ORIGINAL ARTICLE

Weight Loss in Children and Adolescents

A Systematic Review and Evaluation of Conservative, Non-Pharmacological Obesity Treatment Programs

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SUMMARY

Background: 15% of children and adolescents in Germany are overweight, including 6.3% who are affected by obesity. The efficacy of conservative weight-loss treatments has been demonstrated, but there has not yet been a detailed analysis of their efficacy in terms of the amount of weight loss that can be expected. We re-evaluated the available evidence on this question, with particular attention to the methodological quality of clinical trials, in order to derive information that might be a useful guide for treatment.

Methods: We conducted a systematic literature search of Medline for the period May 2008 (final inclusion date for a 2009 Cochrane Review) to December 2013. The identified studies were analyzed qualitatively.

Results: 48 randomized controlled clinical trials with a total of 5025 participants met the predefined inclusion criteria for this analysis. In the ones that met predefined criteria for methodological quality, conservative weight-loss treatments led to weight loss in amounts ranging from 0.05 to 0.42 BMI z score (standard deviation score of the body mass index) over a period of 12–24 months. Information on trial dropout rates was available for 41 of the 48 trials; the dropout rate was 10% or higher in 27 of these (66%), and 25% or higher in 9 (22%).

Conclusion: The available evidence consistently shows that only a modest degree of weight loss can be expected from conservative treatment. Families seeking treatment should be informed of this fact. Future research should focus on determining predictive factors for therapeutic benefit, and on the evaluation of additional types of psychological intervention to promote coping with obesity.

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About 15% of all children and adolescents in Germany are overweight, including 6.3% who are affected by obesity (1). The prevalence of obesity has been stable in recent years in Germany (2), and emphasis is increasingly being laid on prevention (3), but the treatment of children and adolescents with obesity remains an important matter for health-care policy. The likelihood that childhood obesity will persist into adulthood (4), the elevated risks of somatic (5) and mental (6) comorbidity, stigmatization and the psychosocial impairment that it causes (7), and high health-care costs (8) are all reasons why effective treatments for obesity are needed. Overweight and obesity affects many children and adolescents, but relatively few of them participate in the available treatment programs (9, 10).

In the German evidence-based guidelines on the treatment of obesity in childhood and adolescence, conservative (non-pharmacological) weight-loss treatments are recommended, with the goal of long-term improvement in nutritional and exercise habits (11). A multimodal lifestyle intervention is advised, including dietary, physical activity-based, and behavior therapy components. It is stated that adjuvant pharmacotherapy or bariatric surgery for extreme obesity should only cautiously be offered to adolescents, and only after the failure of conservative treatment (11).

The efficacy of conservative treatment is deemed to be well established, but the most recent Cochrane meta-analysis (2009) (10) showed that the effect size is small: the mean amount of weight loss after 12 months of conservative treatment was 0.04 and 0.14 BMI z score (11) (standard deviation score of the body mass index) in children and adolescents, respectively (these figures are derived from two trials for each of the two age groups). Many trials have compared the effects of two or more conservative treatments against each other, but the overall amount of weight reduction that can be expected from any such treatment needs to be assessed in more detail.

In this article, we summarize the current state of the scientific evidence and qualitatively analyze the available research publications. In assessing the findings, we consider not only the amount of weight loss over the intermediate term, but also patient adherence, dropout rates, and the methodological quality of the trials.

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Methods

We performed a qualitative analysis in order to assess the broadest possible spectrum of available randomized controlled trials; the eligible trials were too few, and too heterogeneous, to enable quantitative analysis (see *eMethods*). We searched the literature for research on the efficacy of weight-loss treatments in children and adolescents, published from May 2008 to December 2013. The May 2008 starting point was chosen because this had been the final inclusion date for a 2009 Cochrane meta-analysis that took all prior publications into account (10). The results of the literature search are shown in the PRISMA flow diagram (12, 13) (*Figure*). The inclusion criteria for trials were as follows: a randomized controlled design; an intervention consisting of dietary, physical activity-based, or behavior therapy (at least one of these three); at least 6 months of follow-up after the start of treatment; BMI and/or BMI z score as a study endpoint; and use of the internationally accepted definition of obesity, i.e., BMI z score ≥ 2 , or, alternatively, being in the 97th BMI percentile or above (11). The methodological quality of trials was evaluated with the aid of seven predefined criteria, in accordance with current recommendations (*eMethods*, *eTable 2* [10, e2]):

- Statistical power analysis for BMI or BMI z score
- Intention-to-treat analysis
- Description of the randomization procedure
- Reporting of adverse events
- Information about adherence (participation rate)
- Information about dropout rate during the intervention
- Information about loss to follow-up.

