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ORIGINAL ARTICLE

Significant effects of childhood obesity treatment with a web-based component in a randomised controlled study (Web-COP)

Annelie Thorén[1,2] | Tobias Filipsson[3] | Erling Englund[4] | Olof Sandström[1] | Annika Janson[5,6] | Sven Arne Silfverdal[1]

[1]Department of Clinical Sciences, Paediatrics, Umeå University, Umeå, Sweden

[2]Department of Paediatrics, Sollefteå hospital, Sollefteå, Sweden

[3]Department of Paediatrics, Örnsköldsvik hospital, Örnsköldsvik, Sweden

[4]Department of Research and Development, Västernorrland County Council, Sundsvall, Sweden

[5]National Childhood Obesity Centre, Karolinska University Hospital, Stockholm, Sweden

[6]Department of Women's and Children's Health, Division of Paediatric Endocrinology, Karolinska Institutet, Stockholm, Sweden

Correspondence
Annelie Thorén, Department of Clinical Sciences, Paediatrics, Umeå University, Umeå, Sweden.
Email: annelie.thoren@lvn.se

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Abstract

Aim: We evaluated the effect on body mass index standard deviation score (BMI-SDS) of a combined treatment (Web-COP) for children with obesity, including a web-based component targeting their parents.

Methods: This randomised controlled trial recruited children 5–12 years of age with obesity (International Obesity Task Force BMI [IOTF-BMI] ≥30 kg/m^2) from school health care and outpatient paediatric clinics in in Northern Sweden from 1 June 2019 to 21 June 2020. The children were randomised to Web-COP, an intervention with group sessions and a 12-week web-based component, or standard care. The primary outcome was the change in IOTF BMI-SDS after 6 months.

Results: In total, 75 children (33 girls), mean age 9.5 years, were randomised, and 65/75 (87%) children and their parents completed the study, 35/39 (90%) in the Web-COP intervention and 30/36 (83%) in the standard care group. BMI-SDS at 6 months was changed from 3.08 to 2.81 in the intervention group compared to an increase from 3.07 to 3.16 in the standard care group, representing a significant difference between groups ($p < 0.001$). In the intervention group, 14/30 (47%) reduced their BMI-SDS ≥0.25, compared to none in the standard care group.

Conclusion: The parent-focused intervention significantly improved BMI-SDS in children with obesity as compared to children in standard care.

KEYWORDS
childhood obesity, intervention, parents, randomised controlled trial, web-based treatment

1 | BACKGROUND

Obesity in childhood is an alarming global public health concern. Obesity rates among children have increased worldwide over the past 40 years. According to predictions, 250 million children will live with obesity by 2030.[1] A recent Swedish study with comprehensive national data demonstrated a prevalence of obesity in 13.4% of children 4 years of age.[2] A large school-based study from Sweden showed increasing proportions of overweight and obesity with age. The prevalence of overweight and obesity for girls and boys 5–19 years of age was 18.1% and 18.0%, respectively.[3]

Early-onset obesity is associated with severe complications later in life, such as insulin resistance and type 2 diabetes, liver disease, obstructive sleep apnoea and hypertension.[4] Childhood obesity is a

Abbreviations: BMI, body mass index; IOTF, international obesity task force; SD, standard deviation; SDS, standard deviation score; Web-COP, the study name acronym of web-based childhood obesity prevention.

chronic disease associated with premature mortality and emotional and psychological problems.[5] Further, childhood obesity is a well-known risk factor for adult obesity and cardio-metabolic disease,[6] and children with obesity are more likely to remain with obesity as adults.[7] Therefore, early identification and treatment of childhood obesity are critical in preventing many chronic diseases later in life.[8,9]

Obesity research is marred by using different definitions of overweight and obesity. Age and sex-specific cut-offs for defining obesity were developed by the International Obesity Task Force (IOTF). The IOTF body mass index (IOTF-BMI) age- and sex-specific cut-offs for defining overweight, obesity and severe obesity are used extensively in Sweden,[10] and BMI standard deviation scores (BMI-SDS) can be used to compare results over time.

It is essential to address obesity and excess weight gain early in childhood and begin treatment early.[8,11] The recommended treatments of childhood obesity focus on lifestyle modifications and behavioural change for reducing energy intake and increasing physical activity to promote a healthier BMI. Parents play a fundamental role in treating childhood obesity, and efforts should be directed at the whole family.[12] Parental involvement has been shown to promote dietary self-efficiency in children.[13] A recent meta-analysis by Bae et al. showed that 'exercise intervention without a parent', 'diet intervention with parent' and 'diet, exercise and lifestyle intervention with parent' were significantly effective treatments for children with obesity.[14] Moreover, the meta-analysis emphasises the importance of parental intervention for long-term behavioural change.[14]

The field of digital technology is new and rapidly developing.[15] Digital technology provides opportunities to improve the frequency of contacts, patient information and communication.[16] For treating obesity in children, digital technology has been suggested to be a promising low-cost intervention that can be accessed anywhere and at any time.[17] Previous research supports the acceptability and feasibility of web-based, digital technologies for paediatric obesity, both as stand-alone interventions and as an add-on to standard treatment.[18,19] Further, web-based technologies are scalable to meet the increasing demand for treatments. They may overcome barriers to parental involvement in weight management programmes, such as the time required for attendance.[20]

In a previous study, we evaluated the feasibility of an intervention including group sessions and a web-based treatment (Web-COP),[19] and we modified the programme based on these findings. The aim of this randomised controlled study was to study the effect of Web-COP on the children's BMI-SDS, targeting mainly parents of children 5–12 years of age with obesity.

