

# Economic evaluation of URMEL-ICE, a school-based overweight prevention programme comprising metabolism, exercise and lifestyle intervention in children

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## Abstract

**Objective** Measuring the impact of the URMEL-ICE school-based overweight prevention programme on anthropometric measures in primary-school children, computing incremental cost-effectiveness relation (ICER) and net monetary benefit (NMB).

**Methods** This is an intervention study with historical control. Propensity score method is applied to account for group differences. One-year teacher-driven classroom implementation is used, which is based on especially developed teaching material including health education,

physical activity breaks and parent involvement. 354 children in the control and 365 children in the intervention group at baseline and follow-up were analysed. Effectiveness is measured as cm waist circumference (WC) and unit (0.01) waist-to-height ratio (WHtR) increase prevented in intervention vs. control group using an adjusted two-level model. Standard cost-effectiveness analysis methods, net benefit regression and a societal perspective for a 1-year time horizon are applied.

**Results** WC gain was 1.61 cm and WHtR gain was 0.014 significantly less in intervention vs. control group. Intervention costs were €24.09 per child. ICER was €11.11 (95% confidence interval (CI) [8.78; 15.02]) per cm WC and €18.55 (95% CI [14.04; 26.86]) per unit WHtR gain prevented. At a maximum willingness to pay (MWTP) of €35, both values of the CIs for NMB regarding WC and WHtR are located in the positive range.

**Conclusions** The study gives new information about the cost-effectiveness of structured health promotion embedded in daily routine at primary schools. Assuming a MWTP of €35 the intervention is cost-effective with a positive NMB. This result may help decision makers in implementing programmes to prevent childhood overweight in school settings.

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**JEL Classification** I10 · I12 · I18

## Introduction

Overweight and obesity in childhood are already linked to various health risks [1]. Being overweight or obese as a

child, the likelihood to remain so in adulthood is not negligible, and today's children may have ultimately shorter lives than their parents [2]. According to the various comorbidities, obesity goes along with higher medical costs, leading to estimations of total annual costs of approximately €32.8 billion in the EU (2002) [3] and US\$139 billion in the United States (2003) [4].

Programmes of preventive measures in children and adolescents differ a lot concerning their degree of evaluation, and only few of them are examined towards their cost-effectiveness [5].

Analyses of cost-effectiveness are mainly found in the field of treatment for already apparent overweight or obesity, probably due to the interests of the pharmaceutical industry on one hand and to higher levels of uncertainty concerning primary prevention and subsequent methodological difficulties [6] on the other hand.

The latest review of recent research on economic evaluation of preventive measures by John et al. [7] identifies four studies published in 2008–2009. Two of them were taken from the ACE-Obesity (Assessing Cost-effectiveness in Obesity) Project, and thereof, the most cost-effective intervention was the reduction in TV advertising of energy-dense, nutrient-poor food and beverages, while the other programme exceeded the usual threshold values of cost-effectiveness. According to John et al., the APPLE (A Pilot Program for Lifestyle and Exercise) Project conducted in New Zealand was an economically inferior project concerning the changes in health-related quality of life as primary outcome variable. The fourth study, the FitKid school-based obesity prevention study carried out in Augusta, GA, USA, was successful but with limited meaning, because of the usage of an intermediate outcome measure. But since successful studies on overweight prevention programmes in children are rare and the epidemic is getting worse, we are not in the convenient situation to push aside studies with intermediate outcome measures.

The URMEL-ICE programme [8, 9] was designed from a synthesis of components taken from successful interventions. Even though intermediate outcome measures are used, the purpose of this article is to show the cost-effectiveness and the simplicity of this intervention to help decision makers find an effective and simple way to take action against the growing threat of obesity.

## Participants and methods

### Overview of the URMEL-ICE study

URMEL-ICE stands for Ulm Research on Metabolism, Exercise and Lifestyle Intervention in Children. The basic study was a school-based, cluster-randomized intervention

trial conducted in the region of Ulm, Germany. In close temporal proximity, the intervention was implemented in the Bavarian county of Günzburg, located in immediate neighbourhood to Ulm. The main difference between the two studies is that all cost data in association with the intervention were collected in Günzburg, while a control group was missing. The intervention in Günzburg was initiated by the district administration and the local community foundation and aimed at the benefit of all children in the county; therefore, a control group was not desired.