The methods of analysis are described in detail in the supplementary materials (*eMethods*), as are the methods of data extraction and the general characteristics of the clinical trials (*eMethods*, *eTable 1*).

Results

The overall number of randomized participants in the 48 trials that were included in this analysis was 5025 (mean of 104.7 participants per trial, standard deviation 75.8, range 18–475). A selection of trials meeting predefined methodological criteria is shown in *Table 1a*.

In four trials (14–18) that met all seven of the methodological quality criteria, the reduction of BMI z score after 12 months of treatment ranged from 0.05 to 0.22. In four further trials (19–23) that met at least five of the criteria (including power analysis and intention-to-treat analysis) and that included at least 100 participants who were followed up for at least 12 months, the corresponding range was 0.14 to 0.39 (*Table 1a*).

In summary, in these eight trials (which were the best eight among the 48 included in the study, according to the predefined quality criteria), the mean weight loss among the child and adolescent participants after 12 months of treatment ranged from 0.05 to 0.39 BMI z score. Four of these eight trials also contained data in terms of BMI z score about weight loss at 24 months: these figures ranged from 0.08 to 0.42. *Table 2* contains an illustration of what a BMI z score reduction of 0.3 after 12 months of treat-

PRISMA 2009: Flow of information through the different phases of a systematic review (12, 13). BMI, body-mass index; z score, standard deviation score

ment implies, with simultaneous consideration of the normal growth process; we use extrapolated values of a German reference population for this purpose (31, 32). In a 15-year-old-girl initially weighing 102.0 kg, this degree of BMI z score reduction would correspond to an absolute weight loss of 4.8 kg; in an 8-year-old boy initially weighing 40 kg, it would correspond to an absolute weight gain of 3.5 kg (*Table 2*).

Out of a total of 23 reports of trials in which treatment was compared with routine care or a waiting list condition, 18 contained BMI z score data at 6 or 12 months from the start of treatment. Only 7 of these 18 trials (24–30) revealed a statistically significant difference between groups with respect to BMI z score changes; furthermore, most of them had methodological deficiencies that lessened the informative value of the findings. *Table 1b* contains an overview of the reported intergroup differences at 6 and 12 months, without taking account of the methodological quality of each individual trial or of heterogeneity across trials. The rates of dropout and of

TABLE 1a

Overview of the findings of the available trials that were of the highest methodological quality*¹

Author/year Number of cases	Methodological quality (0–7 points)	Follow-up interval Intervention and duration	BMI z score change	Assessment of findings
Children under age 12				
(14) Mirza et al. (2013) n = 113	7	12 and 24 months: – low-glycemic load diet – low-fat diet for 3 months each, then maintenance therapy up to 12 months	–0.15 –0.08	Time effect* ² significant (effect size not reported), group difference not significant
(15) Croker et al. (2012) n = 72	7	6 months: – 6 months of multimodal, family- based intervention – waiting list as control condition	–0.11 –0.10	Time effect significant (effect size not reported), group difference not significant
(16) Wake et al. (2013) n = 118	7	12 months: – 12 months of lifestyle intervention by family physician – routine care	–0.22 –0.18	Group difference not significant
(20) De Niet et al. (2012) n = 141	6	12 months: – 12 months of lifestyle & SMS- maintenance interventions – no SMS maintenance intervention	–0.25 –0.20	Time effect significant (effect size: d = 2.72), group difference not significant
(21, 22) Collins et al. (2011), Okely et al. (2010) n = 206	6	12, 24 months: – 6 months of parent-centered diet modification program – child-centered physical activity intervention – combined treatment	–0.39, –0.35 –0.17, –0.19 –0.32, –0.24	Time effect and group difference significant (physical activity intervention alone was inferior), no effect size indicated
(23) Magarey et al. (2011) n = 169	6	12, 24 months: – 6 months of family-based lifestyle intervention with parenting skills training – without parenting skills training	–0.31, –0.39 –0.24, –0.42	Time effect significant (no effect size indicated), group difference not significant
Adolescents aged 12 and above				
(17, 18) Nguyen et al. (2013, 2012) n = 151	7	12, 24 months: – 8 weeks of multimodal intervention with maintenance phone calls – without maintenance phone calls	–0.05, –0.20 –0.08, –0.09	Group difference not significant
(19) Ford et al. (2010) n = 106	6	12, 18 months: – 12 months of lifestyle intervention with mandometer (computerized feedback device: energy intake, eating speed) – without mandometer	–0.36, –0.41 –0.14, –0.14	Group difference significant at 12 and 18 months, no effect size indicated

