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Prevention of overweight in children younger than 2 years old: a pilot cluster-randomized controlled trial

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Abstract

Objective: The aim of the present study was to evaluate the effects of a 1-year family-based healthy lifestyle intervention implemented through day-care centres on toddlers' BMI *Z*-scores and reported activity- and dietary-related behaviours.
Design: Pilot cluster-randomized controlled trial.
Setting: Seventy child-care centres in three different intervention communities and three paired-matched control communities in Flanders, Belgium.
Subjects: A sample of 203 Belgian toddlers aged 9–24 months was included in the study. Objectively assessed weight and height were used to calculate BMI *Z*-scores. A parental-report questionnaire was used to assess children's lifestyle behaviours.
Results: Positive intervention effects were found on BMI *Z*-score. No intervention effects were found for activity- and dietary-related behaviours targeted by the intervention. In both intervention and control groups, daily consumption of water, soft drinks, sweets and savoury snacks increased while daily consumption of fruit and vegetables decreased over 1 year. Daily physical activity remained stable but screen-time behaviour increased in both groups over time.
Conclusions: The study showed that a family-based healthy lifestyle intervention implemented through day-care centres can lead to healthier weight outcomes in toddlers. In both groups, an unhealthier lifestyle pattern was observed over 1 year which underlines the importance of the early childhood period as the focus of future behavioural interventions.

Keywords
Overweight prevention
Intervention
Toddlers

A high prevalence of overweight and obesity is currently observed in all age groups around the world[1]. It is of special interest that overweight and obesity are also observed in very young children, even in toddlers (age 12 to 36 months)[2]. As childhood overweight and obesity are likely to impact on later child and adult BMI (tracking phenomenon of obesity)[3–6], preventive efforts are already needed early in life.

Although most evidence on determinants of childhood overweight and obesity is available from pre-school ages onwards (>3 years old), there is evidence that regular physical activity protects against unhealthy weight gain in young children[7–9] and that increased television time[7] and unhealthy food intake[7] can contribute to weight gain in toddlers. Moreover, there is evidence that unhealthy lifestyle behaviours are prevalent in this age group[10–13] and that they are likely to track into later life[12,14]. Therefore, early childhood (between 0 and 5 years of age) is a critical period in life to establish a healthy lifestyle that will have long-lasting effects on later health.

Despite the potential and promising role of early childhood in the prevention of overweight and obesity, there is only a small body of evidence reporting on the effectiveness of interventions to prevent overweight and obesity in young children by promoting healthy eating, physical activity and/or reduce sedentary behaviour[15]. Hesketh and Campbell[15] reviewed the literature on the prevention of obesity in children below the age of 5 years and found twenty-three studies which evaluated the effectiveness of interventions that focused (at least) on a healthy diet as well as increased physical activity or reduced sedentary behaviour. Of special interest is that this review only reported one study that investigated the effectiveness of a dietary- and activity-related intervention on weight outcomes in toddlers[16].

Although the evidence available in the broader age range of 0 to 5 years old is limited, it is supportive for the

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assumption that parents and caregivers are receptive to overweight and obesity preventive efforts during early childhood[17]. Furthermore, it is commonly accepted, and in line with ecological models of behavioural change[18], that the family and especially the parents should be involved as agents of change in the prevention of childhood overweight and obesity[19,20]. However, it is clear from the literature that there is still a lack of multi-topic, family-based interventions that have been implemented and evaluated for their effectiveness in changing behavioural determinants and preventing overweight and obesity during early childhood[15,21].

The aim of the present pilot trial was to address this gap in the literature by investigating the effect of a 1-year family-based healthy lifestyle intervention implemented through day-care centres on toddlers' weight, dietary behaviour, physical activity and screen-time behaviour. It was hypothesized that the intervention would lead to healthier weight outcomes (i.e. more optimal BMI *Z*-scores), significant increases of health-promoting behaviours (consumption of fruit, vegetables, water and unsweetened milk; daily physical activity) and significant decreases of risk behaviours (consumption of soft drinks, sweetened milk, sweets and savoury snacks; daily screen-time).