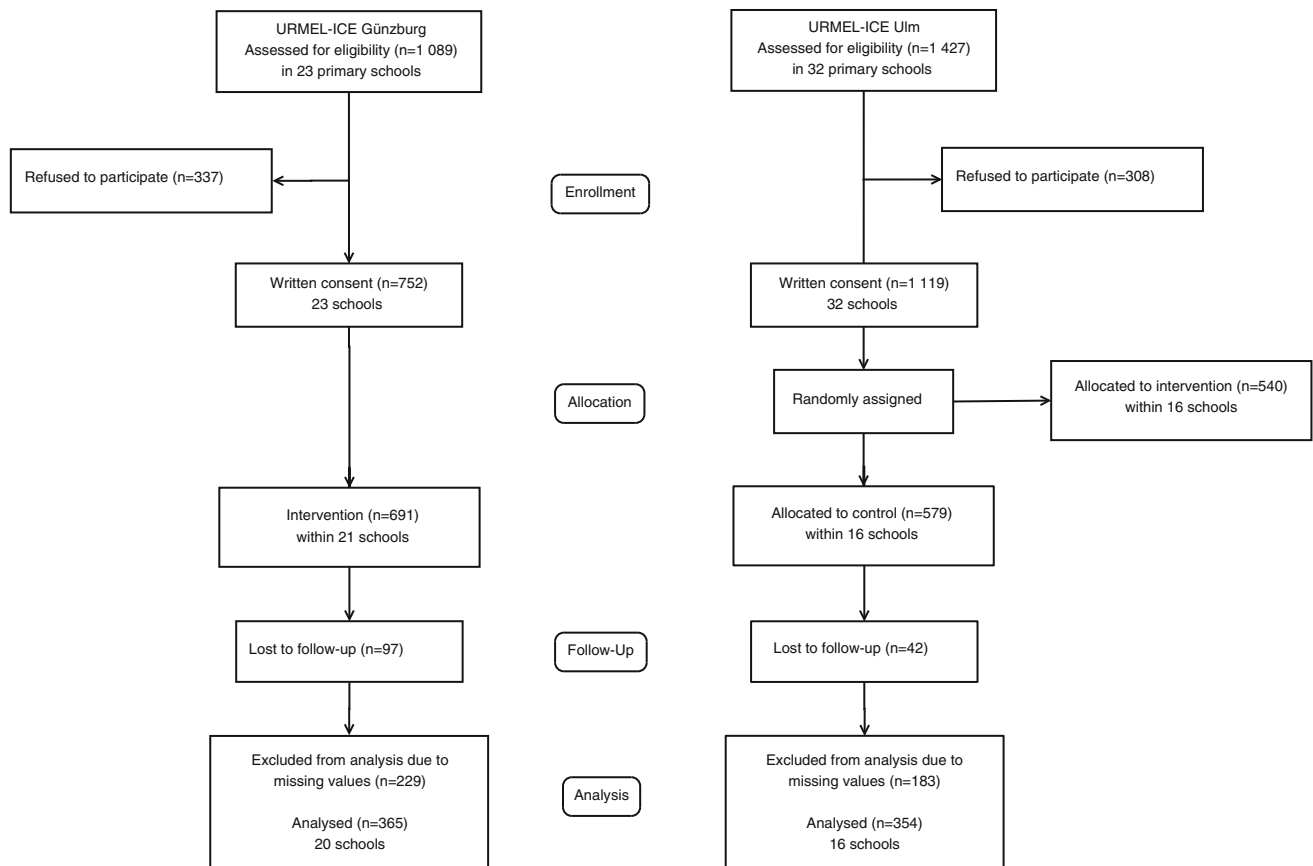
For both parts, approval was obtained from the Ethics Committee of the Ulm University, and parents were asked for their written informed consent.

Figure 1 shows a flowchart with the number of participants, for both intervention and control group, and the final number of participants included in the data analysis. Two schools in Günzburg failed to complete baseline measurements. Reasons for loss to follow-up were removals, repeating 2nd grade and sick leave.

In a previous article, the effects of the basic intervention study on children's BMI and other measures of fat mass were summarized (Brandstetter, Klenk, Berg et al. under revision). Data of 945 children (16 intervention schools:  $n = 495$ ; 16 control schools:  $n = 450$ ) were analysed. Multivariate analyses adjusted for baseline values showed no statistically significant effect of the intervention on BMI, but on waist circumference ( $-0.85$  (95% confidence interval (95% CI):  $-1.59$  to  $-0.12$ ) and subscapular skinfold thickness ( $-0.64$  (95% CI):  $-1.25$  to  $-0.02$ )). After additional adjustment for individual time lag between baseline and follow-up, these effects were reduced in the total group to  $-0.60$  (95% CI:  $-1.25$  to  $0.05$ ) and  $-0.61$  ( $-1.26$  to  $0.04$ ), respectively.

### Intervention

The URMEL-ICE intervention is aiming at primary-school children in their second grade. To ensure feasibility of the programme, scientists of different disciplines were supported by experienced school teachers. The so-developed lecture material is integrated into the usual curriculum and does not require additional lessons. Three crucial risk factors for childhood overweight and obesity are addressed by the intervention: physical activity, consumption of sweetened beverages, and media use [10]. The intervention consists of 28 units for regular teaching time spread over 36 weeks in one school year, regular activity breaks, 6 family homework assignments that have to be completed by the children and their parents and information material for parents. Teachers were trained in 3 courses by a scientific coordinator to familiarize themselves with the material and the implementation of the intervention.



