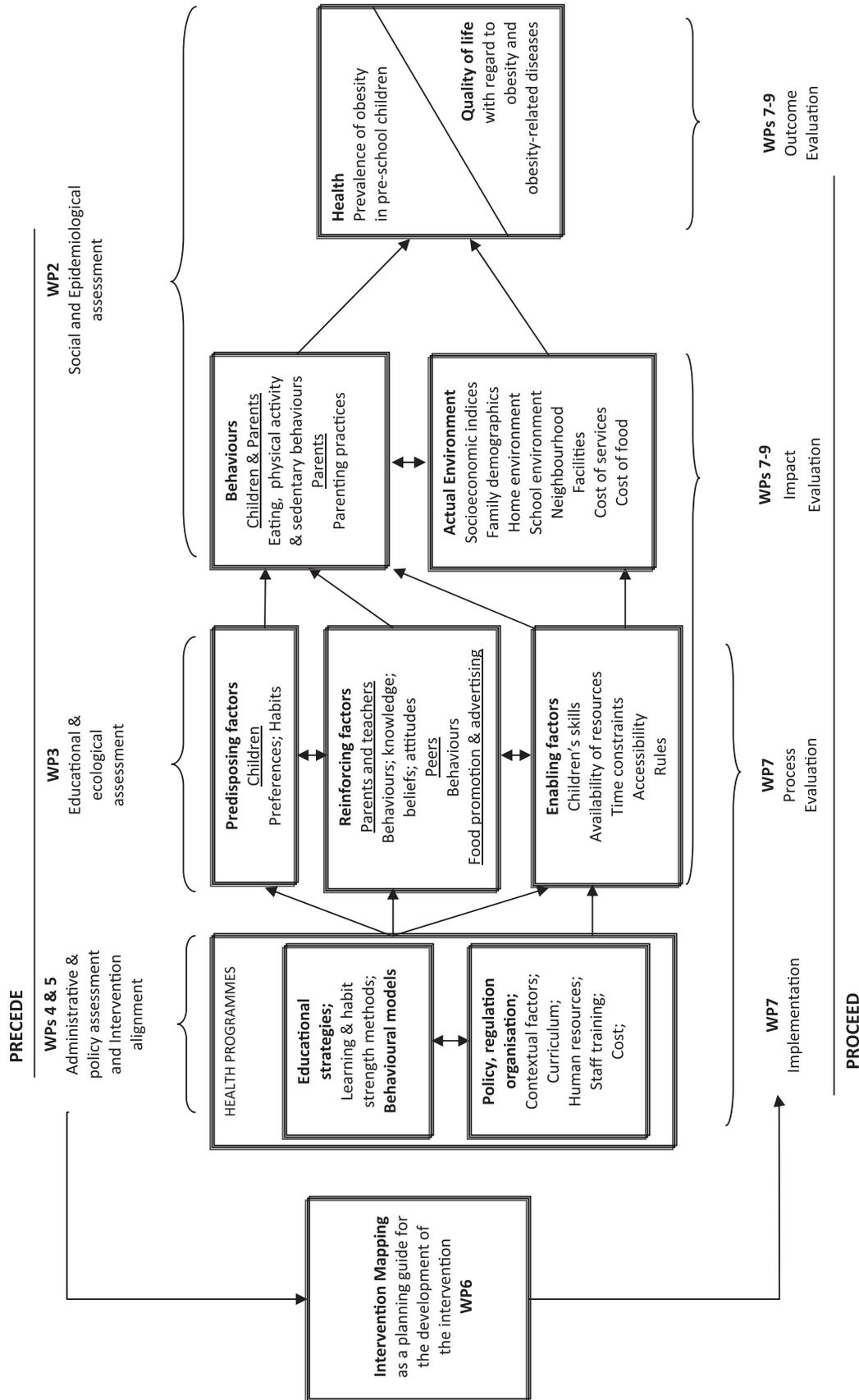


Figure 1 The systematic approach that will be used in the ToyBox project: the adapted PRECEDE-PROCEED model for use in preschool children.

health promotion planning (33,34). This approach will be used in this project (as well as the work packages [WPs] constituting it) as the planning framework for the development, implementation and evaluation of the obesity prevention program. The tasks derived from this systematic approach were operationalized in 10 WPs.