Method

Participants

The present study was conducted in six different communities (i.e. a town or municipality) in Flanders, Belgium. The communities were selected from research regions that were stipulated by the Flemish Policy Research Centre for Welfare, Health and Family, which financed the research project. The selection of the six communities in the research regions was based on five socio-economic characteristics: (i) the number of births in underprivileged families; (ii) the proportion of pupils in primary school with a school delay; (iii) the rate of unemployment; (iv) the number of persons on welfare support; and (v) the number of underprivileged foreigners. High scores on these parameters indicated a lower socio-economic status (SES) of the community. A community was labelled as 'low SES' if it scored higher than the Flemish mean on three to five of the above-mentioned characteristics. A community was labelled as 'medium SES' if one or two scores were higher than the Flemish mean. A community was labelled as 'high SES' if it had no scores higher than the mean. Two communities with a low, two communities with a medium and two communities with a high SES were selected. From each pair-matched community, one community was randomly allocated to the intervention group. The other community was allocated to the control group[22].

In each community, all day-care centres were invited for participation. All day-care centres were officially recognized by the Flemish governmental agency 'Child & Family' (Kind & Gezin)[23], which is accredited to provide recognition and subsidies to day-care centres in Belgium. A day-care centre in Flanders is a facility that is formally responsible for providing non-relative care for children between 0 and 3 years old. Formal child care is highly attended in Flanders[23]. A total of 137 day-care centres were contacted of which seventy were willing to participate in the study (51 %). Reasons for non-participation of the day-care centres were attributable to the age range of the children, closure of the day-care centre, change of management and previous bad experiences with research.

Within each day-care centre, parents of all children aged 9–24 months were invited to enrol their child in the study (*n* 404). The parents of 215 children (53 % of those invited) gave permission for their child to participate (ranges: 16–80 children/community; 4–21 day-care centres/community; 1–12 children/day-care centre). Twelve children were not present in day care on the measurement day. This resulted in a final sample of 203 children (50 % of those invited) who fulfilled the minimal criteria to be included in the study (i.e. objectively assessed weight and standing height at baseline). No BMI *Z*-score could be calculated for seven of these children, one child was excluded because of being underweight (initial BMI *Z*-score < -2) and four children were excluded for being obese (initial BMI *Z*-score > 3), resulting in a final sample of 191 children included in the analyses (47 % of those invited; intervention group: *n* 126 in thirty-five day-care centres; control group: *n* 65 in twenty-two day-care centres). Mean age of the final sample was 15·51 (SD 2·68) months and 54 % were boys. Of this sample, 156 children were re-examined 12 months later at follow-up (82 % of the baseline sample; intervention group: *n* 100; control group: *n* 56).

Parents provided written informed consent for all measurements at the start of the study. The study protocol was approved by the Ethical Committee of the University Hospital of Ghent University.

Measurements and procedures

After randomizing the communities into either the intervention or the control group, data collection took place at baseline (T0; prior to the intervention; autumn 2008) and 12 months later at follow-up (T1; after the intervention; autumn 2009) to control for seasonal effects. It was practically impossible to conduct the baseline measurements before randomization, as the present study was part of a larger government-funded research project that also included other research objectives. This also implied that local professionals and day-care centres in the communities were already aware of their group allocation at the start of the study.

After randomization, parents received a letter in which they were informed about the study but their group assignment was not revealed at that time. However, the day-care centres distributed the letters to the parents and

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they may have incorporated this information in their communication to the parents. Further, blinding of the parents in the intervention communities could not be obtained throughout the study as parents received specific materials as part of the intervention.