Key Notes

- There are limited data on the effect of using digital technology for obesity treatment in children.
- In this randomised controlled trial, four group sessions and a web-based component resulted in a significant reduction of the children's degree of obesity at 6 months as compared to standard care.
- Although integrated approaches are advocated, future research should aim at isolating the effects of digital support to parents of children with obesity.

2 | METHODS

2.1 | Study design

This study was a multicentre, multi-component, prospective, two-arm, non-blinded randomised controlled trial, including children 5–12 years of age with age- and sex-specific IOTF-BMI ≥ 30, and targeting at least one parent or guardian.

2.2 | Setting, participants and recruitment

Children were recruited from school health centres and four outpatient paediatric clinics in Västernorrland and Västerbotten regions in Sweden between 1 June 2019 and 21 June 2020. The recruitment process included communication with nurses in school health care and outpatient paediatric clinics. Information was sent out by e-mail to school nurses and outpatient paediatric clinics, while information to co-workers was given as oral presentations and written information. Some families were self-referred; they had heard from other families or health care professionals about the study and wanted to know more.

2.3 | Eligibility criteria

Eligibility criteria for inclusion in the study were if the child's age was over 5 and less than 13 years, was diagnosed with obesity defined as IOTF-BMI ≥30 and, had internet access at home. Further, the parents had to be able to read and talk Swedish. Children were either new in obesity treatment or had previous treatment, defined as children who prior to the study received regular obesity treatment at a paediatric clinic. Children with obesity-related syndromes, genetic or chromosomal disorders, or other serious diseases, were excluded from the study. Siblings were able to participate, but one sibling was randomly excluded before randomisation and not included in the analysis. Blinding was not possible due to the nature of the study.

2.4 | Randomisation

After obtaining informed consent, families were randomised to either the intervention or standard treatment at the clinic at a 1:1 ratio (Figure 1). The randomisation allocation was printed on paper in a sealed envelope. An equal number of Web-COP and standard care notes were put in the envelopes. Persons outside the study randomised the children by picking an envelope from a basket.

2.5 | Study periodisation

All participants were informed that the intervention would be done in stages. At the baseline appointment after the randomisation, the intervention group participants received a letter inviting them to the group sessions. Parents and children in the standard care group were informed that they would be offered the same intervention about 6 months later (Figure S1).

2.6 | Intervention

The intervention with group sessions and a web-based component has been described in a feasibility study.[19] In short, children with obesity and their parents were invited to participate in a multi-component intervention with four group sessions at the clinic, receive 'physical activity on prescription', and attend a 12-week web-based component from home. Physical activity on prescription is a structured national procedure in Sweden that enables health care providers form different cadres to prescribe physical activity and the patient can choose from different providers.[21] The mobile-phone-friendly and web-based component (developed by For Life Academy AB, Umeå, Sweden) was designed for parents to support their children's obesity treatment with 12 online modules on various topics. Each week ended with a quiz for the participating parent or family (Figure 2).

All children in the intervention group could borrow an activity tracker (Garmin Vivofit Jr, Garmin, Olathe, Kansas, USA) for 6 months to monitor active minutes per day and estimate the number of steps. Children were encouraged to use the activity trackers

