Illness and determinants of health-related quality of life in a cross-sectional sample of schoolchildren in different weight categories

Krankheit und Faktoren gesundheitsbezogener Lebensqualität in einer Querschnitts-Stichprobe von Schulkindern in verschiedenen Gewichtskategorien

Abstract

Aim: To study associations between health-related quality of life (HRQoL), frequency of illness, and weight in primary school children in southern Germany.

Methods: Data from baseline measurements of the outcome evaluation of a teacher based health promotion programme ("Join the Healthy Boat") were analysed. Parents provided information about their children's HRQoL (KINDL[R], EQ5D-Y Visual Analogue Scale). The number of visits to a physician, children's days of absence because of sickness, and parental days of absence from work due to their children's illness during the last year of school/kindergarten were queried. Children's weight status was determined by body mass index (BMI), central obesity by waist to height ratio (WHtR ≥0.5).

Results: From 1,888 children (7.1±0.6 years), 7.8% were underweight, 82% had normal weight, 5.7% were overweight and 4.4% obese. 8.4% of all children were centrally obese. Bivariate analysis showed no significant differences for parental absence and visits to a physician in weight groups classified by BMI, but obese children had more sick days than non-obese. Centrally obese children differed significantly from the rest in the number of sick days and visits to a physician, but not in the frequency of parental absence. In regression analyses, central obesity correlated significantly with EQ5D-Y VAS, KINDL[R] total score and the subscales of "psyche", "family" and "friends". BMI weight groups showed no significant associations.

Conclusions: Central obesity but not BMI derived overweight and obesity is associated with HRQoL and visits to a physician in primary school children. Future studies should include WHtR. Preventive measures for children should focus on a reduction of or slowed increase in waist circumference.

Keywords: child, body weights and measures, quality of life, sick leave, Germany

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Zusammenfassung

Ziel: Untersuchung von Zusammenhängen zwischen gesundheitsbezogener Lebensqualität (HRQoL), Erkrankungshäufigkeit und Gewicht bei süddeutschen Grundschulkindern.

Methoden: Daten der Basiserhebung der Wirksamkeits-Evaluation eines lehrerbasierten Gesundheitsförderprogramms („Komm mit in das gesunde Boot") wurden analysiert. Eltern machten Angaben zur HRQoL (KINDL[R] und EQ5D-Y Visuelle Analogskala) ihrer Kinder. Die Anzahl der Arztbesuche im zurückliegenden Schul-/Kindergartenjahr, Fehltage der Kinder und Tage, die berufstätige Eltern wegen Erkrankung ihres Kindes zuhause bleiben mussten, wurden erfragt. Die Ermittlung des kindlichen

Gewichtsstatus erfolgte nach Body Mass Index (BMI), abdominale Adipositas wurde anhand des Waist to Height Ratios (WHtR ≥0,5) definiert.

Ergebnisse: Von den 1.888 untersuchten Kindern (7,1±0,6 Jahre) waren 7,8% untergewichtig, 82% normalgewichtig, 5,7% übergewichtig und 4,4% adipös. 8,4% aller Kinder waren zentral adipös. In bivariaten Analysen wurden keine signifikanten Unterschiede bei den Fehltagen der Eltern und der Anzahl der Arztbesuche zwischen den BMI-Gewichtsgruppen gefunden, aber adipöse Kinder hatten mehr Krankheitstage als nicht adipöse. Kinder mit abdominaler Adipositas unterschieden sich signifikant von den übrigen bei der Anzahl der Krankheitstage und der Arztbesuche, nicht in der Anzahl der Fehltage der Eltern. In Regressionsanalysen zeigte sich ein signifikanter Zusammenhang der abdominalen Adipositas mit der EQ5D-Y VAS, dem KINDL[R] Totalscore und den Subskalen „Psyche", „Familie" und „Freunde". Für Gewichtsgruppen nach BMI ergaben sich keine signifikanten Zusammenhänge.