*¹ i.e., trials that met all 7 quality criteria and those that met at least 5 of the criteria (including power analysis and ITT) and that also included at least 100 participants who were followed up for a minimum of 12 months (cf. *eTable 1, eMethods*)

*² weight change from baseline to follow-up examination, all groups

SMS, short message service; BMI, body-mass index; z score, standard deviation score; ITT, intention-to-treat

loss to follow-up indirectly reflect the participants' acceptance and subjective views of the interventions, as well as their practical applicability in everyday life. In the included trials, these rates ranged from 0% to 50% and from 0% to 71%, respectively. Out of the 41 trials for which such information was reported, the drop-out rate was above 10% in 27, and above 25% in 9 (*eTable 2*). Data on loss to follow-up was reported in 45 trials: this rate was above 10% in 31 trials, and above 25% in 20. The inclusion rate, i.e., the percentage of screened candidates who went on to be randomized, varied from 10% to 100% across trials, depending on the pathways of participant

recruitment, and was less than 60% in 23 trials (nearly half of all trials).

Conclusion

The available data on the efficacy of non-pharmacological treatments for obesity in children and adolescents yield a heterogeneous picture. The interpretability of the findings is limited by the variable methodological quality across trials; by the heterogeneity of the study populations with respect to age, initial weight, and social background; by differences in the nature, quantity, and intensity of interventions; and by the use of varying endpoints and

TABLE 1b

Concise overview of findings of the available trials that had an untreated control group*¹

Group difference in BMI z score change* ²	Number of trials with available data (n = 18)	Reference (methodological quality points [0–7 scale])
6 months after start of intervention (n = 9)		
+0.10 to 0.00	n = 1	e4 (4)
–0.01 to –0.10	n = 5	15 (7), e17 (4), e27 (3), e32 (4), e33 (4)
–0.11 to –0.20	n = 1	28 (4)
–0.21 to –0.30	n = 2	25 (4), e22 (5)
12 months after start of intervention (n = 11)		
–0.01 to –0.10	n = 4	16 (7), 27 (4), e18 (5), e21 (4)
–0.11 to –0.20	n = 1	25 (4)
–0.21 to –0.30	n = 4	24 (3), 28 (4), 30 (4), e10 (4)
–0.31 to –0.40	n = 0	
–0.41 to –0.50	n = 0	
–0.51 to –0.60	n = 1	e30 (3)
–0.61 to –0.70	n = 0	
–0.71 to –0.80	n = 1	29 (4)

*¹ with reporting of BMI z score at 6 and/or 12 months after the start of treatment

*² The BMI z score differences shown here for the intervention group in comparison to the control group do not correspond to absolute weight reductions in the intervention group, because, in most trials, BMI z score changes were observed in the control group as well.

BMI, body-mass index; z score, standard deviation score

follow-up intervals. For all these reasons, the results cannot be generalized.

Although scientific evidence (10) supports the efficacy of conservative weight-loss treatments, little attention has been paid to the amount of weight loss that can be realistically expected from such treatments. The high-quality clinical trials that we analyzed revealed BMI z score reductions ranging from 0.05 to 0.39 one year after the start of treatment. This implies that most children and adolescents with obesity cannot expect their weight to be normalized by conservative treatment over the intermediate term (for calculated examples, cf. *Table 2*). A patient who achieves an average result in one of the available interventional programs will exit from the officially defined category of “obesity” only if his or her initial BMI was not very far above the threshold value. Conceivably, the main therapeutic value of conservative weight-loss treatment may lie in the reduction of cardiovascular risk and comorbidities: significant improvements in insulin sensitivity, blood pressure, and lipid profiles have been demonstrated even with only mild or moderate degrees of weight loss (33). Conservative weight-loss treatment has also been found to bring about sustained improvements in nutritional and exercise behavior, which, in the long term, may lower the risk of obesity-associated diseases (34). Self-reported data concerning lifestyle should always be interpreted with caution because of a tendency of social desirability in participants’ answers. An improvement in quality of life as a result of conservative weight-loss treatment has been reported in one trial; however, it was only

short-lasting (35). Moreover, the trials that have been performed to date in which psychological variables were measured do not permit any secure judgment as to whether a positive effect on quality of life also extends to participants who did not lose weight as the result of the intervention.