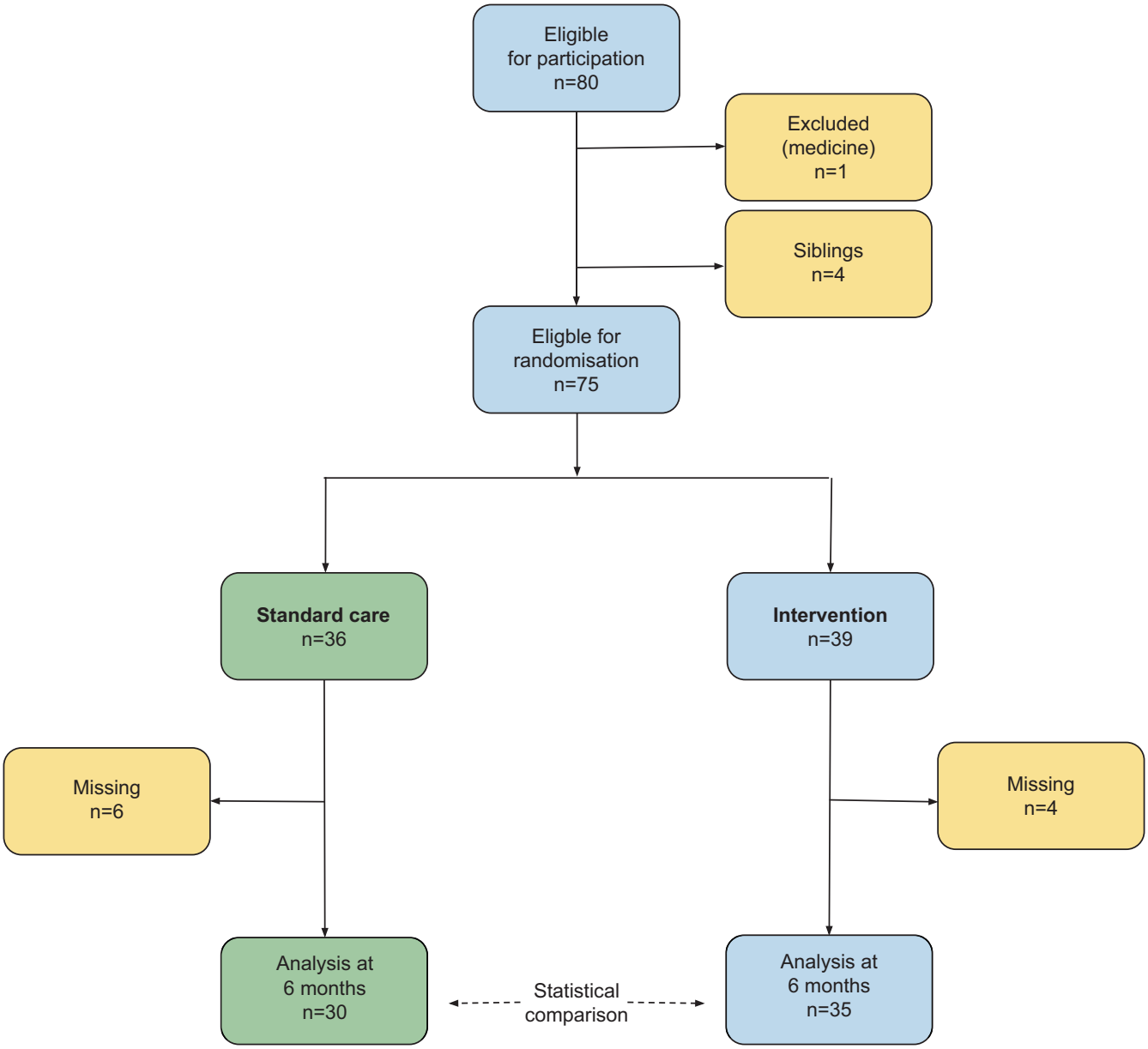


FIGURE 1 Flow chart.

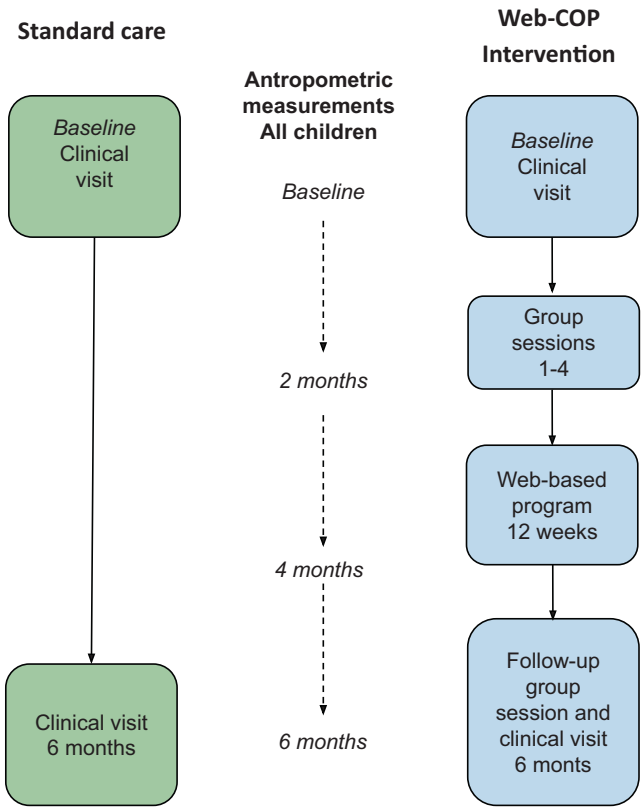


FIGURE 2 The Web-COP intervention. Web-COP, web-based childhood obesity prevention.

daily. Written instructions for each device were provided without any requirements on how and when the device should be worn.

Parents were encouraged to use authoritative parenting skills and make efforts in goal setting, problem-solving and stimulus control. An example of goal setting could be to limit intake of sweets to 1 day per week, drink water at meals, and set a limit of a maximum of 120 min of screen time (watching television and playing video games) per day. To increase compliance with the intervention, parents had the opportunity to chat or have telephone contact with coaches who were dieticians. The direct communication enabled further personalised guidance towards the family's needs and helped the coach to understand what motivated the families.

