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Review Article

Monitoring and reporting of adverse effects in weight loss trials in children

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ABSTRACT

We investigated if the studies included in a Cochrane Review had examined and reported adverse effects of lifestyle intervention for weight loss in children. We evaluated each of the 70 RCTs included. A total of 67 trials (96%) did not report a method for monitoring adverse effects. Six trials (9%) reported physical adverse events. One trial reported a "negative effect on children's feelings". None of the 70 studies examined for or reported social adverse effects. In conclusion, only a few studies of lifestyle intervention for weight loss in children examined for potential harm, and 96% did not meet the present-day standard for reporting trials as described in the CONSORT statement.

KEY POINTS

- Potential harm from lifestyle interventions for weight loss among children was inadequately explored.
- The review elucidated that 96% of weight loss RCTs among children aged 6-11 years did not meet the CONSORT requirements for monitoring and reporting adverse effects.
- None of the included weight loss trials in children examined for social or mental harm.

A high BMI in childhood is associated with various physical complications [1] and psycho-social complications such as discrimination and weight stigma [2]. To encompass these health challenges, numerous randomised controlled trials (RCTs) with lifestyle interventions for weight loss or weight control have been conducted among children worldwide [3].

Any intervention may result in harm, and adverse effects from weight loss efforts are an understudied area. In adults, intensive lifestyle interventions for weight loss may result in loss of bone mineral and increase the risk of osteoporotic fracture [4, 5]. How lifestyle interventions for weight loss affect bone development in children remain unknown.

A focus on weight may have adverse psycho-social effects. For instance, BMI screening in schools has been shown to increase weight dissatisfaction and increase peer weight talk [6-8]. Female college students being randomly labelled as *overweight* resulted in body dissatisfaction and increased weight bias internalisation [6, 9]. Whether this type of psycho-social harm affects children in weight loss interventions seems to be largely unexplored. It is a concern that critique of children's weight and eating habits may lead to decreased self-esteem and increased risk of developing eating disorders [10-12]. Thus, it is possible that participation in a weight loss trial may contribute to the process of weight stigmatisation and have psycho-social health complications [2, 13].

The Consolidated Standards of Reporting Trials (CONSORT) is a globally recognised standard for reporting results from RCTs [14]. The CONSORT guideline was initially published in 1996 and updated in 2001 and 2010. To reveal unintended negative consequences of interventions, CONSORT comprises a checklist for reporting adverse effects, including assessment and reporting of the degree of severity of the adverse effects and reporting of how data on potential harm were gathered. It is of general interest to examine if weight loss RCTs in children meet present-day recommendations for the reporting of adverse effects.

The present review article is based on the 70 RCTs included in the systematic Cochrane review from 2017: *Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years* [3]. In accordance with Cochrane standards, each study was evaluated regarding risk of bias, and studies of low quality were excluded. Thus, the studies included in the present review were from a systematic literature review with a thorough quality assessment conducted by the authors of the Cochrane review.

The Cochrane Review found that behaviour change interventions compared with no treatment/usual care resulted in a mean change of BMI −0.53 kg/m^2, BMI z-score of −0.06 units or −1.45 kg weight change for the participants. Even though the authors concluded that multicomponent intervention studies may lead to short-term reduction of BMI, BMI z-score and weight score in children aged 6-11 years, the reductions were modest. Altogether, the evidence points to that lifestyle and behaviour change interventions in children are ineffective at obtaining clinically relevant reductions in BMI or BMI z-score [15]. Therefore, knowledge about potential adverse effects is warranted to determine if the benefits outweigh the harms in this type of intervention.

The objective of the present study was to investigate to what extent studies included in a Cochrane Review examined and reported adverse effects of weight loss and weight maintenance interventions in children aged 6-11 years.

Methods

This is a review of 70 RCTs included in the Cochrane Review from 2017 entitled *Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years* [3]. The Cochrane Review collected information on harm or adverse effects from the included studies but found only little evidence in the field, and the subject was not presented or discussed much. We reanalysed the included studies and evaluated them in accordance with the CONSORT guideline for monitoring of adverse effects.

Data collection

Each study was evaluated for monitoring and reporting of adverse effects based on the full text main article as well as abstracts and, in some cases, the full text of other publications (listed in the Cochrane review) reporting results from the same RCT (Appendix 1) by CA. Cases of doubt were evaluated with RKR to ensure that both authors of the present review agreed on a categorisation. The authors of the Cochrane review (501 pages) described how they contacted several researchers to obtain more data regarding adverse effects. These data and descriptions contributed to the present review. We evaluated the participant flow chart in each study for descriptions of participant dropout and recorded any drop out that might indicate monitoring of an adverse event.