Schlussfolgerung: Abdominale Adipositas, aber nicht nach BMI definiertes Übergewicht und Adipositas, zeigt Zusammenhänge mit HRQoL und Arztbesuchen bei Kindern im Grundschulalter. Zukünftige Studien sollten das WHtR einschließen. Präventive Maßnahmen für Kinder sollten auf eine Verringerung oder verzögerte Zunahme des Bauchumfangs abzielen.

Schlüsselwörter: Kind, Körpergewicht und -maße, Lebensqualität, Krankenstand

Background

Overweight, obesity and their adverse effects and consequences are considered to be a major challenge to health systems and economies in the 21st century [1]. Many obesity related health conditions that previously seemed reserved mainly for adults, are increasingly observed in children today [2]. A general, negative influence on health-related quality of life (HRQoL) can be assumed [3]. In addition to health and psychosocial consequences for the affected children, an economic burden has to be taken into account. This includes an increased utilization of health care services [4] as well as productivity losses due to parental absence at the workplaces because of caring for their sick child [5].

Sickness is commonly associated with a lower HRQoL. The measurement of HRQoL includes all essential aspects of physical, psychological and social well-being which contribute to the overall health status as defined by the World Health Organization (WHO). A frequently used instrument for the assessment of children's HRQoL is the German KINDL[R] questionnaire. It includes indicators for physical, psychological, family, social and school well-being and self-esteem [6]. In addition, a vertical, graduated Visual Analogue Scale (VAS) to rate the current health state between 0 (the worst) and 100 (the best imaginable) of a child by a parent or proxy can be used for information about HRQoL [7].

Body Mass Index (BMI) is predominantly used to classify excess weight and obesity according to defined boundary values. For children, national reference data are used to define the respective BMI percentiles, mainly because children's BMI differs from adult BMI due to the fact that they are still growing and gaining weight, and boundary values have to be adjusted according to age and gender. On the basis of several data collections from the years between 1985 and 1999, a reference group for children and adolescents was provided to facilitate the weight classification of German children according to obtained age and gender specific BMI percentiles [8]. These reference data ("Kromeyer-Hauschild") are generally used for research in this area. According to a recommendation of the work group "obesity in childhood and adolescence" (AGA) the 90th and 97th percentile was used for the definition of overweight and obesity, respectively, and the 10th percentile for the definition of underweight. Based on this, the German "children and adolescents health survey" (KiGGS, 2003–2006) showed a prevalence of 14.8% for overweight and obesity in children and adolescents in Germany [9]. This number mirrors the worldwide trend of the increasing rates of overweight and obesity in the past years [10]. One problem concerning the definition of overweight and obesity is the applicability of the above mentioned reference curves only for "German" children. Meanwhile, specific weight and height percentiles for Turkish children born in Germany are available, as they represent the largest group of migrants, and their children differ significantly in the area of weight and height development from German children [11]. Due to the non-homogeneous distribution of migrants in the population of Germany, a biased presentation has to be assumed when using German percentile curves for samples with varying shares of migrants.

BMI does not differentiate between higher body weight due to an elevated amount of fat or muscle mass [12], neither is the distribution of body fat taken into account. Many of the obesity related health risks are attributed to a higher abdominal fat mass [12], [13], [14]. The waist

to height ratio (WHtR) offers a measure of abdominal fat distribution, critical abdominal fat mass is achieved at a value of WHtR ≥0.5 [13]. This boundary value is valid for adults as well as children, independent of gender and ethnicity [13]. Alternatively, a critical abdominal fat mass can also be determined using waist circumference, but here again age and gender-specific reference curves are required, which in this case are only available for children of German origin [15].

The aim of this study is the comparative analysis of HR-QoL, days of absence and the number of visits to a physician of primary school children in different weight groups. Of special interest are the differences in dependency on the classification of weight groups according to BMI or WHtR, respectively.