In assessing the effects of weight-loss treatment, one should be aware of the lack of information about the further course of those trial participants’ weight status who were lost to follow-up. In cases where participants went on to lose less than average amounts of weight after their last observation, the overall effect of the intervention would actually be smaller than reported. Efforts to lose weight can, in fact, promote weight gain in the long run (36). On the other hand, it is also conceivable that modest short-term and intermediate-term effects might develop into more substantial weight loss later on. This question can only be answered on the basis of longitudinal observations over several years including intensive efforts to prevent losses to follow-up. The available data suggest that some subgroups of children and adolescents may respond better to weight-loss treatment than others. This conclusion is based on BMI z-score changes ranging all the way from –0.9 to +0.70 in the included trials—provided that this does not simply reflect a random distribution of data.

Predictors of therapeutic success should, therefore, be an object of study in future clinical trials. For example, it would be useful to document the weight status of the parents of each participant; parental weight

TABLE 2

Illustration of weight changes corresponding to a BMI z score reduction of 0.3 in 12 months*

	Age in years	Height in cm (percentile [P])	Weight in kg	BMI in kg/m ²	BMI percentile (P)	BMI z score
Case 1: 8-year-old boy with obesity						
Absolute values	8.0	130.0 (~ P 50)	40.0	23.67	P 99	2.41
	9.0	136.4 (~ P 50)	43.5	23.38	P 98	2.11
Change after 12 months	+1.0	+ 6.4	+3.5	- 0.29	- 1	- 0.3
Case 2: 15-year-old girl with extreme obesity						
Absolute values	15.0	170.0 (~ P 77)	102.0	35.29	> P 99.5	2.97
	16.0	171.0 (~ P 77)	97.2	33.24	> P 99.5	2.67
Change after 12 months	+1.0	+1.0	- 4.8	- 2.05	+/- 0	- 0.3

*Calculated on the basis of extrapolated values from a German reference population (31, 32). BMI, body-mass index; z score, standard-deviation score

status has already been shown to be of major predictive significance, particularly for younger children (4). Clinical research in this area to date has also paid too little attention to the documentation of adverse events, which should be checked for repeatedly at close intervals, because of the possibility that weight-loss treatment in children and adolescents might have negative consequences for long-term weight development and for mental health. Mental disorders are known to be more prevalent in people with obesity (6); nonetheless, a detailed psychological and/or psychiatric evaluation is not yet a standard component of behavior-therapeutic lifestyle interventions for obesity.

The strengths and limitations of this study

Our detailed analysis of the effects of weight-loss treatment over time in children and adolescents with obesity (absolute changes from the baseline to the follow-up examination) is one of the strengths of this study. Another is that our evaluation of randomized controlled clinical trials took account of their methodological limitations through the use of objective quality criteria. We were able to assess the therapeutic potential as well as the limitations of conservative weight-loss treatment in this age group by comprehensive extraction of the relevant data, including all available information on adherence, dropout, and loss to follow-up. A final strength of this study is that it constitutes an updated review of a field of research that is of great relevance to the medical care of a risk population.

The informativeness of this study is limited by the lack of a quantitative analysis of treatment effects. Due to the heterogeneity of the available studies and non-generalizability of results, performance of a meaningful meta-analysis was not feasible. A further limitation of this study is that the methodological quality criteria were all applied with equal weight. Moreover, the inclusion of further endpoints in addition to BMI and BMI z score (i.e., indicators of other aspects of the patient's somatic or psychological

condition) would have been desirable, but was not possible because data of this type were lacking.

Clinical implications

The results reported here have a number of clinical implications. The high dropout rates and even higher rates of loss to follow-up arouse concern about what might happen to these patients' health beyond the end of the intervention. Families seeking treatment usually have high hopes that their child will enjoy sustained weight loss, resulting, in the best case, in a normal weight. Many of the available intervention programs demand an intensive effort from participants over a long period of time, sometimes with multiple appointments each week for the patient and at least one accompanying parent. The realization that these major efforts tend to yield relatively modest benefits may be one reason why the interventions are often broken off prematurely. It may be that many families already know this even before treatment is started; if so, this might account for the low inclusion rates of the clinical trials, in comparison to the number of families to whom treatment was offered. The utilization rate may also be kept low by other factors, including socioeconomic barriers. There is no reliable way to determine the actual percentage of obese children and adolescents who would be willing to undergo weight-loss treatment.

There is also a danger that patients who do not lose weight while under treatment will interpret this as a personal failure. Research on the stigmatization of persons with obesity indicates that discrimination is widely experienced within the family, and in health-care settings as well (37). A common stigmatizing attitude is the assumption that the individual with obesity bears full personal responsibility for his or her abnormal weight; feelings of failure and shame are the result. Patients with low self-esteem often internalize such attitudes which leads to self-stigmatization (38).