Data categorisation

First, we categorised each study as “having” or “not having” a method for monitoring adverse effects. A study was defined as “having a method for monitoring adverse effects” if procedures for collecting information about adverse effects were reported or if the study included a definition of adverse effects. Studies failing to meet one of these criteria were categorised as “not having a method for monitoring adverse effects”.

Subsequently, we categorised each study as “reporting adverse effects”, “reporting that no adverse event had occurred”, or “adverse effects were not mentioned”. A study was defined as “reporting adverse effects” if the articles reporting the trial results explicitly listed observations as potential adverse effects to the intervention. A study was defined as “reporting that no adverse event had occurred” if the study explicitly reported that the intervention had no adverse effects. Finally, studies in which adverse effects were not mentioned were categorised as “adverse effects were not mentioned”. We categorised reported adverse effects as physical, mental or social.

No ethical approval was required to conduct this study, as it was based on previously published material.

Results

Data were extracted from the 70 eligible RCTs. A total of 35 trials (50%) reported briefly that no adverse events had occurred, and 29 trials (41%) did not mention adverse effects [3].

Six trials (9%) reported one or more adverse events. Among these, three trials (4%) reported a method for monitoring adverse effects, and all three reported, in the results section of the main article, that adverse events had occurred [16-18]. The other three trials reporting adverse effects did not state a method for monitoring adverse effects (**Table 1**) [19-21]. Among the six trials reporting adverse effects, two trials reported serious adverse events [16, 17].

TABLE 1 Number of studies having or not having a method for monitoring adverse effects versus reporting adverse effects, reporting no adverse effects or no mentioning of effects in 70 randomised clinical weight loss studies in children.

	Having a method for monitoring adverse effects?	
	yes	no
Reporting adverse effects	3	3
Reporting that no adverse event had occurred	0	35
Adverse effects were not mentioned	0	29

A total of 67 (96%) RCTs did not report a method for monitoring adverse effects (Appendix 1), including all 35 trials reporting that no adverse events had occurred, as well as 29 trials in which it remained unclear whether adverse events had occurred or not, as adverse effects were not mentioned in the articles reporting the trials [3]. Thus, three of 70 trials met the CONSORT guideline requirement for reporting a standard trial regarding adverse effects.

None of the 70 studies described in text, tables or flow charts whether any trial participants withdrew due to unintended negative consequences of the intervention. The total duration of the trials ranged from six months to

three years. Active intervention ranged from ten days to two years. The average duration of post-intervention follow-up was ten months [3].

Method for monitoring adverse effects

Three trials had a method for monitoring adverse effects (Table 1). One assessed adverse effects by a telephone call to all participants comprising a query about any adverse effect [18]. The other two trials recorded "hospitalisation" or "all adverse events and injuries, as well as any medical illnesses that required a visit to a physician or institution" (Appendix 1) [16, 17].

Physical, mental or social adverse effects

All six trials reporting adverse effects reported exclusively on physical harm [16-21]. A single trial (with no description of a method for monitoring adverse effects) reported that the intervention had a "negative effect on children's feelings" [22]. However, in the Cochrane review, it was not classified as harm (**Table 2**) [3]. None of the 70 included studies reported any social side effects of the weight loss interventions.

TABLE 2 Reported adverse effects in 70 randomised clinical weight loss studies in children, categorised into physical, mental and social adverse effects.

Type of adverse effect	Reference	Specific adverse effects reported
Physical	Croker et al., 2012 [19]	1 child in the control group reduced %BMI by 28.8 and BMI by 4.2 kg/m² The study does not provide any explanation as to why this was reported as an adverse effect
	Kirk et al., 2012 [20]	3.6% (3/84) of the participants in both the intervention and the control group developed elevated blood pressure 3.5% (3/86) developed elevated LDL cholesterol 3.5% (3/86) developed high fasting glucose 12.2% (9/74) developed high triglycerides
	Maddison et al., 2011 [16]	8 adverse events were reported in 6 participants: 2 participants in the intervention group and 4 participants in the control group 3 participants were hospitalised due to seasonal influenza 1 blood clot occurred 1 hip operation due to a chronic condition 1 ankle injury 1 person was observed after a fall 1 person got diagnosed with type 1 diabetes
	Maddison et al., 2014 [17]	2 events in the intervention group: bowel replacement surgery and a dislocated hip, and 3 events in the control group: an operation to remove a cyst, a broken ankle, and two broken fingers
	Mirza et al., 2013 [21]	1 participant in the control group experienced a feeling of faintness during the blood draw at the 3-month post-intervention assessment
	Weintraub et al., 2008 [18]	The intervention group had 3 side effects: car collision, newly diagnosed hypothyroidism and skin rash The control group had 6 adverse effects: knee pain while ice skating, foot injury, skin rash, headaches and eye pain, ear infection and ingrown toenail
Mental	Wake et al., 2013 [22]	13% (6/45) of the intervention parents and 14% (6/43) of control parents perceived that being told that their child was obese had a negative effect on their child's feelings < 10% of the parents of the intervention group reported negative effects after visits by the doctor and the specialist However, in the Cochrane Review, this was not classified as an adverse event
Social	-	0 of the 70 articles reported any social adverse effects

LDL = low-density lipoprotein.