Methods

The Baden-Württemberg Study

On the basis of the successful project "Ulm Research on Metabolism, Exercise and Lifestyle Intervention in Children" (URMEL-ICE) [16], [17], an extensive health promotion programme for primary schools has been developed. "Join the Healthy Boat – Primary School" has been implemented from the academic year of 2009/10 at many primary schools in the entire German state of Baden-Württemberg. The aim of this programme is to help children to develop a healthy lifestyle. Teachers are supported with lecture materials addressing three crucial health behaviours: consumption of soft drinks, physical activity and media use.

The corresponding evaluation of the programme was initiated in autumn 2010 with the first measurements (T1) of the "Baden-Württemberg Study". The trial protocol of this randomised, controlled prospective study was reviewed and approved by the ethics committee of Ulm University. The Baden-Württemberg Study is registered in the German Clinical Trials Register (DRKS), Freiburg University, Germany, with the DRKS-ID: DRKS00000494. A detailed description of this study has been published elsewhere [18].

Participants and data

Parents of 1,968 children gave their written informed consent. 1,947 children took part in baseline anthropometric measurements between September and October 2010, and parental questionnaires were completed by 1,714 participants. Parents provided information on lifestyle and health behaviour, physical activity patterns and the living environment of the children.

Children's health and health behavior

Parents were asked to recall the number of days of school absence and visits to a physician due to illnesses of their child in the past year of school or kindergarten respect-

ively. Working parents gave information on the number of days it was necessary for them to miss work to care for their sick child. Parents filled in the proxy version of the KINDL[R] HRQoL questionnaire [6] and the visual analogue scale (VAS) of the EQ5D-Y [7]. KINDL[R] total score (Ts) was calculated, as well as all underlying subscales (physical wellbeing, psychological wellbeing, self esteem, family, friends, school), and transformed into a scale of 0–100. Both measurements, EQ5D-Y VAS and KINDL[R], have already been applied in the context of excess weight and obesity in children and possess the required discriminatory power respectively to display differences in the HRQoL under various social and health conditions [6], [19], [20].

Furthermore, parents were asked how many days per week their child achieved the WHO guideline of engaging in at least 60 minutes of moderate to vigorous activity per day [21]. The reported data were dichotomised at the median into less than four days vs. four days and more.

Children's anthropometry

Anthropometric measurements of children were taken in underwear and without shoes according to a standardised protocol. Children's height was measured to the nearest 0.1 cm (Stadiometer, Seca®, Germany), and body weight to the nearest 0.1 kg using calibrated and balanced portable digital scales (Seca®, Germany). Waist circumference was measured in the middle between ileac crest and lower costal arch to the nearest 0.1 cm using a flexible metal tape (Lufkin Industries Inc., Texas, USA). All measurements were taken by staff trained to ISAK-standards [22]. BMI percentiles were allocated using German reference curves [8]. Excess weight and obesity were classified using the 90th and 97th age and gender-specific percentiles as cut-off points, respectively. WHtR ≥0.5 was utilised to categorise central obesity.

Socioeconomic background

The parental educational background was classified on the basis of the CASMIN classification [23] and family educational level defined as the highest level of both parents or the single parent. Family education was dichotomised for analysis, elementary and intermediate level combined and contrasted with tertiary level. Income groups were queried according to the KIGGS survey [24] and for analysis purposes divided into two groups, the lower group including monthly household incomes of ≤1,750 €. A child with a migration background was defined as having at least one parent who was born abroad or at least one parent who mainly spoke a foreign language during the child's first years of life.