Regardless of whether weight is ultimately lost, participation in a treatment program reveals that the patient is

intensely concerned about the problem. Weight looms large in everyday life in comparison to other typical developmental issues, and the patient's self-esteem is largely determined by the success or failure of the attempt to lose weight—all the more so if the parent-child relationship tends to focus on weight loss, to the exclusion of other matters. In vulnerable children and adolescents, excessive preoccupation with weight can lead to dysfunctional weight-control mechanisms and to loss of self-esteem, potentially culminating in depressive episodes with social isolation (39). Unhealthy weight-control mechanisms are known to be a potential precursor of eating disorders; such disorders, once they arise, make it more likely that the patient will continue to gain weight (40). Resignation, with the abandonment of all efforts to lead a healthy lifestyle, is another possible reaction to the failure of treatment. On the other hand, children and adolescents might derive various benefits from participation in a weight-loss program that are independent of weight loss per se, for example, a more healthy lifestyle, improved quality of life, and more regular medical check-ups. Another positive scenario is that a patient who has achieved only a modest degree of weight loss might draw the conclusion that the ability to control his or her own weight is, in fact, limited, and thus develop a new, emotionally more helpful attitude to obesity.

To prevent treatment failure as far as possible, physicians should take care to inform the parents and the affected children or adolescents early on about the degree of weight loss that they can realistically expect from the currently available treatments, and about their potential adverse effects, as determined from the consistent findings of clinical trials. Unrestricted recommendations to undergo conservative treatment, with an exclusive focus on weight loss, may have the adverse consequences already mentioned above; additionally, a disappointing experience with such treatment may end up weakening the patient's (and the family's) confidence in medical care in general, possibly prompting a total withdrawal from care. It is very important for the patient to remain in regular contact with a physician over the long term, in view of the elevated risk of illnesses associated with obesity (regular check-ups can enable, for example, the timely diagnosis of hypertension). If the patient expresses willingness to be treated for obesity, the physician should discuss the patient's and the family's expectations with them extensively, so that they will be able to deal with the problem of obesity constructively. On the other hand, if the family decides against conservative treatment for obesity because of the limited prospect of success, this decision should be respected, and the family should continue to benefit from the physician's medical support in dealing with obesity. In view of the fact that conservative methods can generally only bring about a modest degree of weight loss, one may well ask whether the proof of failure of conservative methods ought still to be considered a prerequisite for the consideration of bariatric surgery, as it is at present (11). It might be reasonable to loosen this requirement when extreme obesity threatens to severely impair the physical and mental health of a young patient.

Future perspectives

The goal of treating a chronic disease is, above all, to help the patient cope with it. Since obesity can be seen as a chronic disease, it would seem advisable to refocus the treatment away from weight loss as a goal in itself, and toward better coping with the health problem. Interventions should be provided that are aimed at the following targets: improved quality of life and self-esteem, a more positive body image, dealing with stigmatization, overcoming social isolation, a more healthy lifestyle regardless of the amount of weight that is lost, and regular check-ups in primary care. Especially in the case of young children, the parents should be involved in the treatment process, so that stigmatization within the family can be avoided. The acceptance and efficacy of coping-oriented interventions that are intended to improve the patient's quality of life and psychosocial functioning should be the primary end-points of future clinical trials in this field.

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Conflict of interest statement

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KEY MESSAGES

- Conservative weight-loss treatments for obesity in children and adolescents have, on average, only a modest effect on weight status (BMI z score reduction of 0.05 to 0.39 in one year). Any weight loss resulting from successful treatment is superimposed on the normal weight gain that accompanies growth. Thus, in a 15-year-old-girl initially weighing 102 kg, a BMI z score reduction of 0.3 would correspond to an absolute weight loss of 4.8 kg after one year; in an 8-year-old boy initially weighing 40 kg at baseline, it would correspond to an absolute weight gain of 3.5 kg after one year.
- In general, children and adolescents with extreme obesity cannot be expected to achieve a normal weight within two years by participation in one of the currently available weight-loss programs.
- Families seeking treatment should be informed of the limited efficacy of conservative weight-loss treatments and of their potential adverse effects (e.g. lessened self-esteem, unhealthy weight-control mechanisms).
- Family counseling can also prevent stigmatization of the obese child or adolescent within the family.
- The main goals of physicians caring for children and adolescents with obesity should be to help their patients cope with obesity, to promote a healthy lifestyle for better physical and mental health no matter how much or how little weight is lost, to improve their patients' psychosocial functioning, and to motivate them to make use of the available health-care resources over the long term.