Before baseline measurements, identification numbers were given to the participants in a way that did not enable the identification of participants. Also, researchers did not have access to personal data of the participants, as day-care centres in Belgium are not allowed to provide them to others. Children's weight and standing height were measured barefooted and in light clothing in the day-care centre by two researchers who were not blind to participant assignment at baseline and follow-up. Weight was measured to the nearest 0·1 kg with digital scales (Seca Robusta 813; Seca, Hamburg, Germany) and standing height to the nearest millimetre using a mobile stadiometer (Seca 214). Weight and height were used to calculate BMI (kg/m^2) and BMI *Z*-scores on the basis of the WHO 2007 reference data using the LMS method[24]. Sex- and age-specific BMI *Z*-scores provide a relative measure of adiposity adjusted for age and sex. The Z-score is the number of SD units that a person's BMI is deviated from a mean or reference value. If a child's BMI *Z*-score has not changed over time, his/her BMI deviates an equal number of SD units from the mean or reference value at all time points, despite the possible decrease in absolute BMI over time that is observed in 10–24-month-old children[24]. Children with a BMI *Z*-score > 2 were considered overweight[25].

Parents received a questionnaire through the day-care centre and were asked to complete it at home. The questionnaire included a validated twenty-four-item semi-quantitative FFQ[26] to assess the daily consumption of water, soft drinks, milk, fruit, vegetables, sweets and savoury snacks. The FFQ was relatively validated in a sample of 650 children, aged 2·5–6·5 years, using an estimated 3 d diet record as a reference. Reproducibility (*n* 124) was measured by repeated FFQ administrations five weeks apart. For most foods, a moderate level of relative validity was observed for estimated food group intake[26]. The FFQ enabled to make a distinction between sweetened and unsweetened milk consumption. Sweetened milk included growing-up milk, dairy drinks, milk shakes and milk products flavoured with sweet additives (soya drinks, fresh cheese and yoghurt, and milk or soya desserts). Unsweetened milk included buttermilk, (semi)-skimmed or whole milk, natural soya drinks and unflavoured fresh cheese and yoghurt.

The parental questionnaire assessed screen-time behaviour by means of a closed-ended question asking parents to report the usual time per day their child watches television, videos and/or digital video disks during weekdays and weekend days, separately. Time spent in these screen-time behaviours was divided in eight response categories: (i) not at all; (ii) 0·5 h/d; (iii) 1 h/d; (iv) 2 h/d; (v) 3 h/d; (vi) 4 h/d; (vii) 5 h/d; and (viii) ≥6 h/d. Daily time spent in screen-time behaviour was calculated as follows: [(weekday × 5)+(weekend day × 2)]/7.

Daily physical activity was also assessed through the parental questionnaire by using a closed-ended question about the child's daily physical activity (e.g. walking, running, crawling, using a push-bike). Time spent in physical activity was divided in eight response categories: (i) not at all; (ii) 0·5 h/d; (iii) 1 h/d; (iv) 2 h/d; (v) 3 h/d; (vi) 4 h/d; (vii) 5 h/d; and (viii) ≥6 h/d. Parents were asked to indicate the time their child spent being physically active during weekdays and weekend days separately. Daily time spent in physical activity was calculated as follows: [(weekday × 5)+(weekend day × 2)]/7.

Demographic factors like birth date, sex and SES were also acquired through the parental questionnaire. SES was classified into two groups based on the mothers' highest educational level: (i) those who completed elementary, vocational, technical or general secondary education (low SES); and (ii) those who completed higher education or university (high SES).

Intervention

A family-based healthy lifestyle intervention was developed and implemented through day-care centres. The intervention aimed at increasing daily consumption of water (instead of soft drinks), milk, fruit and vegetables, increasing daily physical activity and decreasing daily consumption of sweets and savoury snacks and daily screen-time behaviour.

In line with well-known health-promotion planning approaches[27], changeable determinants of these target behaviours were selected. Based on the literature and behaviour change theories, it was decided that the intervention had to increase parental knowledge, awareness, self-efficacy, parental modelling of the expected behaviours and availability of the healthy foods in the home environment.

Specific behaviour-oriented theories were selected to develop the intervention: (i) theories of information processing[27]; (ii) the elaboration likelihood model[28]; and (iii) the precaution-adoption process model[29]. Theories of information processing suggest that information should be successfully transferred to the communication receiver when aiming to change behaviour[27]. The elaboration likelihood model suggests that skills and motivation are needed to obtain thoughtful information processing which is a perquisite for behavioural change[28]. The precaution-adoption process model is a stage theory that was developed to describe the process of behavioural change according to different steps that people go through before changing their behaviour[29].