PRECEDE; systematic and planned assessments

The PRECEDE component aims to unveil who has the problem and why they have it. Obesity prevalence in young childhood will be assessed and unique variations (country- and socioeconomic status [SES]-specific differences) will be detected with the use of situational analysis; this will be performed for both behavioural (for young children and their parents and parenting practices) and environmental factors (e.g. physical or socioeconomic) (addressed by WP2). Then the causal factors of behaviours and environment will be assessed, namely the predisposing factors (children's preferences and habits), the reinforcing factors (parental and teachers' knowledge, beliefs, attitudes and behaviours, food promotion and advertising) and the enabling factors (skills, resources or barriers that can help or hinder the desired behavioural changes as well as environmental changes), examining the involved stakeholders' views (addressed by WP3). Finally, having the scope of an intervention program that can be applied at a European level, the contextual factors and organizational structure (available personnel, curricula, time, policies and legislations) will be assessed in different European countries (addressed by WP5) but also most appropriate behavioural models and educational strategies applicable in the kindergarten setting will be sought (addressed by WP4).

Intervention mapping; evidence-based development of the ToyBox intervention

The information and knowledge obtained during the PRECEDE phases will guide the development of the intervention; thus the intervention scheme will not be an intuitive process but it will rather be the result of a systematic and dynamic procedure addressing in the most effective way the needs of the corresponding population and providing a tailor-made and therefore potentially more cost-effective approach. The insights gained in the PRECEDE assessments will feed the first stages of IM (Fig. 2) to establish specific, measurable, achievable, relevant, time-framed intervention objectives. For each of these objectives, the most appropriate theory and evidence-based methods (derived from effective behavioural models) and educational strategies, both identified in PRECEDE, will be combined in a comprehensive intervention program (addressed by WP6). Finally, a plan for the implementation and evaluation will be schemed based on the findings of

PRECEDE on policy, regulation and organization factors, to identify most appropriate entry points and alliances in the kindergarten setting.

PROCEED; implementation and evaluation of the ToyBox intervention

PROCEED is marked by the strategic implementation of the intervention providing also the framework for the evaluation of process, impact and outcome of the intervention. In ToyBox, the Proceed phases will follow the IM-drafted plan to perform the implementation and the comprehensive evaluation based on measurable objectives (addressed by WPs 7 and 8). In addition, cost effectiveness will be explicitly considered as one of the primary outcomes (addressed by WP9). Cost effectiveness is defined as the ratio between the (expected) net cost of an intervention (investment cost minus later expected savings) and the (expected) health outcomes (35).

Operationalization of work in ToyBox

WP1 comprises the co-ordination task to promote and ensure integrated and timely progress of the project. This WP is responsible for the overall running and implementation of the project, carries out the administrative tasks, is responsible for the financial and organizational management of the project, communicates and reports to the European Commission and oversees and guards quality-controlled data management and storage. This WP is also responsible for setting up the structure for communication through regular meetings. In addition, this WP gathers and organizes all results achieved in WPs 2–5, in order to have all input for WP6 available in one research centre and one database that can easily be accessed by WP6 and other participants.

WP2 executes a systematic review of the literature to identify energy balance-related behaviours associated with overweight and obesity (see te Velde *et al.* (36)). In addition, it performs secondary data analyses of existing data available in the participating European countries not only to identify the most relevant and important energy balance-related behaviours in early childhood but also to identify children at increased risk for overweight/obesity with regard to sociodemographic characteristics, in order to ensure that all country-, cultural- and SES-specific differences are addressed (see van Stralen *et al.* (37)).