At one of the group meetings, information about the Mealsizer® (Mealsizer, Lidingö, Sweden) was given to children and parents. Mealsizer® meal measure is a tool for portion control that facilitates the composition and size of a meal that is available in three sizes, small, medium and large. At the end of the session, every family was given a size small Mealsizer® meal measure. Overall, efforts were made to make the activities in the intervention as attractive and fun as possible (Table 1).

2.7 | Standard care

The standard care group received standard treatment. The standard care treatment consisted of a doctor's visit at baseline and measurements by a paediatric nurse every 2 months, a total of four measurements during the study period. The standard care group was offered the intervention after 6 months.

2.8 | Adaptations to the design

From experiences gained in the Web-COP feasibility[19] and qualitative study,[22] the web-based programme was improved in terms of technology for login and a range of educational movies, including a grocery store walking tour. A section on dental health was added as well as tasks to practise healthy behaviours. Also, the study material was standardised to ensure that all participants received the same basic information. Handouts were provided after the group meetings and a brochure presented 10 key messages on lifestyle adaptations that were further reinforced in the web-based component.

2.9 | Dissemination and feed-back

Outside the intervention but for follow-up, the group leader invited families to a 2-h reunion 6 months after the start of the intervention. The session included physical activity for the children and parents. In groups, oral evaluations were carried out to share the children's and parents' experiences and possible suggestions for improvements. Activity trackers were returned and a short survey about Mealsizer® was handed out. The participants received a summary of the intervention, encouragement and practical support in maintaining healthy habits.

2.10 | Data collection and measurements

All children and parents were invited to the paediatric clinics for baseline measurement, including a visit to a paediatrician. Trained paediatric nurses and, for one site, a paediatric assistant nurse performed all anthropometric measurements at all visits throughout the study.

Height, weight and waist circumference were measured with children barefoot in light clothing at the start of the intervention and after 2, 4 and 6 months. BMI was calculated by weight (kg) divided by height squared (m^2), and an algorithm was used for the numerical value of IOTF BMI-SDS. Height was measured to the nearest 0.1 cm and weight to the nearest 0.1 kg using a digital scale (Digital Personal Scale). Data were entered in the National Childhood Obesity Treatment Register (BORIS), supervised by the National Board of Health and Welfare in Sweden.

2.11 | Ethics

Participating children and their parents received information, both verbal and written. Children's assent, as well as their parents' verbal

and written informed consent for the child to take part of the study, were received for the baseline measurements at the doctor's appointment. The study was approved by the Ethics Board at Umeå University (Dnr 2018-113-31M, Dnr 2018-461-32M, Dnr 2019-02343).

2.12 | Statistics

2.12.1 | Outcome measures

The primary outcome was the change in IOTF BMI-SDS after 6 months comparing children who were initially randomised to the intervention or standard care.[10] The secondary outcome was the retention rates.

To calculate the sample size, partial eta-squared was used, which was then converted to Cohen's f. These are measures of effect size for ANOVA. The calculation was based on repeated measure ANOVA with interaction and was performed with the software G*Power 3.1.9.7. With a partial eta-squared = 0.03, giving an effect size (Cohen's f) of 0.18, with an alpha of 5% and power of 80%, a total sample size of 46 was needed to detect a statistically significant interaction between time and group. An eta-squared of 0.03 indicate an effects size between small and medium, according to rules of thumbs from Cohen.[23]

All continuous data were presented with mean and standard deviation (SD). We compared data for all children who completed the intervention ($n = 35$) with all children who completed standard care ($n = 30$).

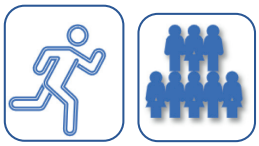
Clustering on family-level was avoided by excluding one sibling in each of four pairs from the randomisation and further analyses. In addition, we analysed all treatment results by sex.

T-test was used to test pairwise differences at baseline between groups for continuous variables and chi-squared test for categorical variables. Linear mixed models (LMM) were used to assess the effect of treatment on primary outcome, that is, the change in BMI-SDS at 6 months comparing children who were initially randomised to the intervention or standard care.

Group designation to intervention or standard care, age group (5–8 or 9–12 years of age), sex and time was used as fixed factors, together with two-way interactions involving time and each group factor. The assumption of normal distribution was based on the skewness of the residuals from the models in LMM. If the value of the skewness was inside (−1.5, 1.5) the normal distribution was assumed.[24] The unstructured covariance type was used.

Participation was defined as those children who had at least two out of four valid values. The missing data were assumed to be missing at random and the linear mixed models were performed using the existing data for the cases. To verify the assumption, we compared the mean value of BMI-SDS at baseline, distribution of sex and age, between the subjects with and without BMI-SDS values at 2, 4 and 6 months for each group. We also analysed the data with LMM based on all subjects with complete BMI-SDS data. In addition, we

TABLE 1 Components in the Web-COP intervention.