The behaviour-oriented theories informed the selection of methods to influence the determinants. Elaboration and chunking were the behavioural change methods derived from theories of information processing. Elaboration and persuasive communication were derived from the elaboration likelihood model and tailoring and

consciousness raising were derived from the precaution-adoption process model[27].

The selected methods were translated into different strategies which were aggregated in an intervention programme that consisted of two components: (i) guidelines and tips presented on a poster and (ii) a tailored feedback form for parents about their children's activity- and dietary-related behaviours.

The poster consisted of a colourful and animated A3 sheet with five stickers. Each sticker dealt with a targeted behaviour and provided parents with practical information and/or strategies. The stickers were distributed to the parents every two months and were gradually stuck on the poster by the parents. The stickers were always accompanied by a letter with information about the target behaviour. The tailored feedback was based on the activity- and dietary-related measures as reported by the parents in the baseline questionnaire. The poster and the tailored feedback were provided to the parents through the day-care centres. A more detailed description of the translation from theoretical methods to different intervention components and a more detailed description of the intervention materials and the corresponding implementation strategy can be found in Table 1.

Statistical analyses

Data were analysed using the statistical software package IBM SPSS Statistics version 19. Data distribution of quantitative variables was checked using the Shapiro–Wilk test. All behavioural data were skewed and were therefore transformed, with a $\log_{10}$ transformation best approximating a normal distribution. BMI *Z*-score at baseline was negatively skewed but logarithmic transformation (based on $\log_{10}(x + a)$ to deal with negative BMI *Z*-scores) did not improve normality, so non-transformed data were used. BMI *Z*-score at follow-up was normally distributed and was therefore not transformed.

Descriptive statistics were used to describe the study population using means and standard deviations. Independent-samples *t* tests and χ^2 tests were used to test differences between the control and intervention groups. Logistic regression analyses were conducted to examine if the dropout rate was associated with baseline characteristics of the participants (i.e. sex, weight status, SES, research condition).

To assess the effect of the intervention on BMI *Z*-score and behavioural outcomes, linear mixed models were applied with an additional random effect for day-care centre to consider the clustered study design in the analyses. The analyses were adjusted for SES, age of the child and BMI *Z*-score at baseline to control for the observed baseline imbalance in these variables between intervention and control groups.

Unless specified otherwise, non-transformed data are reported in the tables and the text. *P* values of ≤0·05 were considered statistically significant.

Results

Table 2 presents baseline data for the total sample included in the study and for the intervention and control groups separately. After 1 year of intervention, 21 % of the children in the baseline sample dropped out from the study in the intervention group (*n* 26) and 14 % dropped out in the control group (*n* 9). Dropout analysis showed that normal-weight children were just as likely to drop out from the study as overweight children (OR = 0·52; 95 % CI 0·16, 1·69). No significant difference was also found for sex, SES and research condition.

A significant time-by-condition interaction effect indicated that the intervention had a positive effect on BMI *Z*-score. BMI *Z*-score decreased in both groups but decreased more in the intervention group compared with the control group (Table 3).

The intervention was not effective in increasing parental-reported daily time spent in physical activity and in increasing daily consumption of water, unsweetened milk, fruit and vegetables. The intervention was also not effective in decreasing parental-reported daily time spent in screen-time behaviour and in decreasing daily consumption of soft drinks, sweetened milk, sweets and savoury snacks. Table 3 presents the pre- and post-intervention values of all activity- and dietary-related behaviours by condition, as well as effect estimates and *P* values of the time-by-condition interaction effects.

Significant main effects of time were found for all dietary-related behaviours, except for sweetened and unsweetened milk consumption (Table 3). In both the intervention and control groups, the parental-reported daily consumption of water, soft drinks, sweets and savoury snacks increased significantly over 1 year. The parental-reported daily consumption of fruit and vegetables decreased significantly over time in both groups. No significant main effect of time was found for daily physical activity levels but daily screen-time behaviour increased in both groups between the two measurements (Table 3).