WP3 executes a systematic review to identify the key determinants of energy balance-related behaviours (see De Craemer *et al.* (38)) and is also responsible for executing focus group interviews with parents and teachers of young children. This process will lead to the identification of the most important predisposing (children's preferences and habits), reinforcing (parental and teachers' beliefs,

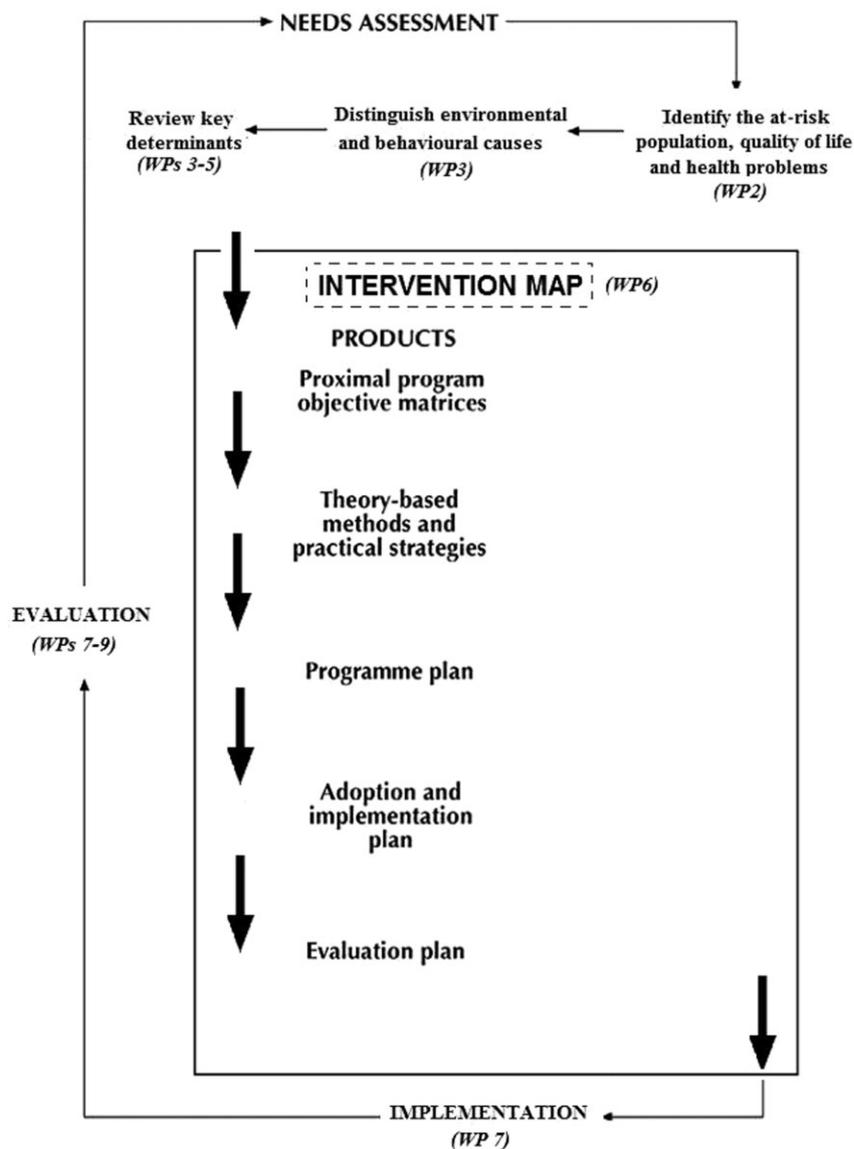


Figure 2 The five steps of the intervention mapping will be used for the development of the ToyBox intervention. (Adapted from Bartholomew *et al.* (34)).

attitudes, behaviours, food promotion and advertising) and enabling (resources, barriers or skills) factors determining engagement in specific energy balance-related behaviours. The determinants identified from the focus groups will lead to the development of the desired and effective intervention components, which will be partly similar across all countries, and partly focusing on the country-specific determinants (cultural adaptation) (see De Decker *et al.* (39)). Results will be synthesized into clear recommendations which will help to define the objectives in WP6.