**Fig. 1** Flowchart for the participation and analysis in URMEI-ICE

### Data collection

Data collection included anthropometric measurements of the children in a standardized manner and self-administered questionnaires for the parents. The baseline data collection T0 in the control group in Ulm took place at the end of grade 1 and the beginning of grade 2 from May to October 2006, and the follow-up data collection T1 one year later from September to December 2007. Data collection at T0 in the intervention group in Günzburg was completed in October 2008 with the beginning of the grade 2, and follow-up assessment T1 in October 2009 at the beginning of grade 3. All data were checked for their plausibility.

### Questionnaires and derived variables

Parents received a self-completion questionnaire, *inter alia* capturing data about early childhood and nutrition, physical activity patterns and media use of the child.

The parental level of education and migration background were assessed, and parental body mass index (BMI)

was computed as weight (kilogram) divided by height (meter) squared, as self-reported in the questionnaires, and categorized as overweight (BMI  $\geq 25.0$ ) and obesity (BMI  $\geq 30.0$ ), according to the international classification of the World Health Organization (WHO) [11].

Teachers of the intervention group in Günzburg were asked to fill in weekly questionnaires, recording their labour input to prepare the lessons. 32 of the participating 43 teachers documented their labour input, resulting in a response rate of 74%.

### Anthropometric measurements

Anthropometric measurements were taken by trained staff according to a standardized protocol. Children were examined in underwear without shoes. Height was measured to the nearest 0.1 cm (Ulm Stadiometer, Busse Design, Ulm, Germany). Weight was measured to the nearest 0.1 kg using calibrated and balanced portable digital scales (Seca, Hamburg, Germany).

Children's BMI was computed as weight (kilogram) divided by height (meter) squared, and overweight and

obesity were defined using the cut-off points recommended by the International Obesity Task Force (IOTF) [12].

Waist circumference (WC) was measured twice to the nearest 0.1 cm at umbilicus level, using an executive diameter tape (Seca, Hamburg, Germany), calculating the average for the analysis.  $WC \geq 50$ th and  $WC > 90$ th percentile were defined according to the German data presented by Schwandt et al. [13]. Waist-to-height ratio (WHtR) was calculated by the ratio of WC, and height in centimetres and participants with  $WhR \geq 0.5$  were determined. Individual WHtR, WC and BMI differences were computed. WHtR differences were multiplied by  $10^2$  to facilitate comparability, so one unit in the economic analysis represents 0.01 WHtR.

In the Ulm control group, individual time lag between baseline and follow-up was registered. Because of the narrow time frame of the measurements in the Günzburg intervention group, a due date for each measurement T0

and T1 was set, and the time interval between these due dates was defined as reference.

#### Statistical analyses

Imbalances between the Günzburg intervention and the Ulm control group baseline data were analysed using the Wilcoxon test for continuous data and the Fisher exact test for categorical data.

To settle these group differences and to adjust for the missing randomization, a propensity score was computed for each participant, including all variables listed in Table 1, except the outcome variables (anthropometric measurements of the children). Propensity score was included as an explanatory variable in the regression model. By using the propensity score method, an almost unbiased estimate of the intervention effects can be achieved with balancing the covariates [14, 15].

**Table 1** Baseline characteristics of URMEL-ICE participants

	Missings	Intervention ( <i>n</i> = 691)	Control ( <i>n</i> = 574)	<i>P</i> -value
Boys, <i>n</i> (%)	1	361 (52.3)	294 (51.2)	0.73
Age, years [m (SD)]	8	7.64 (0.60)	7.53 (0.48)	<0.01
Migration, <i>n</i> (%)	4	165 (24.0)	221 (38.5)	<0.01
Anthropometric measures				
BMI, kg/m <sup>2</sup> [m (SD)]	18	15.56 (2.62)	16.22 (2.11)	0.06
WC, cm [m (SD)]	29	59.70 (7.40)	59.18 (6.41)	0.63
WHtR m (SD)	21	0.47 (0.05)	0.47 (0.04)	0.72
Overweight, <i>n</i> (%)	29	127 (18.5)	83 (15.1)	0.12
Obesity, <i>n</i> (%)	29	36 (5.3)	19 (3.5)	0.13
Maternal attitude				
Smoking during pregnancy, <i>n</i> (%)	17	97 (14.2)	73 (12.9)	0.51
Breastfeeding, <i>n</i> (%)	23	456 (68.6)	469 (83.2)	<0.01
Parental characteristics				
Maternal education >10 years, <i>n</i> (%)	28	130 (19.3)	191 (33.9)	<0.01
Paternal education >10 years, <i>n</i> (%)	75	175 (27.2)	226 (41.4)	<0.01
Maternal BMI, kg/m <sup>2</sup> [m (SD)]	59	24.21 (4.53)	23.87 (4.40)	0.08
Paternal BMI, kg/m <sup>2</sup> [m (SD)]	128	26.19 (3.43)	26.16 (3.62)	0.61
Maternal overweight, <i>n</i> (%)	59	224 (34.6)	175 (31.4)	0.24
Paternal overweight, <i>n</i> (%)	128	369 (61.1)	315 (59.1)	0.50
Lifestyle characteristics				
Watching TV $\geq 1$ h on weekdays, <i>n</i> (%)	22	294 (43.1)	244 (43.6)	0.86
Watching TV $\geq 1$ h on weekends, <i>n</i> (%)	31	564 (83.8)	430 (76.7)	<0.01
Club sports <1 time a week, <i>n</i> (%)	77	188 (29.2)	159 (29.2)	1.00
Nonclub sports <1 time a week, <i>n</i> (%)	132	214 (34.8)	150 (29.0)	0.04
Consumption of soft drinks $\geq 3$ times a week				
At school, <i>n</i> (%)	142	98 (16.3)	73 (14.0)	0.32
At home, <i>n</i> (%)	60	189 (29.1)	146 (26.3)	0.27
No breakfast before school, <i>n</i> (%)	14	91 (13.3)	77 (13.6)	0.93
Time difference T0–T1, m (SD)	67	0.0	84.2 (67.15)	<0.01