Discussion

Overall results

Adverse effects were inadequately monitored and reported in otherwise good quality weight loss trials involving children. Among the 70 RCTs included in the Cochrane Review from 2017 entitled *Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years,* only a few examined for and reported adverse effects. Most of the analysed trials neither monitored nor reported any adverse effects. Only three trials reported a method for monitoring adverse effects, while 29 trials made no

mention of adverse effects.

Three of 70 trials met the CONSORT guideline for reporting an RCT regarding adverse effects. Even though some studies were designed and conducted before the CONSORT guideline was fully implemented as a standard for reporting trials, it is an issue of concern that 96% of experimental weight loss trials with children apparently did not monitor potential harm. One study reported potential harm within the domain of mental health, and six studies reported physical harm. None of the trials reported any social harm, whereas the anticipated benefits of the interventions were typically reported in detail. The lack of monitoring and reporting of adverse effects makes it impossible to weigh the advantages of the interventions against their disadvantages. Thus, based on weight loss RCTs with children aged 6-11 years until 2017, it is impossible to evaluate if the interventions caused more harm than good.

Strengths and limitations

Only studies of a certain quality were included in the Cochrane review, and the studies analysed in the present paper likely represent the best studies in the field until 2017. However, studies published after this year were not included. Newer studies may have reported adverse effects more thoroughly. Some studies may have been miscategorised. Studies categorised as "not having a method for monitoring adverse effects" may have had a method for monitoring adverse effects that was not reported in the main articles listed in the Cochrane review. In line with this, a study found underreporting of adverse effects in trials on orlistat for weight loss [23]. This may have resulted in an underestimation of monitoring of harm, but not in an underestimation of the reporting of harm. Altogether, the inadequate reporting of adverse effects is a robust finding.

Interpretation of results

Adverse effects were monitored differently in the three trials that reported having a monitoring method. Maddison et al. 2014 [17] gathered data about adverse effects by making telephone calls to all participants. However, they did not specify which symptoms were queried for or how they were recorded. Both Maddison et al. 2011 [16] and Weintraub et al. [18] specified in their method sections that a participant had to be seen by a doctor or hospitalised for an adverse effect to be considered. Thus, the monitoring of adverse effects in these two studies primarily focused on injuries and physical harm. Considering the WHO definition of health (physical, mental and social well-being [24]) and evidence on the detrimental effects of weight stigma on mental and social health [2, 6, 9-11, 13, 25-28], the definition of an adverse effect in Maddison et al. 2011 [16] and Weintraub et al. 2008 [18] may be considered inadequate. Their narrow focus on physical harm may leave the reader with the impression that neither mental nor social adverse effects occur in these interventions. Wake et al 2013 did not report a method for monitoring adverse effects but reported the occurrence of psychological harm [22]. Some parents had the perception that their child's feelings were negatively affected when the child was labelled as overweight. A similar reaction was found in an experimental study of 113 female college students where random labelling as 'overweight' (compared with 'normal weight') resulted in increased body dissatisfaction and weight bias internalisation, irrespective of actual BMI [9]. A substantial body of evidence indicates that weight focus may impact body image negatively and that a negative body image is associated with developing disordered eating, clinical eating disorders and depressive symptoms [2, 6, 10-12, 24, 25, 27, 28]. Therefore, it is relevant to investigate whether weight loss interventions among children influence their social interaction, self-esteem, weight bias internalisation, symptoms of anxiety or depression and their risk for developing eating disorders over time.

The average follow-up time was ten months, and the longest follow-up period was three years [3]. The length of the follow-up period is relevant as potential harm like developing an eating disorder rarely occurs before the age of 12 years [29].

Conclusion

Only a few weight loss RCTs among children 6-11 years have examined for harm or adverse effects. Among these, 96% of the trials studied did not meet present-day requirements for adequate reporting of adverse effects, i.e. the CONSORT standard. Physical adverse effects were monitored or reported in some studies. Mental or social harm was not monitored at all. It is problematic that the risk of harm from weight loss interventions remains largely unknown as these interventions are widely used among children. The research community carries an ethical obligation to explore the potential adverse effects of such interventions.

Future research

Future weight loss studies among children should monitor and report harm systematically in accordance with standard guidelines for research and basic ethics.

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