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For eReferences please refer to:
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eMethods, eTables, eFigure:
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ORIGINAL ARTICLE

Weight Loss in Children and Adolescents

A Systematic Review and Evaluation of Conservative, Non-Pharmacological Obesity Treatment Programs

Yvonne Mühlig, Martin Wabitsch, Anja Moss, Johannes Hebebrand

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eFIGURE

Methodological
quality of trials

eTABLE 2

Evaluation of trials according to defined methodological quality criteria (see also e2, 10)

Authors	Power analysis	ITT ¹	RP ²	AE ³	Adherence	Dropout	Loss to follow-up	Sum (points)
Dietary interventions, children under age 12								
Mirza et al. (2013)	X	X	X	X	X	X	X	7
Kirk et al. (2012)		X	X		X	X	X	5
Parillo et al. (2012)						X	X	2
Iannuzzi et al. (2009)						X	X	2
Kelishadi et al. (2009)	X		X			X	X	4
Dietary interventions, adolescents aged 12 and older								
Ebbeling et al. (2012)	X	X		X	X	X	X	6
Partsalaki et al. (2012)						X	X	2
Berkowitz et al. (2011)					X	X	X	3
Krebs et al. (2010)						X	X	2
Ford et al. (2010)	X	X	X		X	X	X	6
Demol et al. (2008)	X					X	X	3
Activity-based interventions, children under age 12								
Duggins et al. (2010)	X		X		X	X		4
Activity-based interventions, adolescents aged 12 and older								
De Piano et al. (2012)								0
Tjonna et al. (2009)			X			X		2
Multidisciplinary lifestyle interventions, children under age 12								
Arauz Boudreau et al. (2013)			X		X	X	X	4
Hystad et al. (2013)			X			X	X	3
Wake et al. (2013)	X	X	X	X	X	X	X	7
Taveras et al. (2013)		X	X		X	X	X	5
Davis et al. (2013)	X		X	X	X	X	X	6
Bocca et al. (2012)			X			X	X	3
Lison et al. (2012)	X	X	X		X		X	5
De Niet et al. (2012)	X	X	X		X	X	X	6
Crocker et al. (2012)	X	X	X	X	X	X	X	7
O'Connor et al. (2011)	X		X		X	X	X	5
Pedrosa et al. (2011)	X				X	X	X	4
Coppins et al. (2011)	X				X	X	X	4
Wafa et al. (2011)	X		X		X		X	4
Collins et al. (2011), Okely et al. (2010)	X	X	X	X		X	X	6
Boutelle et al. (2011)			X			X	X	3
Magarey et al. (2011)	X	X	X	X	X		X	6
Stark et al. (2011)	X		X			X	X	4
West et al. (2010)		X				X	X	3
Sacher et al. (2010)			X	X	X	X	X	5
Diaz et al. (2010)		X	X		X		X	4
Waling et al. (2010)		X				X	X	3
Shalitin et al. (2009)	X		X			X	X	4
Kalarchian et al. (2009)	X	X	X		X		X	5

Authors	Power analysis	ITT* ¹	RP* ²	AE* ³	Adherence	Dropout	Loss to follow-up	Sum (points)
Wake et al. (2009)	X		X		X	X	X	5
Janicke et al. (2008)	X		X		X	X	X	5
Weigel et al. (2008)					X	X	X	3
Multidisciplinary lifestyle interventions, adolescents aged 12 and older								
Pbert et al. (2013)			X		X	X	X	4
Nguyen et al. (2013, 2012)	X	X	X	X	X	X	X	7
Walpole et al. (2013)			X		X	X	X	4
Lloyd-Richardson et al. (2012)		X	X		X	X	X	5
Vos et al. (2011)	X		X			X	X	4
Savoye et al. (2011)		X	X			X	X	4
Johnston et al. (2010)		X	X			X	X	4
Naar-King et al. (2009)	X		X		X		X	4

*¹ intention-to-treat analysis

*² description of randomization procedure

*³ reporting of adverse events

Weight Loss in Children and Adolescents

A Systematic Review and Evaluation of Conservative, Non-Pharmacological Obesity Treatment Programs

Yvonne Mühlig, Martin Wabitsch, Anja Moss, and Johannes Hebebrand

This review article was developed in the following phases:

1. Determination of the objectives
2. Definition of inclusion and exclusion criteria
3. Systematic literature search
4. Selection of eligible studies
5. Data extraction
6. Qualitative analysis of the included trials.