Component	Number and content	Participation
 Group sessions	Four weekly 2-h group sessions for parents and children. One group session 6 months after baseline. Groups were led by a nurse and a physiotherapist. The content focused on healthy eating, physical activity, healthy sleeping pattern and parenting	86% of parents and their child attended the group sessions
Physical activity on prescription	This established Swedish national procedure enabled the children to get free access to activities from a local provider. Depending on the age of the child, they could choose between family aerobics, swimming, spinning, gym weight training, aerobic circuit training, or swimming	Not measured
 Web-based programme	A 12-week web-based programme targeting parents covering topics on food and eating, physical activity and creating sustainable healthy habits. A personal web-coach encouraged healthier lifestyle and work towards personalised goals	74% of the parents used the web-based programme
 Mealsizer®	A commercially available measuring tool for portion size was given to the children	57% of parents used the tool. The extent to which it was used was not measured
 Garmin activity tracker	To promote increased physical activity and to increase awareness of the degree of physical activity. Daily use was recommended	94% of the children picked up a tracker at the start of the study. The frequency or duration of use was not measured

compared data for children who started with standard care and went on to the intervention.

A p-value < 0.05 was considered statistically significant. Analyses were performed using IBM SPSS Statistics, Version 29.0, IBM Corp, Armonk, NY, USA.

3 | RESULTS

3.1 | Baseline characteristics

In total, 80 children and their parents were recruited in four communities: Sundsvall, Sollefteå, Örnsköldsvik and Umeå. Several persons were involved in the recruiting process, and we could not determine the number of families that were informed about or invited to the study. One child was excluded for medical reasons. One child from each pair of siblings ($n=4$) was randomly selected to be randomised and the other sibling was excluded from the analysis but participated in the same group for ethical reasons. A total of 75 children were randomised (33 girls), mean age 9.5. Four patients (two girls) in the intervention group and six patients (three girls) in the standard care group withdrew their participation in the study before start or during the study, three of the 10 children who withdrew were 5–8 years old. Hence, 65 patients participated in the study in two groups per year and location. Three sites had three start-up occasions (August 2019, January 2020 and August 2020), while one site had two (January 2020 and August 2020).

The number of children who started the study in the intervention and standard care groups at the four sites was 13/11, 8/6, 8/8 and 6/5 (intervention/standard care), in total 24, 14, 16 and 11 children. The mean BMI at baseline was 27 kg/m^2 for the intervention group and 28.1 kg/m^2 for the standard care (n.s.), and the mean BMI-SDS was 2.92 for the intervention group and 2.91 for the standard care (n.s.). Of all, 18/65 (28%) had been previously treated at the clinic (who prior to the study received regular obesity treatment at a paediatric clinic). There were no significant differences in baseline characteristics between groups (Table 2).

3.2 | Participation rates

The attendance in the group sessions in the intervention group was 30/35 (86%) defined as participation by at least one parent at all four meetings.

Complete data with four measurements for BMI-SDS were available from 44 of 65 (68%) of all children. Valid data for each time point was present for 35/30 (intervention/standard care) at baseline, 30/27 at 2 months, 28/22 at 4 months and 30/27 at 6 months. Because of the pandemic, only measurements at start and 6 months were performed for one group in Umeå. For all, a total of 31/260 (12%) values of BMI-SDS were missing.

Most parents, 26/35 (74%) in the intervention group, used the web-based programme. On average, parents completed about 8 of the 12 weeks, considering the data of the parent who had been active for the longest time if both parents were users of the programme.

Almost all children in the intervention group, 33/35 (94%) were interested in testing and using the activity tracker. One child had a similar watch before the intervention and one was not interested.

All families in the intervention group were interested in the Mealsizer®. A majority 20/35 (57%) of the parents completed a questionnaire at 6 months from baseline, that showed that the families used the tool frequently, mainly in the beginning of the intervention, and that it was considered easy to use.

3.3 | Change in BMI-SDS

Estimated marginal means for the 65/75 (87%) children completing the intervention changed from 3.08 (CI 2.89–3.27) to 2.81 (CI

TABLE 2 Baseline characteristics for children in intervention and standard care groups. Continuous measures are presented as mean (SD).

	Web-based intervention group ($n=35$)	Standard care group ($n=30$)	p-Value
Age years			
5–8	9 (26%)	7 (23%)	0.82
9–12	26 (74%)	23 (77%)	
Sex			
Female	16 (46%)	12 (40%)	0.64
Male	19 (54%)	18 (60%)	
Previous treatment	10 (29%)	8 (27%)	0.86
Neuropsychiatric diagnosis	3 (9%)	3 (10%)	0.84
No parent born in a Nordic[a] country	6 (17%)	6 (20%)	0.77
BMI (kg/m^2)	27 (3.9)	28.1 (5.0)	0.29
BMI SDS	2.91 (0.51)	2.92 (0.67)	0,78
Waist circumference[b] (cm)	85.3 (12.4)	90.2 (14.2)	0.17

[a]Nordic countries: Denmark, Finland, Iceland, Norway and Sweden.