Parental anthropometry and health awareness

Parental BMI was calculated as the weight in kilograms divided by height in meters squared (kg/m²) and WHtR as waist circumference in cm divided by height in cm as

Table 1: Baseline characteristics of participants in the Baden-Württemberg Study

	Missing Values	Boys (n=995)	Girls (n=948)	Total (n=1,944)
Age, years [m (sd)]	1	7.09 (0.63)	7.06 (0.64)	7.08 (0.64)
Migration background, n (%)	298	255 (30.9)	270 (32.9)	525 (31.9)
Weight groups				
Underweight, n (%)	51	79 (8.1)	70 (7.6)	149 (7.9)
Normal weight, n (%)	51	788 (81.2)	765 (82.9)	1,553 (82.0)
Overweight, n (%)	51	54 (5.6)	54 (5.9)	108 (5.7)
Obesity, n (%)	51	49 (5.1)	34 (3.7)	83 (4.4)
Central obesity, n (%)	55	73 (7.5)	85 (9.2)	158 (8.4)
Parental characteristics				
Single parent, n (%)	266	82 (9.7)	95 (11.4)	177 (10.5)
Tertiary family educational level, n (%)	316	262 (31.8)	261 (32.5)	523 (32.1)
Household income ≤1,750 €, n (%)	453	101 (13.4)	106 (14.4)	207 (13.9)
Overweight (mother), n (%)	364	247 (30.8)	250 (32.1)	497 (31.5)
Overweight (father), n (%)	469	443 (59.1)	455 (62.7)	898 (60.9)
Smoking (mother), n (%)	288	172 (20.7)	175 (21.2)	347 (21.0)
Smoking (father), n (%)	357	234 (29.4)	238 (30.1)	472 (29.7)
Health awareness (mother), n (%)	286	487 (58.6)	486 (58.8)	973 (58.7)
Health awareness (father), n (%)	397	362 (46.5)	335 (43.6)	697 (45.1)
Health and lifestyle characteristics				
KINDL[R] Ts 100, [m (sd)]	417	80.08 (8.66)	81.06 (8.35)	80.57 (8.52)
EQ5D-Y VAS, [m (sd)]	303	91.59 (9.57)	90.97 (10.78)	91.28 (10.19)
Days of absence from kindergarten/school, [m (sd)]	393	6.83 (6.40)	7.28 (6.50)	7.05 (6.45)
Days off work (mother), [m (sd)]	948	2.58 (4.25)	2.66 (4.41)	2.62 (4.33)
Days off work (father), [m (sd)]	1,215	0.64 (2.25)	0.53 (1.63)	0.59 (1.96)
Visits to a physician, [m (sd)]	405	2.87 (2.92)	3.08 (3.03)	2.97 (2.98)
Playing outside >60 min/day, n (%)	297	615 (73.8)	515 (63.3)	1130 (68.6)
Physical active ≥4 days/week ≥60 min/day, n (%)	321	260 (31.7)	177 (22.1)	437 (26.9)
Physical active 7 days/week ≥60 Min/Tag, n (%)	321	33 (5.4)	26 (3.2)	70 (4.3)
TV or PC >1 h/day, n (%)	346	125 (15.7)	101 (12.6)	226 (14.1)
Soft drinks >1 time per week				
at school, n (%)	276	61 (7.3)	68 (8.2)	129 (7.7)
outside school, n (%)	275	220 (26.0)	199 (24.2)	419 (25.1)
No breakfast before school, n (%)	237	89 (10.4)	134 (15.8)	223 (13.1)

m (sd), mean (standard deviation)

self-reported in the questionnaires. Being overweight was categorised having a BMI ≥25 and obesity as having a BMI ≥30, according to the international classification of the World Health Organization (WHO) [1]. Central obesity was defined by WHtR ≥0.5, according to the cut-off point recommended by Browning et al. [25]. Parental health awareness was dichotomised by combining the two upper responses and again the lower responses to the question "How much do you generally care for your health?" (options: Not at all – a bit – much – very much).

Statistical analysis

Differences between groups were tested with respect to the scale level and the underlying distribution with Fisher's exact test for categorical data, as well as the Mann-Whitney U-test, t-test or Welch-test (considering heterogeneity in variance) for continuous data. Significance level was set to $\alpha < 0.05$ for two-sided tests. The

relationship between sick days and HRQoL scales were determined by Pearson's correlation coefficient.