Inclusion and exclusion criteria

The inclusion criteria are listed in the main text of the article. Trials with the following characteristics were excluded:

- Obtaining of self-reported rather than objectively measured anthropometric data
- Inclusion of children and adolescents whose weight was normal, by the definition of the World Health Organization (e1)
- Participants 18 years or older
- Treatment goal other than weight reduction
- Exclusively maintenance therapy
- Pharmacological or surgical treatment
- No full text available in German or English.

No limitation was placed on the setting, nature, or number of comparison conditions, the mode of treatment during the follow-up interval, the number of cases, or other methodological features. We decided not to impose any limitations of these types in order to enable a comprehensive overview of the literature and to include trials reflecting the everyday reality of clinical practice.

Literature search

This article is based on a systematic, Internet-based literature search in the Medline medical database, which was carried out via PubMed (first search on 13 June 2013, search update on 22 January 2014). The search item was: (weight loss OR weight reduction OR diet OR exercise) AND (therap* OR treatment OR intervention) AND obesity AND (child* OR adolesc* OR youth). A filter for randomized controlled trials was applied.

Selection of studies

All references were checked for relevance by the first author on the basis of their title and abstract and selected in accordance with the inclusion and

exclusion criteria. The references remaining after this step were evaluated as full text.

Data extraction and qualitative analysis

Data were extracted with the aid of a data table (spreadsheet) (*eTable 1*). All full texts of the included trials were processed for data extraction at least twice. To improve perspicuity, the spreadsheet was subdivided into categories corresponding to the main feature of the intervention in question (dietary interventions, activity-based interventions, multidisciplinary lifestyle interventions) and the average age of the participants (children under age 12, adolescents aged 12 and above). The articles were sorted by date of publication.

After data extraction, the included trials were evaluated for methodological quality on a scale of 0 to 7 points that was developed for this review (*eTable 2*). The quality criteria were chosen on the basis of internationally recognized recommendations for randomized controlled therapeutic trials (power analysis, description of the randomization process, and reporting of adverse events) (e2), a Cochrane review of 2009 (intention-to-treat analysis) (10), and considerations of content with respect to critical features of the treatment of obesity in childhood and adolescence (reporting of adherence, dropout rate, and rate of loss to follow-up); one point was awarded for each feature. Blinding of randomization is often considered a quality criterion for randomized controlled trials (e2, 10) but would not be feasible in a trial of weight-loss treatment. Data extraction was performed by the first author and checked for plausibility by the last author. The criteria for quality analysis were developed jointly by these two authors and assigned by the first author.

After data extraction, the trials were examined for their eligibility for quantitative evaluation. Meta-analysis is a scientifically established method of deriving objective, evidence-based conclusions from multiple trials; however, it requires a number of methodological preconditions to be fulfilled. An important prerequisite for a meta-analysis is an adequate number of clinically and methodologically homogeneous individual trials (e3). For a meaningful meta-analysis to be possible, trials of conservative treatments for obesity would have to be

clinically homogeneous in terms of, among other things, the study population (age, mode of recruitment, weight status before treatment), the nature of the comparison conditions, the setting and duration of the intervention, the provision of maintenance therapy, the timing of follow-up, and the measured endpoints. They would also have to be methodologically homogeneous in terms of critical features such as trial design, the number of intervention conditions, and the performance of an intention-to-treat analysis and a statistical power analysis. Too few of the trials retrieved by our literature search met these criteria for a meaningful meta-analysis to be possible. When there are too few homogeneous trials, qualitative analysis is preferable to meta-analysis (e3).

Reporting of findings

The reported endpoints of this study are formulated as conclusions and presented without any quantitative analysis other than descriptive statistical characterization. BMI z score is used as the main endpoint, because this figure is more precisely informative in studies of children and adolescents. No data other than those appearing in the publications of the trials are considered. Findings are reported for trials that met all seven methodological quality criteria and for those that met at least five of the seven criteria, including two key statistical features (power analysis and intention-to-treat analysis), and that had at least 100 participants who were followed up for at least 12 months from the start of treatment.

Results (Supplement)

Description of the included trials

19 of the trials were performed in the USA (14, 26, 28, 29, e4–e18), 6 in Australia (16–18, 21–23, e19, e20), 4 in the United Kingdom (15, 19, e21, e22), 3 in the Netherlands (20, 24, 30), 2 each in Israel (e23, e24), Italy (e25, e26), and Norway (e27, e28), and one each in Brazil (e29), Germany (e30), Greece (e31), Iran (e32), Canada (34), Malaysia (e33), Mexico (25), Portugal (27), Sweden (e34), and Spain (e35). Multidisciplinary lifestyle intervention was the most commonly studied form of treatment (34 trials). Dietary interventions with various diets were studied in 11 trials (14, 19, e5, e9, e12, e13, e24–e26, e31, e32) and activity-based therapy in 3 (e8, e28, e29).