*m* mean, *SD* standard deviation

Individual differences between T0 and T1 in BMI, WC and WHtR were the main outcome measures. To determine the intervention effects on these outcome measures, the clustering in schools was taken into account by computing a two-level model with adjustment on propensity score and the respective baseline value.

All above-mentioned analyses were carried out with SAS 9.2 (SAS Institute, Cary, NC, USA). A *P*-value less than 0.05 was considered as significant.

#### Assessment of intervention costs

A social perspective was used including all costs that were directly incurred by the intervention. All prices were real market prices, and the reference year was 2008 corresponding to the year of the Günzburg intervention.

All costs associated with the programme delivery were assessed at the time of incurrence. Costs for the development of the intervention materials as well as costs for the scientific evaluation were not included, and only costs that would incur with a repeated implementation, as described by McAuley et al. [16], were to be assessed.

Average costs for hourly wages of primary-school teachers were estimated using data from official statistics of the state of Bavaria [17, 18]. Classroom time was not included in the intervention costs because no additional time was needed for the implementation, but the time teachers spent on preparing the lessons with the intervention materials and the time teachers were trained by the scientific coordinator were counted.

Costs of the scientific coordinator for the training and support of the teachers were included, and together with the costs for the printed material, copies and postal charges were added up to the fixed costs.

All costs were summed up and computed to costs per class and then divided by the number of pupils in the respective class at T0, assuming that all children were reached by the intervention. This computation leads to an individual cost parameter per participant, which was used for the bootstrapping procedure.

No discounting was applied due to the relatively short intervention period of 1 year.

#### Cost-effectiveness analysis

Standard methods of cost-effectiveness analysis were applied. All cost-effectiveness analyses were carried out with Stata 11 (StataCorp LP, College Station, TX, USA), the mainly used modules `bscr.do` and `bsceaprogs.do` provided by Glick et al. [19] in the Internet. Net benefit regression was computed with SAS 9.2 (SAS Institute, Cary, NC, USA).

ICER, NMB and CEAC were computed on the basis of a bootstrap sample derived from the data of the individual

cost parameter per participant as described above and the unadjusted individual effect parameter WC and WHtR, respectively.

The ICER is defined as the ratio of net intervention costs and net intervention effects, with  $C_I$  representing the average costs per participant in the intervention group and  $C_C$  the average costs per participant in the control group, which in this scenario equals null:

$$\text{ICER} : \frac{C_I - C_C}{E_I - E_C} = \frac{\Delta C}{\Delta E}$$

Likewise,  $E_I$  and  $E_C$  represent the average effects in their respective group.

The MWTP stands for the resources society is willing to sacrifice in order to obtain a given benefit. In cost-effectiveness analysis, this threshold is represented by  $\lambda$ . To transform health effects in monetary terms, net monetary benefit is calculated:

$$\text{NMB} = \lambda * \Delta E - \Delta C$$

In case  $\text{NMB} > 0$ , this is to be considered as positive [20]. The graphical representation of the acceptance of the intervention in dependency on the MWTP is illustrated by the cost-effectiveness acceptability curve (CEAC), a further method to specify the uncertainty in estimates of cost-effectiveness [21].

Finally, net benefit regression combines cost-effectiveness methodology with statistical advances of regression analysis, like covariate adjustment [22], which means in this case propensity score adjustment.

#### Missing data, censoring

Common to observational studies is the problem of missing data and loss to follow-up censoring. To examine baseline differences between lost to follow-up records and records used in the analyses, the Wilcoxon test for continuous data or the Fisher exact test for categorical data were used. The same applies for differences between records excluded due to missing values and records used for analyses.