Discussion

The main finding of the present study was that a family-based healthy lifestyle intervention focusing on dietary behaviour, physical activity and screen-time behaviour implemented through day-care centres resulted in healthier weight outcomes in a Belgian sample of 9–24-month-old toddlers. No significant intervention effects were found on the lifestyle behaviours targeted by the intervention but, over a period of 1 year, dietary-related behaviours developed in the unhealthy direction in both conditions. This indicates that development of an unhealthy lifestyle pattern contributing to the development of childhood obesity already starts at very young age.

In line with our hypothesis, the family-based healthy lifestyle intervention resulted in healthier weight outcomes

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Table 1 Description of the intervention components, corresponding intervention materials and implementation strategy

Theoretical methods used to develop the intervention†	Description of intervention components and corresponding intervention materials	Implementation strategy
Chunking (TIP): the use of stimulus patterns that are made up of parts but that people perceive as a whole (e.g. by assigning labels or acronyms to materials). Elaboration (TIP, ELM): stimulate a person to add meaning to the information that needs to be processed (e.g. by using personally relevant messages, messages that are repeated, easily understandable and messages with direct instructions). Persuasive communication (ELM): the use of arguments or other means to guide people towards the adoption of an idea, attitude or action (e.g. by using relevant messages, messages that are in line with the beliefs of the individual).	1. GUIDELINES AND TIPS PRESENTED ON A POSTER ● Five figures were presented on the poster, each corresponding to one or more target behaviours: ○ Figure 1: consumption of water ○ Figure 2: consumption of milk ○ Figure 3: consumption of fruit and vegetables ○ Figure 4: increasing physical activity and decreasing screen-time behaviour ○ Figure 5: consumption of sweets and savoury snacks. ● Initially, the front of the poster did not contain any information about the target behaviours but was gradually completed by means of the stickers. The stickers dealt with one ore more target behaviours and had to be stuck on the corresponding figures. ● Together with the poster, the first sticker was provided. Two months later, a new sticker was provided. This was done until the information on the poster was completed. ● Each sticker provided parents with practical information and/or strategies about the target behaviour(s) targeted on the sticker (e.g. 'Put water on the table during every meal', 'Make rules about the snacking behaviour of your child'). ● Each sticker was always accompanied by an information letter providing parents with additional information and guidelines about how to promote the target behaviour(s). ● On the back of the poster, five general tips were provided about how parents can support and stimulate their child's healthy eating behaviour (e.g. 'Do not think too fast that your child does not like the food', 'Provide different tastes and make sure that your child can try them quietly').	● Materials were developed by the research team in close collaboration with the regional health boards and the Flemish governmental agency 'Child & Family'[23]. ● Materials were distributed to the parents through the day-care centres. ● Day-care centres were also asked to use the poster and to apply the information in their daily practices.
Tailoring (PAPM): the adaptation of intervention components to characteristics of the participant that were previously measured. Consciousness raising (PAPM): provide people with information and feedback, or confront them with the causes, consequences and alternatives for a problem or behaviour.	2. TAILORED FEEDBACK FORM FOR THE PARENTS ● Feedback was given for each target behaviour separately in one feedback form of approximately three pages. ● The feedback for each target behaviour included a fixed (same information for all parents) and a variable part (information tailored to the behaviour of the child). ● The fixed part included a short overview of the current recommendations (e.g. 'Vegetables are important for the growth of your child; they provide carbohydrates, fibres, minerals and vitamins. Your child needs 50–100 g of vegetables per day (1–2 spoons). You can eat vegetables together with bread or at lunch or dinner but also as a snack'). ● The variable part included normative feedback in which the child's behaviour was related to the current recommendations (e.g. 'Your child eats 200 g of vegetables per day. This means that your child eats enough vegetables per day, congratulations! Keep encouraging your child to eat vegetables every day'). Guidelines and tips were provided for the parents to promote and support that specific behaviour.	● The feedback was developed by the researchers and was based on the information reported by the parents in the baseline questionnaire. ● The feedback form was distributed to the parents through the day-care centres.