WP4 addresses the behavioural models and educational strategies that should be included in a health promotion program. It explores and critically appraises successful behavioural models by means of a careful systematic literature review (see Nixon *et al.* (40)) and it additionally

reviews and evaluates educational strategies used for the formation of energy balance-related behaviours in early childhood (see Gibson *et al.* (41) and Kreichauf *et al.* (42)). Behavioural models identified as effective for the prevention of obesity will provide the theoretical framework of the ToyBox intervention whereas the latest findings of research will bring out the most important educational strategies to achieve effective and sustainable behavioural changes. The behavioural models and educational strategies used in ToyBox-study will be tailored (by age, gender, etc.) and combined within a socioecological framework to address young children and effectively result in changes of their energy balance-related behaviours. Parents will also be educated on how to use these strategies at home, to further support their children in improving their behaviours.

WP5 refers to the policy, regulation and organization that usually affect the integration and success of such a program. WP5 makes an overview of the existing policies and health promotion activities concerning healthy eating and physical activity in kindergarten settings. The inventory also includes what is known about obstacles and success factors that influence the development and implementation of these programs for the target group. Finally, in WP5 cross-cultural aspects of school policies are analysed, e.g. looking into the national education policies of the six intervention countries (Belgium-Flanders, Bulgaria, Germany, Greece, Poland and Spain), regulations and legislation on a national, regional and local level (such as the national school curriculum, bans on the sales of sweets and soft drinks in schools, local regulations on banning sweet shops in the vicinity of the school, creating safe walking and cycling tracks to school, etc.) (see Nethe *et al.* (43)). This will lead to a set of recommendations for the development and implementation of the ToyBox at a national and European level.

WP6 will use the outcome of WPs 2–5 to design the new multi-component school-based and family-involved intervention scheme. In WP6, the development of the intervention is guided by the five steps of IM and elements of previous successful interventions. Objectives and determinants are identified (by WPs 2 and 3), effective methods and strategies (by WP4) are included and the operationalization of the programme is explored (by WP5, which identifies implementers, stakeholders and synergies). A multi-component school-based family-involved intervention is produced and is enriched with behavioural models, educational strategies and ‘how to implement’ procedures based on the best practices identified by both reviews of the literature and successful practice.

WP7 is devoted to the implementation and process evaluation of the newly developed intervention in six Member States (namely Belgium, Bulgaria, Germany, Greece, Poland and Spain), representing different regions in Europe. ToyBox will be applied in kindergartens including children from different sociodemographic backgrounds. For this reason, municipalities within 50-km vicinity in all participating countries will be sorted by common (i.e. available in all countries) SES variables, i.e. parental educational level. For the selection of the schools, a step-by-step procedure has been established. Tertiles of municipalities will be created and a random sample of municipalities will be selected from each tertile. Within each tertile, a list of the kindergartens in the selected municipalities will be created; kindergartens will be randomly selected from each tertile. The selected kindergartens within each tertile should be randomly assigned as intervention or control at a 2:1 ratio. The intervention will be implemented in 13 kindergartens per country and seven other kindergartens will serve as controls. The total sample will thus comprise around 4,800

children. Power calculations based on previous studies of school-based interventions indicate that this sample size is sufficient to detect changes in energy balance behaviours and their determinants (44). The pre- and post-intervention period is estimated to last 2 months and in order to avoid seasonality effect, the pre- and post-examination will take place at the same time of the year leaving 8 months in between for implementation. This period has been considered as enough to exert favourable behavioural changes (19,23,24). Process evaluation will indicate the fidelity of intervention delivery across the different countries.

WP8 is devoted to the development and validity testing of assessment tools for eating, sedentary and physical activity behaviours and their determinants to be used for the impact and outcome evaluation of the intervention. Regarding impact and outcome, children’s BMI changes (outcome evaluation) are not the only focus of this intervention programme; it primarily focuses on evaluating the impact of the intervention on behaviours, such as dietary, sedentary or physical activity behaviours and their determinants (e.g. teachers’ or parental knowledge, beliefs and attitudes, parental BMI, physical activity, eating and sedentary behaviours, parenting practices, school environment) (19). Valid and reliable tools will be developed for application in preschool populations as part of this WP8, based on the results of WPs 2–5 and the review conducted within WP8 (see Mouratidou *et al.* (45)).