#### Sensitivity analysis

The number of parameters that could enter a sensitivity analysis is restricted. Since the examination of cost-effectiveness was conducted with real world data and no modelling was applied, variables for sensitivity analysis are mainly the respective differences in costs and effects.

All costs were precisely collected along the trial, and there remains only a small possibility for variation (teachers individual working time to prepare the lessons), and no discount rate was used. The remaining variable of interest for sensitivity analysis is the difference in effects,

whose influence on cost-effectiveness shall be tested at a 10, 20 and 30% lower value.

## Results

Characteristics of the participants in intervention and control group at baseline are presented in Table 1. From a total of 1,265 children at baseline, 655 (51.8%) were boys and 610 (48.2%) were girls, with no significant difference between the groups. Anthropometric baseline data showed no significant differences.

### Loss to follow-up, missing data

Participants who were lost to follow-up were older (Günzburg) or boys (Ulm), had higher BMI and WHtR (Günzburg) or lower BMI (Ulm), more often had a migration background (Ulm), consumed more soft drinks at school (Günzburg) and watched TV more frequently on weekdays (Ulm). Their mothers smoked more often during pregnancy (Günzburg).

Participants who were excluded from the analysis due to missing values more often had a migration background (Ulm, Günzburg), more often were obese (Günzburg), less often had breakfast before school (Ulm), watched TV more frequently on weekdays (Ulm, Günzburg) and consumed more soft drinks at home (Ulm). Fathers (Ulm) or mothers (Günzburg) had lower levels of education, and mothers smoked more often during pregnancy (Ulm).

### Intervention effects

For children in the intervention group, the unadjusted relative risk (RR) for incident overweight at follow-up (T1) was 0.66 (95% confidence interval (CI) [0.39; 1.14]). The unadjusted RR for incident WHtR  $\geq 0.5$  at T1 was 0.51 (95% CI [0.29; 0.90],  $n = 1,077$ ) and for incident WC > 90th percentile was 0.44 (95% CI [0.21; 0.90],  $n = 1,085$ ). All available data from the participants at follow-up ( $n = 1,131$ ) were used for these calculations.

Table 2 shows mean values and standard deviations of the unadjusted outcome variables at baseline and follow-up, plus the respective means of differences between T0 and T1, for both the control and the intervention group.

Table 3 shows results of the two-level analysis in consideration of the clustering in schools for the outcome variables. After adjusting for propensity score, BMI lost its significance, while WC and WHtR remained significant.

Subgroup analyses for participants divided by the 50th percentile of WC showed greater values of effects for those in the upper part.

### Costs

There were 81 of total 365 records of pupils with missing data for the individual time investment of their teachers. Since these records did not differ significantly from the others concerning outcome variables and covariates, it was decided to keep them in the analyses also because cost data were not missing completely, but only partly. These missing data were imputed from the mean value of the working time invested by teachers to prepare the lessons (6.67 h).

Costs are described in Table 4. In the economic evaluation, these costs had to be compared to null costs in the control group.

### ICERs

Nonparametric bootstrap method with 4,000 drawings for WC and WHtR, respectively, leads to following ratios of costs and effects:

1. WC ICER:  $\frac{24.091}{2.168} = \text{€}11.11$  per cm 95% CI [8.78; 15.02]
2. WHtR ICER:  $\frac{24.091}{1.299} = \text{€}18.55$  per unit 95% CI [14.04; 26.86]

Figure 2 shows the graphical representation of the bootstrap distribution for WC in the cost-effectiveness plane with a clear limitation to the northeast quadrant, and the same applies for WHtR.

**Table 2** Unadjusted values of outcome variables at baseline (T0) and follow-up (T1)

	Günzburg intervention ( $n = 365$ ) Mean (SD)			Ulm control ( $n = 354$ ) Mean (SD)		
	T0	T1	T1-T0	T0	T1	T1-T0
BMI (kg/m <sup>2</sup> )	16.328 (2.135)	16.776 (2.420)	0.485 (0.976)	16.135 (1.923)	16.941 (2.349)	0.856 (0.954)
WC (cm)	59.174 (6.560)	60.690 (7.198)	1.524 (3.897)	58.981 (5.981)	62.658 (7.448)	4.407 (4.242)
WHtR	0.471 (0.057)	0.465 (0.056)	-0.007 (0.031)	0.470 (0.048)	0.475 (0.055)	0.008 (0.030)