[b]Missing values in web-based intervention ($n=4$) and standard care ($n=5$).

2.62–3.01) ($n=35$) compared to a change of BMI-SDS from 3.07 (CI 2.86–3.27) to 3.16 (CI 2.95–3.37) ($n=30$) in the standard care group (Figure 3). The main effect of BMI-SDS for time, age group and sex was statistically significant ($p<0.001$) for time and age, and for sex ($p<0.05$), where boys had higher mean BMI-SDS compared to girls. When testing the two-way interactions between time and the between-group variables, only time with the randomisation group was statistically significant ($p<0.001$), meaning that the effect of time depended on the group, that is, on having the intervention or not. The parameter from the interaction, estimating the difference of the change in BMI-SDS from 0 to 6 months between groups, was statistically significant (0.37 [CI 0.47–0.27], $p<0.001$) (Figure S2).

When using LMM for the subjects with complete data (18 standard care, 26 intervention) the effect on BMI-SDS was still highly significant ($p<0.001$), but sex was not significant. The parameter for difference of change in BMI-SDS from 0 to 6 months between the randomisation groups also remains significant ($p<0.001$). The estimated marginal means for baseline and 6 months was 3.26 (CI 3.04–3.48) and 2.99 (CI 2.76–3.22) for the intervention group and 3.30 (CI 3.04–3.56) and 3.35 (CI 3.08–3.62) for the standard care group. There was no statistical significance (all $p>0.05$) for standard care and intervention groups, between missing and non-missing groups at 2, 4 and 6 months when testing baseline BMI-SDS, sex and age group (Table S1).

Looking at children with data at 6 months, 14/30 (47%) in the intervention group reduced their BMI-SDS ≥0.25, compared to 0/27 (0%) in the standard care group. A decrease of BMI-SDS ≥0.5 was seen in 4/30 (13%) in the intervention group (Figure 4).

The secondary analysis of paired data, ($n=28$), referring to children who started as standard care and then received the intervention, was analysed with mixed linear models. In the paired data ($n=28$) BMI-SDS changed from 2.92 (CI 2.72–3.12) to 2.98 (CI 2.76–3.21), ($p<0.05$ for the parameter of the change between 0 and 6 months) for the patients during the period in standard care and then changed from 2.96 (CI 2.74–3.19) to 2.78 (2.54–3.01), ($p<0.001$ for the parameter of the change between 6 and 12 months) during the Web-COP intervention. Only the effect of time from 0 to 12 months was statistically significant ($p<0.001$). The parameter for the change in BMI-SDS from 0 to 12 months was statistically significant (0.14, CI 0.06–0.22, $p<0.01$) (Figure 5).

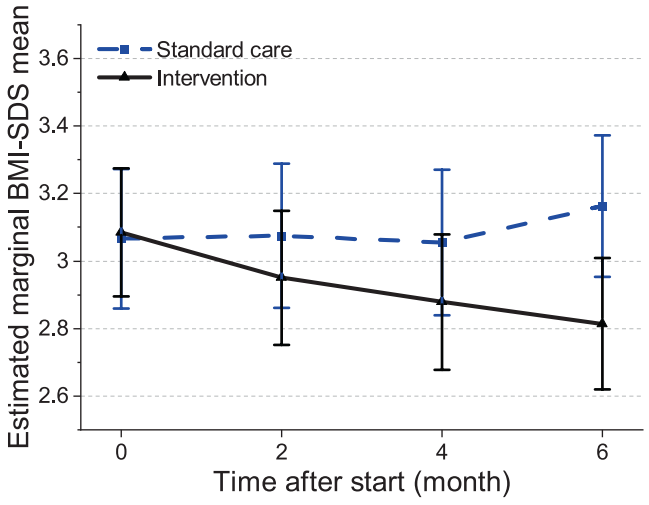


FIGURE 3 Mean BMI-SDS over time per group. BMI-SDS, body mass index standard deviation score.

4 | DISCUSSION

This randomised controlled, multicomponent and multicentre study of children aged 5–12 years with obesity showed a significant decrease in BMI-SDS over a 6 months' period for those receiving the intervention compared to standard care. This finding is consistent with previous research that evaluated web-based treatment as a part of a multicomponent intervention targeting childhood obesity.[25] Staiano et al. suggested that digital tools could serve as an opportunity for supporting in-person care with digitally delivered care, with the advantage of bridging the gap between counselling sessions with tools to encourage progress to a healthier lifestyle.[25] Further, Smogeli Holter recently suggested that digital interventions should be integrated in clinical practice, but that more research is needed on implementation.[26]

This study showed that engaging parents and children in group sessions and a web-based intervention targeting childhood obesity treatment improved BMI-SDS. Dropout rates in childhood obesity treatment are known to be high.[27] Participating children and parents in the intervention group had a high retention rate in the group sessions, despite the ongoing COVID-19 pandemic. Despite the pandemic that hampered the measurements at one study site, the attendance rate defined as at least two out of four valid measurements of height and weight was 65/75 (87%). Importantly, the 44/75 (59%) children with complete data for all four measurements had higher BMI-SDS than the total group. We believe that the dropout rate in this study was low due to highly motivated families.