WP9 analyses the cost effectiveness of the intervention program as described through previous WPs. In ToyBox-study, health economic modelling is used to estimate the cost effectiveness of the intervention. If childhood overweight prevalence is reduced and this in turn reduces adulthood obesity, there will possibly be large economic benefits (46); the resulting net investment (initial investment minus future savings) will be balanced with the predicted health gain (often expressed in quality-adjusted life years or in avoided disability-adjusted life years) (35). The initial investment cost will be calculated based on the value of the used resources (material, staff, etc.). The health economic researchers will collect data regarding the unit costs for each type of resource in the involved countries (cost of scientific staff time, cost of teacher time, printing material, etc.). The observed resource use is then afterwards multiplied with the unit cost of each type of resource, e.g. the number of hours of teacher time multiplied with the cost per hour. All unit costs are considered from a societal perspective. The final cost-effectiveness estimation draws upon the extrapolation of the program outcomes to predict its impact on obesity in adulthood, based on published epidemiological data that relate observed childhood overweight and/or behaviour to adulthood overweight and obesity. The model will be a Markov model, consisting of different health or disease states and predicting the evolution of a hypothetical cohort of children

undergoing the programme vs. a control cohort. The time horizon of the model is at least 50 years in order to capture all relevant future costs and outcomes. The perspective of analysis is societal, meaning that the impact of healthier life is not only assessed from a healthcare payer perspective but also from a societal perspective, i.e. including the economic impact of work productivity.

WP10 undertakes dissemination activities for the ToyBox program and thereby contributes to the activities of the European Union (EU) platform on diet, physical activity and health and also supports decision-making for European public health policy. ToyBox-study uses methods to increase the relevance of research findings by enhanced reporting of contextual factors that can lead to improvements in the future translation and adoption of prevention interventions (47,48).

Discussion

In health promotion planning, it is important to follow a protocolized, stepwise process of development and evaluation to (i) increase the likelihood that the program will reach its target audience and achieve its goals and objectives; (ii) help ensure the program is implemented and evaluated effectively; (iii) provide opportunities to involve the community and ensure the program is inclusive (in terms of gender and culture) and addresses social equity issues; and (iv) maximize the likelihood that the program will become sustainable. To accomplish this, the ToyBox-study makes a combined use of the P-P model and IM protocol; such synergy has been proposed previously by both Green & Kreuter (P-P model) (33) and Bartholomew *et al.* (IM) (34). ToyBox-study applies this approach for the first time at a European scale aiming to promote healthy weight and healthy energy balance-related behaviours for the prevention of obesity in early childhood.

The recent ministerial conference of the World Health Organization (WHO) European region concluded that the obesity epidemic is a multifactorially determined problem, requiring a multidisciplinary and multisectoral approach (49,50). Building upon proposed strategies stated in the 'White paper on Nutrition, Overweight and Obesity' by the European Commission (51) and in the 'European Charter combating obesity' by WHO Europe (52), the ToyBox-study group spans the necessary multidisciplinary variety of experts such as public health experts, epidemiologists, nutritionists, physical activity experts, educational scientists, psychologists, behavioural scientists, nutritionists, paediatricians, early childhood psychologists, health economists, health promotion specialists, totalling 15 partners, from 10 countries. In addition, it incorporates the necessary range of research methodologies (systematic reviews, secondary data analysis, qualitative research

methods, economic modelling, multilevel and general linear modelling, evaluation of school-based interventions).

So far, different school-based intervention programmes aiming to prevent obesity and/or promote healthy energy balance-related behaviours and focusing on primary schoolchildren or adolescents have managed to show positive effects on the desired outcomes. Some examples such as the Pro Children Study (promotion of fruit and vegetable intake in 10–12-year-olds) (53,54), the JUMPIn (systematically developed primary-school-based intervention aiming to increase physical activity) (55), DOiT (aiming to prevent weight gain in three different age groups including teenagers by increasing physical activity) (56), Kiel Obesity Prevention Study (school-based intervention to prevent overweight and obesity in pre-pubertal children) (57,58) or Health and Nutrition Education Programme in Crete (school-based intervention (59,60)) have been effective in promoting the targeted healthy behaviours and/or positively changing body composition measures.