SD standard deviation



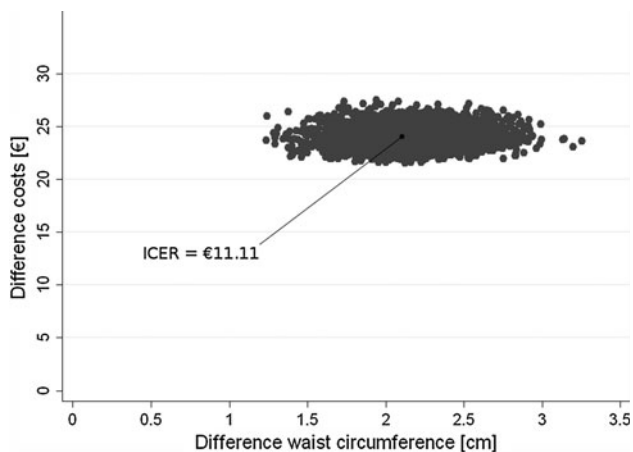
**Table 3** Multilevel analyses results of differences between control and intervention group for BMI, WC and WHtR

All ( $n = 719$ )	Model 1 Adjusted for baseline value		Model 2 Adjusted for baseline value and propensity score	
	Estimator	95% CI	Estimator	95% CI
BMI ( $\text{kg}/\text{m}^2$ )	-0.387	[-0.553; -0.221]	-0.173	[-0.401; 0.056]
WC (cm)	-2.163	[-2.741; -1.585]	-1.544	[-2.448; -0.646]
WHtR	-0.013	[-0.017; -0.009]	-0.014	[-0.021; -0.007]
<50 percentile of WC ( $n = 388$ )				
BMI ( $\text{kg}/\text{m}^2$ )	-0.273	[-0.447; -0.099]	-0.177	[-0.431; 0.078]
WC (cm)	-1.514	[-2.204; -0.823]	-1.270	[-2.321; -0.218]
WHtR	-0.009	[-0.015; -0.003]	-0.012	[-0.021; -0.003]
≥50 percentile of WC ( $n = 331$ )				
BMI ( $\text{kg}/\text{m}^2$ )	-0.497	[-0.744; -0.250]	-0.140	[-0.501; 0.221]
WC (cm)	-2.881	[-3.869; -1.893]	-1.850	[-3.465; -0.234]
WHtR	-0.017	[-0.025; -0.010]	-0.016	[-0.028; -0.004]

CI confidence limits

**Table 4** One-year intervention costs in 2008 Euro

Item	Quantity	Unit costs	Total cost
Teacher time			
Training	3 times 2 h, 46 teachers	22.62/h	6,243.12
Prepare lessons	Mean 6.57 h, 46 teachers	22.62/h	6,836.22
Scientific coordinator	40% of total working time	30,000.00/year	12,000.00
Work books and copies	46 classes	30.00/each	1,380.00
Postal charges	6 packages, 46 teachers	1.45/package	400.20
Total			26,859.54



**Fig. 2** Incremental cost-effectiveness ratio (ICER) for waist circumference. Scatter plot in the cost-effectiveness plane showing the mean differences in costs and effects from the trial data using 4,000 bootstrap re-samples (differences based on intervention minus control)

### NMB and net benefit regression

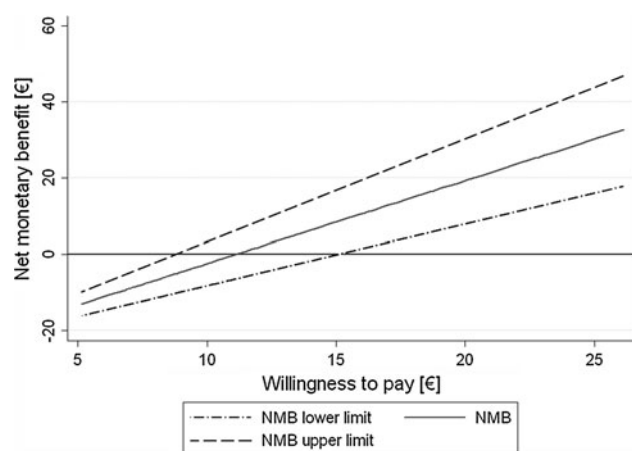
The graphical representation of the NMB, concerning WC in Fig. 3, computed on the bootstrap data, shows a positive net benefit since at the point of intersection of the line with the X-axis, with a willingness to pay of €11.11.

Observations in this graphic coincide with the parameter intervention in the net benefit regression without adjustment on propensity score. Table 5 shows parameters of the net benefit regression in dependency on MWTP.

After adjustment, at a MWTP of €35 with an estimator of €31.80 for the net benefit, both values of the corresponding CI are located in the positive range (95% CI [3.91; 59.69]).

For WHtR, at a MWTP of €35, the estimator for the net benefit amounts to €25.93 and the adjusted CI is located in the positive range (95% CI [2.55; 49.31]).

The confidence intervals for the NMB for both WC and WHtR are located in the positive range but reflect little precision of the estimates.