†Description of theoretical methods taken from Bartholomew *et al.*[27]; TIP = theories of information processing; ELM = elaboration likelihood model; PAPM = precaution-adoption process model.

Table 2 Participant characteristics at baseline in the total group and in the intervention and control groups separately: Belgian toddlers (*n* 203) aged 9–24 months

		Total group		Intervention		Control		
Total sample	*n*	Mean	SD	Mean	SD	Mean	SD	*t* or χ^2 value
Age (months)	191	15·51	2·68	15·84	2·75	14·90	2·43	1·91*
Boys (%)	188	54·3		53·2		56·2		1·21
Low SES (%)	188	16·5		12·8		23·8		23·69*
BMI (kg/m^2)	191	17·87	1·40	18·12	1·35	17·39	1·40	3·52**
BMI *Z*-score	191	1·10	0·93	1·29	0·84	0·74	0·99	4·00***
Overweight† (%)	191	17·3		22·2		7·7		6·33*

SES, socio-economic status.
Data are presented as means and standard deviations or as percentages.
Statistically significant difference between intervention and control group: *$P \leq 0{\cdot}05$, **$P = 0{\cdot}001$, ***$P < 0{\cdot}001$.
†BMI *Z*-score > 2.

Table 3 Effects of the healthy lifestyle intervention on BMI *Z*-score and lifestyle behaviours in Belgian toddlers (*n* 203) aged 9–24 months

		Baseline		Follow-up		Estimate†	Estimate†
	n	Mean	SD	Mean	SD	time	time × condition
BMI *Z*-score							
Control	54	0·74	1·02	0·30	0·98	0·93***	–0·50*
Intervention	99	1·33	0·86	0·38	0·89		
Total	153	1·12	0·96	0·35	0·92		
Water consumption (ml/d)							
Control	38	207·97	153·63	293·79	155·75	−0·23***	0·05
Intervention	68	196·06	137·42	311·08	139·64		
Total	106	200·33	142·83	304·88	145·12		
Fruit consumption (g/d)							
Control	36	181·15	90·17	153·48	83·09	0·14*	−0·05
Intervention	58	201·49	85·60	158·72	78·30		
Total	94	193·70	87·46	156·71	79·76		
Vegetable consumption (g/d)							
Control	33	169·06	72·74	93·49	47·87	0·33***	–0·05
Intervention	62	155·13	76·10	86·63	62·56		
Total	95	159·97	74·86	89·01	57·71		
Unsweetened milk consumption (ml/d)							
Control	34	228·13	261·74	254·02	234·24	−0·17	0·01
Intervention	65	242·43	239·54	269·16	208·96		
Total	99	237·52	246·15	263·96	216·89		
Sweetened milk consumption (ml/d)							
Control	32	283·45	239·30	260·39	237·53	0·01	0·07
Intervention	58	292·63	255·36	230·79	242·72		
Total	90	289·37	248·45	241·31	239·97		
Soft drink consumption (ml/d)							
Control	38	6·05	14·66	30·58	46·09	–0·40**	−0·14
Intervention	69	3·00	11·30	19·07	41·64		
Total	107	4·08	12·61	23·16	43·41		
Sweets and savoury snacks (g/d)							
Control	30	30·55	21·57	42·73	22·49	–0·26***	0·06
Intervention	55	25·44	20·81	42·43	25·49		
Total	85	27·24	21·10	42·54	24·34		
Physical activity (h/d)							
Control	35	4·16	1·36	4·00	1·28	–0·04	0·06
Intervention	61	3·79	1·30	3·84	1·21		
Total	96	3·92	1·33	3·90	1·23		
Screen-time behaviour (min/d)							
Control	34	18·91	22·63	41·85	31·42	–0·24***	0·09
Intervention	64	11·25	19·13	37·23	30·90		
Total	98	13·91	20·62	38·83	31·00		

*$P \leq 0{\cdot}05$, **$P = 0{\cdot}01$, ***$P < 0{\cdot}001$.
†Effect estimates and *P* values obtained via mixed model analyses adjusting for socio-economic status, age of the child and BMI *Z*-score at baseline and correcting for clustered design (day-care centre).

in toddlers. Relative BMI decreased in both conditions but decreased more in children who received the healthy lifestyle intervention. This result is in line with those found by Harvey-Berino and Rourke[16]. These authors evaluated the effectiveness of a home-based multi-topic parental support programme focusing on general parenting skills.