Parental information on the HRQoL of their children in the EQ5D-Y VAS, KINDL[R] Ts and all subscales were examined using linear regression models, and sometimes linear mixed models, used in the event of existing cluster effects. Thereby possible associations with all variables listed in Table 1, with a special focus on weight groups, were examined in stepwise backward elimination. All analyses were carried out using the statistical software packages IBM SPSS Release 19.0 for Windows (SPSS Inc, Chicago, IL, USA) and R Release 2.13.0 for Windows (http://cran.r-project.org/).

Results

The mean age of the participating children in the first and second grade was 7.1±0.6 years, ranging from 5.4 to 9.8 years, with 48.8% being female. Table 1 shows an overview of the variables used for analysis. Significant differences between boys and girls were found in the field of physical activity, notably playing outside ($p<0.001$) as well as in being physically active ≥4 days ($p<0.001$) and 7 days ($p<0.05$), and having no breakfast before school ($p<0.01$).

Weight groups

Data for the classification of weight groups was available for 1,893 children. According to the classifications, 7.9% of the children were underweight, 82%, normal weight, 5.7% were overweight and 4.4% obese. From 1,888 children with data available to calculate WHtR, 8.4% were found to have central obesity.
Accordingly 17.1% of normal weight, 32.9% of overweight and 50% of obese children were centrally obese.

Health-related quality of life

Unadjusted analysis of the data with paired t-tests or Welch-tests showed significant differences between measured HRQoL (EQ5D-Y VAS), in obese and normal weight children (88.0 vs. 91.7; $p<0.05$) and in children with central obesity and the others (88.1 vs. 91.6; $p<0.01$). For the KINDL[R] subscale of "friends", significant differences were found between abdominally obese children and the others (75.4 vs. 78.3; $p<0.05$). Table 2 shows the results of regression analyses for the determination of associated factors to the various scales of HRQoL. The stated variables result from the respective regression model. A cluster effect for schools was detected for the subscales "friends" and "physical wellbeing".
Significant reverse correlations were found for the number of sick days with VAS (–0.15) and KINDL[R] (–0.11).

Sick days, parental days of absence from work, visits to a physician

To visualise the number of children's sick days, paternal days of absence from work, and the visits to a physician between BMI-weight groups, Figure 1 shows the respective mean values and standard errors. The same applies for the weight groups according to central obesity shown in Figure 2. The Mann-Whitney-U test showed significant differences in children's sick days between children with central obesity and the others ($p<0.001$), as well as between children of general obesity and the others ($p<0.05$). But the latter was not significant in the regression analysis [26]. The number of visits to a physician was also significantly different between children with central obesity and other children ($p<0.05$).
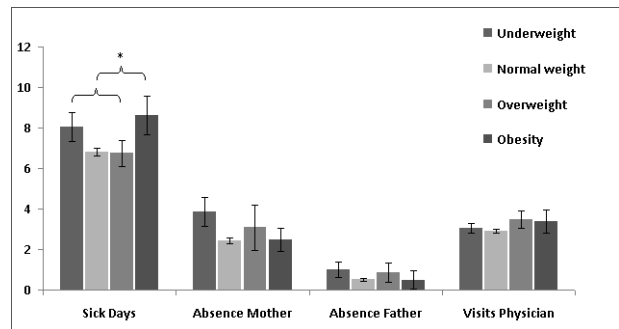