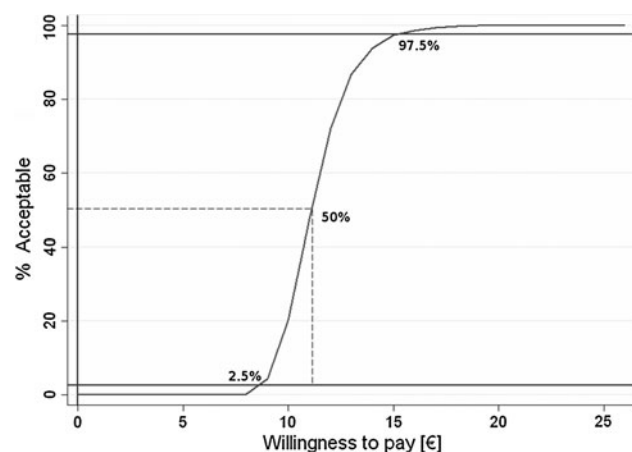


**Fig. 3** Net monetary benefit (NMB) statistics for waist circumference as a function of willingness to pay. The intersections of the net benefit curves with the NMB = 0 axis define the point estimate and 95% confidence interval on cost-effectiveness

**Table 5** Net benefit regression for WC

Model	Estimator		
	$\lambda = 0\text{€}$	$\lambda = 15\text{€}$	$\lambda = 30\text{€}$
No treatment	Reference	Reference	Reference
Intervention	-23.32	-0.59	23.72
Intervention without propensity score	-22.08	8.42	40.85
Propensity score	1.70	15.67	30.25

$\lambda$  = maximum willingness to pay MWTP



**Fig. 4** Cost-effectiveness acceptability curve (CEAC) for waist circumference showing the probability that the intervention is cost-effective compared to the control (no intervention) under various assumptions of willingness to pay

## CEAC

The cost-effectiveness acceptability curve in Fig. 4 illustrates the estimates of the probability that net monetary

benefit is positive in dependency on the MWTP for WC in the intervention group compared to the control group. Since all cost-effectiveness pairs of the bootstrap sample are located in the north-east quadrant of the cost-effectiveness plane (more costly, more effective), the CEAC intersects the Y-axis at 0%. For the same reason, the present CEAC is an increasing function of MWTP and asymptotes to 100% acceptability. 95% CI for the acceptability covers MWTP from €8.78 to €15.04.

The same applies for the CEAC for WHtR (95% CI [€14.04; €26.87]).

## Sensitivity analysis

At a 10% lower difference in effects, the costs for a one-centimetre change in WC lead to 11% higher costs:  $ICER : \frac{24.091}{1.951} = \text{€}12.35$  per cm (25% higher costs for a 20% change and 43% higher costs for a 30% change).

The same percentage of higher costs applies for changes in effects in WHtR.

## Discussion

### Strengths and limitations

The strength of this investigation lies in the prospective assessment of cost data and workload of the teachers, which is important for the quality of the economic evaluation. To account for the missing randomization, propensity score adjustment is used to deal with observed covariate differences and to obtain valid unbiased estimates of the average causal effects [23].

The strength of the URMEL-ICE intervention lies first within its uncomplicated implementation through teachers in regular classes, thus reaching as many children as possible in an age group in a school-setting. Parental involvement reinforces the efficacy. Second strength lies within its multidirectional design aiming at three risk factors for the development of childhood overweight, namely consumption of soft drinks, sedentary lifestyle and time spent with screen media. According to the reviews of Kropski et al. [24] and Livingstone et al. [25], school-based multicomponent preventive measures have better chances to be successful.

The first limitation that should be mentioned is the lack of a parallel control group for the Günzburg intervention. The participants in the used control group from Ulm, tested 2 years earlier, showed some differences to the participants of the Günzburg intervention group concerning covariates, but not baseline values of the outcome parameters. Thus, the results of the study are exploratory findings and should



be interpreted as such. Further limitations are loss to follow-up and missing values for analyses. The number of missing data in this study was elevated due to the amount of variables needed to compute the propensity score. This was necessary for the adjustment for group differences and influence factors.

Missing data and censoring may imply a form of selection bias but, in the best case, only lessen the precision of the study [15]. Even in the frequently cited study of Wang et al. [26], a loss to follow-up from initial 1,203 to 641 participants in the end is reported.

Possible reasons for the better success in the Günzburg cohort than in the original Ulm cohort may lie in the fact that teachers in Günzburg were asked to fill in weekly questionnaires to record their labour input to assess costs, and this may have led to a more intensive engagement with the implementation. Another fact is that all teachers in the county of Günzburg were advised to take part by their supervisory school authority, whereas the Ulm cohort consists only of teachers who decided to opt in on their own, which may have led to a selection bias. So, the effects in Ulm had a smaller size and would have needed more participants to confirm the statistical evidence. And although the regions in which the studies were conducted are in close neighbourhood, there may be a number of marginal differences, which in sum could have led to different effects.

#### Willingness to pay (WTP) versus quality-adjusted life years (QALYs)

The URMEL-ICE intervention has significantly reduced the growth of WC and WHtR in the participating children. Costs of €11.11 per cm WC growth inhibited and €18.55 per unit (0.01) WHtR increase avoided show favourable cost-effectiveness ratios.