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They found a decrease in weight-for-height *Z*-score in the toddlers whose parents received the intervention while the *Z*-scores increased in the control condition. To our knowledge, the study of Harvey-Berino and Rourke[16] is the only one that previously evaluated the effects of an intervention on weight outcomes in toddlers by focusing on the same behaviours as the present study and focusing on parents as agents of behavioural change in very young children. Therefore, it is not possible to compare the results with other studies in this age group. However, we believe that the effectiveness of the present study is of special importance as it demonstrates that interventions during early life are promising in counteracting childhood overweight.

In contrast with what we hypothesized, no significant positive intervention effects were found on the lifestyle behaviours targeted by the intervention. This may be attributable to several factors. Possibly, the parental-report measures used were not sensitive enough to detect differential changes that occurred between the control and intervention groups and we are not aware of their ability to detect changes over time that are clinically meaningful in children younger than 2 years. However, these instruments are frequently used in young children and no other instruments were available for children below the age of 2 years at the time the study was conducted. The questions to assess children's physical activity and screen-time behaviour were quite generic and might not have been specific enough to detect and measure differences attributable to the intervention. It may also be possible that parents were not able to adequately recall their children's behaviour because the children spent most of the day at day care. All of these factors could have resulted in imprecise parental-reported measures at the two points in time, which may have increased the error associated with change and reduced the ability of the instruments to detect true changes. Therefore, the use of objective measures for physical activity and sedentary behaviour (e.g. accelerometers) and the use of more specific measures for dietary intake (e.g. employees of the day-care centre as a proxy reporter) are recommended in future studies evaluating the effectiveness of behavioural lifestyle interventions in toddlers. Another possible reason could also be that the individual lifestyle changes (e.g. changes in several dietary-related behaviours separately) were too small to show significant changes over time between the intervention and the control groups. Although we did not find significant intervention effects, the data suggested a greater increase in water and unsweetened milk consumption, a greater decrease in sweetened milk consumption, a lesser decrease in vegetable consumption and a lesser increase in soft drink consumption in the intervention group compared with the control group. However, these small but different lifestyle changes, in combination with physical activity (which tended to increase slightly in the intervention group and decrease in the control group), might all together be causing the greater reduction of relative BMI in the intervention group as compared with the control group. An alternative explanation is that reductions in BMI *Z*-score might be the result of changes in behaviours that were not captured by the methods used in the present study, such as total sedentary time, moderate-to-vigorous physical activity or portion sizes.

An interesting finding of the present study was the negative development of lifestyle behaviours observed in toddlers in both conditions. Except for the consumption of water and sweetened milk, all dietary-related behaviours evolved in the unhealthy direction over 1 year of time. This negative development of dietary-related behaviours coincided with the period in which the child starts eating the same foods as the rest of the family and in which the child is taking over the habits of the family, which will track into later life. Therefore, this observation indicates that the first two years of life are critical for establishing healthy lifestyle patterns and underlines the need for behavioural interventions during early childhood. In Belgium, parents are strongly supervised, advised and supported about their child's growth and development by a governmental agency during their child's first year of life. However, this consultative role decreases and parents receive less strong messages regarding healthy lifestyle behaviours as soon as the child is getting more independent (around the age of 18 months). Therefore, the negative development of lifestyle behaviours observed in the present study shows the importance of health-care professionals to strongly encourage and promote healthy infant feeding practices in line with national recommendations during the early childhood period. Furthermore, health-care professionals should not only focus on the behaviour of the child but should also focus on the establishment of health-promoting family habits which are the basis for a social environment in which children's healthy lifestyle behaviours can be developed and sustained.