Watson et al. showed in a qualitative study that initial attendance was driven by family motivation and influenced by a desire for a brighter future for the child. In this study, a non-judgemental approach, fun activities and a lifestyle-focused approach were likely contributing to continued attendance.[28] This is in line with the responses in qualitative interviews of parents participating in the previous Web-COP feasibility study.[22] Their shared experiences were taken into consideration when planning this randomised controlled trial.

There is a need to develop and apply personalised approaches to treat obesity in children.[29] Motevalli et al. suggest more focus on personalised intervention strategies instead of a generalised approach when managing childhood obesity.[29] It remains to be elucidated what contribution the personal attachment to a health care provider and personalised approach adds to the treatment of children, or if all interactions can be based on web-based care. For adolescent patients, the staff-member's relation to the patient has been associated with better treatment results.[30]

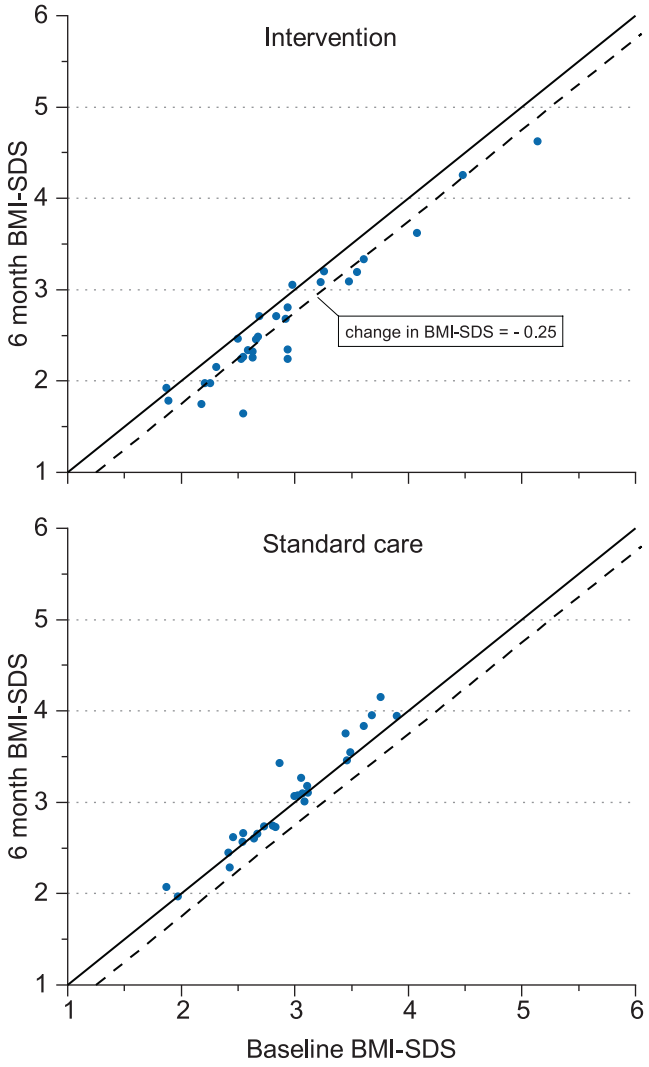


FIGURE 4 Children's individual change in BMI-SDS. BMI-SDS, body mass index standard deviation score.

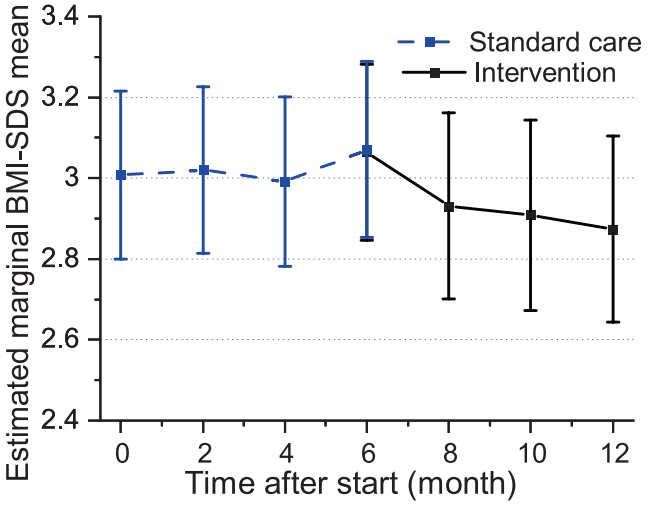


FIGURE 5 Mean BMI of children who were controls at first. BMI, body mass index.

Most parents used the web-based component. The introduction of the web-based component at one group session facilitated the start for parents to use the web-based component, and many parents were active in each week's assignments. The parents also had regular contact with the coaches in the programme.