The results of this investigation show clearly that prevention of overweight and obesity in a school setting with low financial input, achieved by implementing the intervention in classrooms by teachers in regular lessons, can be effective and cost-effective as well.

One possibility to decide whether an intervention is cost-effective is to compare its costs to a threshold of the WTP for a specific change in health status. The costs of €24.09 (US\$35.41) per child in the URMEL-ICE intervention to cut incidence of WC > 90th percentile and WHtR  $\geq$  0.5 by the half fall below the value of US\$46.91 Cawley et al. [27] found in their contingent valuation analysis of WTP for a 50% reduction of childhood obesity. Though one should not forget that the costs of US\$35.41 incurred per child (second grade) and the WTP of US\$46.91 is measured per adult individual (aged 18 and over), it may not be compared directly. The MWTP values

mentioned in the economic evaluation of the URMEL-ICE project remain hypothetical.

WTP and QALYs are alternative measures of the value of reductions in health risk. The QALY assessment for children is difficult, and the number of instruments suitable for cost–utility or cost–benefit analyses is limited. One reason is the inability of young children to value changes in health directly and the potential biased valuation of proxy respondents [28]. Only few authors report utility assessment in children. A review carried out in 2008 by Tarride et al. [29] identified 34 studies, most of them in the area of cancer and using the Health Utility Index (HUI). Nonetheless, some studies suggest a lower HRQoL for overweight and obese school children, measured with instruments that do not support the generation of utility weights [30–32].

#### Cost and risk reduction through lower WC and WHtR

BMI is the accepted standard index for the definition of overweight and obesity, but BMI does not differentiate between overweight due to increased muscle and fat mass. A great deal of adolescents (32.1% of females and 42% of males) who were classified as overweight or obese due to their BMI did not have truly high adiposity [33]. So the effectiveness of programmes comprising physical education, where an increase in muscle mass or the transformation of fat mass into muscles is part of the effect cannot be measured exactly via BMI. For the measurement of fat distribution, measures like WC and WHtR that take abdominal fat tissue into account are more suitable.

Especially visceral fat accumulation holds higher risk of metabolic syndrome and is associated with increased secretion of free fatty acids, hyperinsulinemia, insulin resistance, hypertension and dyslipidemia [33, 34]. The new IDF (International Diabetes Association) definition of at-risk groups and of metabolic syndrome in children and adolescents uses WC  $\geq$  90th percentile as the main and essential component [35]. WC may even be a helpful parameter in identifying prepubertal children with higher cardiovascular risk [36]. Maffei et al. [37] found out that each centimetre increase in WC at the age of 8 years doubled the risk of having 20% greater BMI 4 years later. They consider WC as a promising index to assess adiposity as well as to make a prognosis.

The same applies to WHtR. Ashwell and Hsieh [38] publicized six reasons why WHtR is a rapid and effective global indicator for health risks of obesity and how it could simplify the health message on obesity. There are some studies that prove WHtR is also a suitable risk predictor for children and adolescents [39–41].

Greater WC has been shown to be associated with excess burden of ill health. Cornier et al. [42] provided

evidence that WC but not BMI significantly correlates with total health care charges in a population sample from outpatient medical clinics in Denver, USA. The highest costs were incurred in the group with the highest WC quartile. Similar results come from Hojgaard et al. [43] who conducted a prospective cohort study with almost 32,000 participants. They found out that WC is a more sensitive measure than BMI to identify individuals who will cause higher future health care costs. In this study population in Denmark, health care costs rose at a rate of 1.25% in women and 2.08% in men per added centimetre of WC above normal waistline [44]. Hence, it can be assumed that the deceleration in growth of WC and the reduction in WHtR in primary-school children, achieved by the UR-MEL-ICE intervention, support the prevention of future health care costs and the reduction of health risks.

### Conclusion and perspective

School-based health promotion programmes are an important component in the effort to make children healthier. The UR-MEL-ICE experience shows that these programmes can be effective and that teachers are qualified to motivate pupils to change their lifestyle. Society, government and school authorities should not hesitate to invest in an early beginning of structured health promotion. UR-MEL-ICE offers a promising concept, but further research in form of randomized controlled trials for more precision has to be done.

Whether the deceleration in the growth of WC and WHtR persists cannot be foreseen. But regarding the growing necessity for action on the one hand and the need for further investigation on the other hand, as it is requested by almost every scientist working in the field of childhood overweight and obesity, there is no time to waste but to search for effective, easy-to-implement solutions for low budgets. Accordingly, the UR-MEL-ICE intervention was revised and expanded on four grades of primary school. Starting in September 2010, about 160 classes in primary schools in the state of Baden-Württemberg with approximately 2,000 children are implementing the intervention and are taking part in a randomized trial to evaluate its impact. All cost data and HRQoL will be assessed for further reports of cost-effectiveness.

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