Figure 1: Bar chart of sick days, maternal and paternal absence from work, and visits to a physician by BMI weight groups
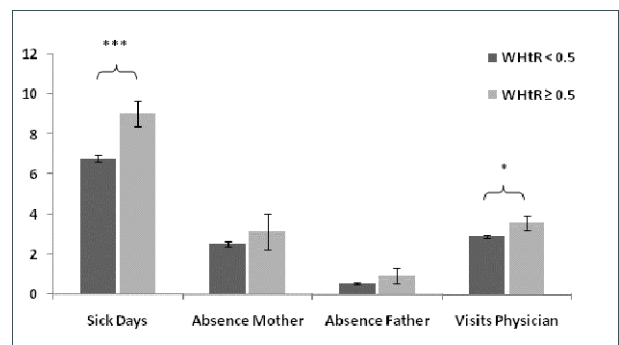

Figure 2: Bar chart of sick days, maternal and paternal absence from work, and visits to a physician by WHtR

Discussion

Weight groups according to BMI versus central obesity according to WHtR

Missing or small associations of weight groups classified by BMI with HRQoL values, and sick days of children refer to potentially incomplete coverage of well-known comorbidity factors of excess weight and obesity, which however, does not mean that these comorbidities are missing. Otherwise, the classification scheme through BMI may be insufficient. Regarding the alternative sectioning through central obesity, the obesity-related link between HRQoL and sick days is clearly illustrated.
At first sight, overweight and obesity rates, as defined by BMI, do not differ substantially between the examined population and the reference group of Kromeyer-Hauschild et al. [8]. However, there is some evidence that the worldwide rapid increase in prevalence of childhood overweight is plateauing [27]. This should not mean considering measures of primary weight gain prevention as being obsolete or viewing the suspension of such measures as a welcome opportunity for savings. This is contradicted by the missing consideration in previous studies of central fat which is mainly responsible for the comorbidities of overweight and obesity [14]. Data from Australia, Canada and the USA show increases of alarming dimensions in the development of central obesity in children and adolescents [28], [29], [30]. Even the parents of the examined children were centrally obese, according

Table 2: Non-standardized estimators from linear and linear mixed regression models for HRQoL

	EQ5D-Y VAS[a] (n=1,479)	KINDL[R] Ts[a] (n=1,267)	Physical wellbeing[a] (n=1,316)	Psychological wellbeing[a] (n=1,335)	Self esteem[a] (n=1,404)	Family[a] (n=1,265)	Friends[a] (n=1,363)	School[a] (n=1,503)
Intercept	89.9 (0.4)	74.9 (0.9)	79.8 (1.4)	90.4 (3.5)	70.5 (0.7)	79.4 (0.6)	76.1 (1.9)	99.4 (4.4)
Child								
Girl		1.8 (0.5)***					2.0 (0.7)**	3.6 (0.7)***
Age [year]				−1.2 (0.5)*				−3.5 (0.6)***
Migration background							1.8 (0.7)*	
Central obesity	−4.1 (1.0)***	−1.9 (0.9)*		−2.6 (1.2)*		−2.8 (1.4)*	−3.4 (1.3)**	
Playing outside >60 min/day		2.3 (0.5)***	1.7 (0.8)*	2.5 (0.7)***	1.6 (0.7)*		3.3 (0.7)***	
Physical active ≥4 days/week ≥60 min/day	1.5 (0.6)**	2.2 (0.5)***	2.8 (0.8)**	2.5 (0.7)***	2.1 (0.8)**		2.4 (0.7)**	
Parents								
Single parent			−3.0 (1.3)*				−2.7 (1.2)*	
Tertiary family education level						−1.9 (0.7)*	−2.0 (0.7)**	−2.7 (1.2)*
Household income ≤1,750 €			−4.1 (1.2)**			2.7 (1.1)*		
Health awareness (mother)	2.1 (0.5)***							
Health awareness (father)		2.5 (0.5)***		2.1 (0.6)**	4.3 (0.7)***	3.3 (0.7)***		3.2 (0.7)***

Standard error in parentheses
[a] Adjusted for the listed variables in this table as a result of stepwise backward elimination in a regression model
*** $p<0.001$; ** $p<0.01$; * $p<0.05$

to the WHtR definition, with 46.8% (mothers) and 74.2% (fathers) fulfilling the criterion, although these self-reported values are anticipated to be rather conservative.