Cueto et al. used a mobile app-based health coaching and behaviour change programme to provide weekly individual coaching via video chat. The results showed that engagement with coaching sessions was associated with decreased weight status, and increased engagement at coaching sessions was associated with extended periods of commitment.[31]

A key challenge for childhood obesity treatment is the transition from the safe and supportive group environment to long-term behaviour change at home. During our study there were no major technical issues, and no observed negative side effects of the programme. The intervention group was offered a follow-up meeting outside the study period approximately 6 months after the start. The purpose of the follow-up session was to bring the group together again and listen to their experiences and challenges during the intervention. This last group session also provided a valuable opportunity to provide feedback on experiences during the Web-COP intervention and advice for the future.

A reduction of ≥0.25 in BMI-SDS has been associated with reducing the risk for metabolic syndrome in children.[32] In this study about half of the intervention group reduced their BMI-SDS more than >0.25 compared to none in the standard care group, which is likely to have clinical benefits.

It should be noticed that the children in the standard care group had doctors' appointments and regular measurements. In adults, self-weighing on a regular basis is likely to improve weight outcome in adults,[33] and the regular measurements might impact the control group in our study. Despite this, the BMI increased in the standard care group, which may reflect the effect of COVID-19 and possibly also a disappointment with the randomisation. A similar COVID-19 effect was likely in the intervention group.

Using the experiences from the previous feasibility study, we designed this randomised controlled trial to validate the Web-COP programme. A strength in this study was the randomisation. The groups were comparable at baseline and the power calculation demonstrated recruitment to be appropriate for the primary outcome. Furthermore, all measurements were performed in a standardised way by experienced paediatric staff. Most parents in the intervention groups were active in the web-based component. It has previously been shown that personalised coaching is likely to have an impact on both traditional and mHealth weight loss interventions.[25,34] It was not possible to state how much the personal coaching contributed to the study result.

Another strength is that we included children with ongoing treatment and those with no previous obesity treatment. This mix of treatment backgrounds is often a clinical reality and improves the generalisability to other settings.

A considerable challenge was the attempt to conduct the clinical RCT-trial during the ongoing COVID-19 pandemic. A

shutdown in swimming and training facilities to reduce the spread of COVID-19 infection resulted in children and families having to adapt their plans and not use that part of the intervention. Recent studies have described challenges in the weight-related behaviours of children with obesity after the onset of the COVID-19 pandemic.[2,35] Dietary changes included increased snacking and more meals consumed at home and an increase in leisure-based screen time was shown.[36] Moreover, children with obesity had decreased physical activity and went to bed later during the pandemic.[37] The pandemic also affected the caregivers and for one of the study groups patients were measured only at the start and end of the study.

One limitation was the intervention period was limited (6 months). Another was the randomisation procedure where we should have used blocks of six at the randomisation to minimise the risk of imbalance. The choice of statistical method allowed us to use data for all patients with at least two measurements, but it is a limitation that 8/65 (12%) lacked the final measurement at 6 months. Another limitation was the lack of information on parental education, ethnicity and household income. This limits the generalisability of our study. Further, other limitations were the absence of registration on physical activity or diet behaviours. Also, we could not evaluate factors that may have influenced the intervention: fidelity to Web-COP, including the role of parents, the quality of group sessions, or the use of other resources. The small number of children in each group is also a limitation and future studies should aim at larger groups. Finally, it was impossible to investigate the importance of the separate components in the Web-COP programme. Still, childhood obesity is a multifaceted problem and multicomponent interventions are advocated.[38]

5 | CONCLUSION

This RCT with a parent-focused intervention with group sessions and a web-based programme significantly improved BMI-SDS in children with obesity as compared to children in standard care.

Future research should investigate the effectiveness of web-based interventions, isolated and combined treatments, over a more extended study period and longer follow-up time.

AUTHOR CONTRIBUTIONS

Annelie Thorén: Conceptualization; data curation; funding acquisition; investigation; methodology; project administration; writing – original draft; writing – review and editing. **Tobias Filipsson:** Investigation; methodology; project administration. **Erling Englund:** Formal analysis; methodology; project administration; writing – original draft; writing – review and editing. **Olof Sandström:** Conceptualization; data curation; methodology; writing – original draft; writing – review and editing. **Annika Janson:** Conceptualization; methodology; supervision; writing – original draft; writing – review and editing. **Sven Arne Silfverdal:** Conceptualization; funding acquisition; methodology; project administration; supervision; writing – original draft; writing – review and editing.

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CONFLICT OF INTEREST STATEMENT

Annelie Thorén is a consultant to and has equity in For Life Academy AB. The other authors have no conflict of interest to declare.

TRIAL REGISTRATION

This study was registered at Clinicaltrials.gov, ID: NCT04013230, on 8 July 2019.

ORCID

Annelie Thorén https://orcid.org/0000-0003-4193-3141
Annika Janson https://orcid.org/0000-0001-5106-5670
Sven Arne Silfverdal https://orcid.org/0000-0002-3606-3797

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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