The present study also found that toddlers' screen-time behaviour increased significantly in both groups before the age of 2 years. This finding is in line with results found by Zimmerman *et al.*[30] who studied screen-time behaviour in the same age group. In line with the findings of the present study and because of the positive association observed between screen-time behaviour and childhood overweight and obesity, health-care providers should also include screen-time recommendations in their advice to parents of very young children and support them in setting limits to screen-time behaviour already at very young age[31].

Although the present study found that toddlers' physical activity levels remain stable over 1 year of time, it is recommended to measure physical activity levels in subsequent obesity preventive efforts. Previous studies have shown that physical activity at a very young age is associated with overweight and obesity and other health aspects in general[32]. Furthermore, low levels of physical

activity were previously observed in young children[11] and tend to track into later childhood[14]. Results of the present pilot trial suggest that physical activity should be objectively assessed in future studies, which has already been found to be valid and feasible in this age group[33,34]. In addition, there is currently a growing research interest in the independent association between physical activity and sedentary behaviour and health outcomes[35]. This emphasizes the importance of assessing both physical activity and sedentary behaviour as separate constructs in following trials.

Strengths of the present study include the use of objectively assessed weight and height and the cluster-randomized design. Furthermore, the present study is one of the first to add to the small evidence base that is available in the literature on childhood obesity prevention in toddlers. A first limitation is the rather low participation rate at the level of the child-care centres and the individual retention rate at follow-up. However, comparable attrition rates were observed in the intervention and control groups after 1 year of intervention. Another limitation is the use of a parental-report questionnaire to assess children's lifestyle behaviours. Parental-report measures of these behaviours can be susceptible to social desirability and it might be possible that parents are not able to adequately recall their children's behaviour as children potentially spent most time during the day at the day-care centre. A third limitation is the fact that baseline differences were observed between the control and intervention groups in sociodemographic characteristics and body composition. We also acknowledge that regression to the mean may have taken place, which must be considered while interpreting the main results of the study. Finally, practical compromises had to be made and not all levels of blinding were possible. Baseline measurements took place after randomizing the communities in the intervention and control groups. Although group allocation was not revealed for the parents at baseline, it might be possible that day-care centres included this information in their communication with the parents. Blinding of the parents in the intervention group could not be obtained throughout the study as parents received specific materials as part of the intervention. Therefore, parental knowledge of group assignment may have influenced the completion of the parental-reported behavioural data. Also, the researchers who conducted the measurements were not blinded to group allocation, which may have unintentionally biased the measurement of children's weight and height.

Due to the small number of participants, this is considered a pilot study and should be seen as a rehearsal and informative for subsequent large-scale, fully powered trials. Future studies are recommended to use accelerometers as an objective measure for physical activity and sedentary behaviour and to include employees of the day-care centres to proxy-report the dietary intake of the children during their time spent in day care. In addition, future intervention research should not only focus on the child's behaviour but also on the development of healthy family habits, which too are essential for the establishment of children's early healthy lifestyle behaviours.

Conclusion

The present study showed that a family-based healthy lifestyle intervention implemented through day-care centres can lead to healthier weight outcomes in toddlers. No behavioural intervention effects were identified but the study instruments used might have been inadequate to evaluate intervention effects on lifestyle behaviours in toddlers. It might also be possible that the observed individual lifestyle changes were too small to show positive behavioural intervention effects. However, the combination of these small lifestyle changes might have caused the expected changes in objectively assessed weight outcomes, which is encouraging for further overweight and obesity preventive research in toddlers.

The study also showed that an unhealthy lifestyle pattern is already developed during children's first two years of life. This underlines the importance of behavioural interventions during early childhood to establish a healthy lifestyle that will have lasting effects on children's health in later life.

There remains a current need for interventions to be implemented and evaluated to determine their effectiveness on changing behavioural determinants and preventing childhood obesity in toddlers.

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