However, limited school-based research has focused on preventing obesity in preschool age despite the fact that the majority – in some countries up to almost 100% – of all young children (4–6 years old) attend either kindergartens or primary school (61). Exceptions are the Idefics and the TigerKids programmes. Idefics has targeted a broader age range (2–10 years old) and has developed different modules of intervention for children 2–6 and 6–10 years old (62). In the ToyBox, the very specific goals (energy balance-related behaviours) and narrow age range allow more focus and potentially effective approaches compared to the very wide 'developmental wise' age range of 2–6 years old as well as the wide thematic area of the Idefics project, including stress, bone mass and scoliosis. TigerKids, on the other hand, is a behavioural intervention developed for use in preschool day care settings in Germany (44), which was highlighted in the EU White Paper on Nutrition, Physical Activity and Health (51) as one of two European model projects for obesity prevention but the only school-based one. However, contextual and legislation frameworks of pre-primary education regarding curriculum, physical education classes, food services, etc., as well as any conflicts or opportunities for synergies with ongoing health promotion activities (that could significantly affect the outcome of the intervention) throughout the EU Member States was not examined in either Idefics or TigerKids project.

ToyBox-study follows a stepwise approach guided by P-P model and IM and initially carries out a systematic review of prospective studies (see te Velde *et al.* (36)) and a secondary data analysis of existing data to identify key behaviours related to obesity in young children (see van Stralen *et al.* (37)). It then conducts systematic reviews and executes focus groups to identify the determinants of energy balance-related behaviours, i.e. understand why

young children eat the foods they eat or why they do (or do not) participate in physical activity and sedentary behaviours (see De Kraemer *et al.* (38) and De Decker *et al.* (39)). Kindergarten setting is an ideal place to apply, in a potentially cost-effective way, health promotion activities; however, schools as well as schools' food services, health services and personnel are acting within a given contextual and legislative framework which varies at a local and national level (51,63). This framework as well as school personnel (as key stakeholders) is an important stakeholder in any intervention applied in the school setting because they will be the actual implementers of the intervention. Based on insights gained at local level, using the results of reviewing and critically appraising existing behavioural models that could underpin obesity prevention interventions (see Nixon *et al.* (40)) and educational strategies on what works best with young children (see Gibson *et al.* (41) and Kreichauf *et al.* (42)), but also examining the contextual framework at schools (see Nethe *et al.* (43)), ToyBox-study envisions contributing in combating childhood obesity at a European scale.

Even though ToyBox-study has a strong behavioural focus, the ToyBox-study consortium considers policy and sociocultural factors to be of critical importance to behavioural change. It therefore chose to use P-P model as a guiding framework and to devote two WPs (WP5 and WP9) to assessment of policy and contextual factors, and cost effectiveness. In addition, ToyBox-study addresses different policy or sociocultural factors in most WPs, namely in WP3 the sociocultural determinants of behaviours are assessed; in WP6 intervention material will be culturally adapted; in WP7 process evaluation will be performed including assessment of sociocultural and contextual factors; and finally WP10 will support public health policy decision-making and inform relevant stakeholders.

Within ToyBox-study, a multi-component school-based and family-involved intervention will be developed, aiming to facilitate the local needs within a European scale approach. This intervention will be applied in a selected number of European countries and will perform a comprehensive (process, impact, outcome and cost effectiveness) evaluation. The results of ToyBox-study will be disseminated among key stakeholders including scientists, policy makers and the general population. In that sense, ToyBox-study will support decision-making for public health policy by providing all necessary information for policy makers and health promotion planners while the material and intervention plan could be adapted and expanded on a pan-European scale.

Conflict of Interest Statement

The authors have no conflicts of interests to declare.

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