The mean age of the subjects was less than 12 years in 32 trials and 12 years or above in 16 trials (17–19, 28, 30, 34, e5, e9, e10, e13–e15, e17, e23, e28–e31). Overweight or obesity was an inclusion criterion in 42 trials, and obesity (exclusively) in 6 (16, 30, e11, e22, e26, e27). Extreme obesity, variously defined, was an exclusion criterion in 10 trials (17, 18, 21–23, e5, e12, e14, e16, e17, e19, e35).

35 trials were performed in an outpatient clinical setting, 4 in schools (28, e10, e17, e21), 3 in municipal health facilities (25, 26, e4), and 3 in family medicine or pediatric practices (16, e18, e19). Of the

remaining trials, one each was performed in a school and a sports center (e22), in a school and a hospital (e20), or via telemedicine (e7). None of the trials was performed in an inpatient setting. The participants were recruited mainly by referral from pediatricians in private practice (16 trials), and also from the regular outpatient clinic of the trial institution (14 trials), from schools (12 trials), via newspaper advertisements (8 trials), via advertisements in unspecified media (5 trials) or on television (1 trial), by letters of invitation to the inhabitants of the surrounding area (4 trials), by posters in other medical institutions (3 trials), in religious institutions (2 trials) or in public facilities (1 trial), and from school-entrance examinations (1 trial). The duration of recruitment was explicitly stated in 11 trials (16, 19, 21–23, 25, e7, e8, e16, e23, e26, e34). Most of the trials recruited their participants through multiple pathways; in two trials (e5, e11), the method of recruitment was not described.

The longest follow-up interval from the start of treatment was 6 months in 10 trials, 7, 8, 9, 10, or 11 months in 1 trial each, 12 months in 20 trials, 18 months in two trials, 24 months in 10 trials, and 36 months in a single trial. In 8 trials, it was explicitly stated that maintenance therapy was provided after the end of the trial observation period (15–17, 20–22, 30, e4, e11, e27).

The methodological quality of the trials

Four trials (14–18) met all seven of the predefined quality criteria; 6 met 6 criteria, 10 met 5, 14 met 4, 8 met 3, 5 met 2, and one failed to meet any of the criteria (eTable 2).

25 trials contained a power analysis or a statement of effect sizes for BMI or BMI z score, 19 contained an intention-to-treat analysis, 35 contained a description of the randomization process, 9 contained information about adverse events, 29 contained information about adherence, 41 mentioned a dropout rate, and 45 mentioned a rate of loss to follow-up.

In recent years, there has been an upward trend in trial quality (eFigure). The trials evaluating multidisciplinary lifestyle interventions were the most numerous and had the best methodological quality, followed by the trials evaluating dietary interventions. Those evaluating activity-based therapy were fewer in number and of much lower quality.

The nature of the intervention

There was no evidence for the superiority of any one of the treatment approaches studied over the others. Just as was found in a meta-analysis of the treatment of obesity in adults (e36), activity-based therapy as the sole treatment for obesity brought about very little change of weight in children and adolescents. It must be pointed out, however, that the three trials of activity-based therapy analyzed in the present study were all of low methodological quality (with 0, 2, and 4 quality points). The more recently published trials included an

increasing number of trials of technology-based interventions (18–20, e7). There are still too few data in this area to permit any definitive conclusion regarding efficacy in children and adolescents; in one trial, the superiority of the technological intervention was demonstrated with statistical significance (-0.24 BMI z score) (19).

Adverse events

Adverse events occurring during treatment were registered in nine trials. In six, no such events were observed (15–18, 21–23, e7, e22). In one trial (14), a participant was reported to have felt weak during blood-drawing. In another trial (e9), seven adverse events involving various somatic symptoms were reported, without any discussion of a possible causal relationship with the treatment. Only one trial (16) contained a report of a possible harmful effect of the intervention: 14% of the parents reported that their child had felt bad on being given the diagnosis of obesity.

Adherence

Adherence is an important indicator of the acceptance of an intervention. In the trials analyzed in this study, adherence was not reported consistently or uniformly, so no general conclusion can be drawn. The various publications mentioned either the mean number of sessions attended by each participant, or the mean number of participants per session, or the number of participants who attended a defined percentage of sessions (variously defined in different publications).