The primarily discussed reasons for the development of central obesity are, in addition to excessive energy intake, a deficiency in physical activity [31], [32]. Physical inactivity is considered to be an important and independent risk factor for obesity, and Yang et al. confirmed that youth physical activity had an indirect effect on abdominal obesity in adulthood, through continuity of physical activity habits [32]. In this context, the alarming character of this study is that only 3.2% girls and 5.4% boys (according to parent information) fulfil the WHO guideline [21] of engaging in at least 60 minutes of moderate to vigorous activity per day, 7 days during a school week. A further decline in physical activity with increasing age is to be feared according to the comparative figures of the KiGGS survey [33]. The need for action to promote physical activity, especially in childhood is evident [34], and the present study provides information supporting the positive effect of sufficient activity on primary school children. Playing outside for more than 60 min/day and/or the achievement of the WHO guideline on at least 4 days a week seem to have a positive effect on the children's HRQoL measured in EQ5D-Y VAS and KINDL[R]. Another relationship was found between physical activity and the number of children's sick days. Those with higher levels of sick days were less often in compliance with the WHO guideline on 4 or more days physical activity than children with a lower number of sick days (OR 0.66; 95%CI [0.51; 0.85]) [26].

Although no causal relationship can be established because of the cross sectional character, this study suggests a stronger association between health and illness with central obesity rather than with obesity defined through BMI. Hence, paediatric central obesity in particular has not yet been taken into account, and the present results should encourage further research in this direction.

Strengths

The present research is based on data generated by one of the largest German intervention studies in a school setting. These data come from almost all parts of the federal state of Baden-Württemberg. With 157 participating classes in 86 schools, the results allow conclusions to be drawn on a broad basic population. The quality of the anthropometric measures is very high, due to the method of collection by trained staff according to a standardised protocol. The return rate of 87% of parental questionnaires is excellent. The broad variety of collected variables allows research in multiple directions and, enabled by the large sample size, a comprehensive adjustment of results. The prompt analysis of the data ensures the current relevance of the results.

Limitations

This research shows several limitations, most however due to the nature of the underlying epidemiologic intervention study, or cross-sectional study, respectively. The precision of a clinical trial is unattainable for two reasons. On the one hand, the quality of data cannot be ensured, as a great deal was drawn from questionnaires. Secondly, a self-selection of participants is inherent in the study.

In the present study, selection occurs on several levels. Firstly, teachers decide to take part with their class on a voluntary basis and it can be assumed that particularly committed teachers represent the majority of participants in the evaluation. The second selection level lies within the parent population, who decide whether or not their child takes part. This is where language difficulties and social barriers can play a role. Further compromises in data quality may be related to, for instance, the parents' self-report on body measurements. Also, socially desirable response behaviours may occur. A recall bias in the recollection of events pertaining to sick leave, and visits to a physician, is also possible. Some questions may be perceived as incursions into private space and are therefore not truthfully or completely answered. Thus the results provide relevant references and suggestions for further research.

Conclusions

Differences in HRQoL and visits to a physician are clearly shown for central obesity but not for BMI derived overweight and obesity. Future studies should include WHtR as a measure of central obesity. More research is necessary to clarify the advantages and possible limitations of this measure in comparison to BMI.

These findings suggest that preventive measures with effects on waist circumference and WHtR respectively as modifiable factors of both frequency of illness and health-related quality of life, are reasonable. A cost-effective project that significantly reduced the increase of waist circumference, is the above mentioned URMEL-ICE intervention [17]. Costs per child and school year for the implementation of this school- and teacher-based intervention amount to € 24.09 [17]. As a further development of that programme, "Join the Healthy Boat" was extended to all 4 grades of German primary school and alongside the current evaluation of cost-effectiveness, shall be examined once again.

Notes

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Competing interests

The authors declare that they have no competing interests.

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