BMJ Paediatrics Open

Health-related quality of life after camp-based family obesity treatment: an RCT

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To cite: Benestad B, Karlsen T-I, Småstuen MC, *et al.* Health-related quality of life after camp-based family obesity treatment: an RCT. *BMJ Paediatrics Open* 2019;**3**:e000413. doi:10.1136/

bmjpo-2018-000413

Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/ 10.1136/bmjpo-2018-000413).

Received 3 December 2018 Revised 19 February 2019 Accepted 26 February 2019

Check for updates

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ABSTRACT

Objective To compare the effects of a 2-year campbased immersion family treatment for obesity with an outpatient family-based treatment for obesity on healthrelated quality of life (HRQoL) in two generations. **Design** Randomised controlled trial.

Setting Rehabilitation clinic, tertiary care hospital and primary care.

Patients Families with at least one child (7–12 years) and one parent, both with obesity.

Interventions Summer camp for 2 weeks, with four repetition weekends, or lifestyle school, including four outpatient days over 4 weeks. Behavioural techniques to promote a healthier lifestyle.

Main outcome measures Children's and parents' HRQoL were assessed using generic and obesity-specific measures. Outcomes were analysed using linear mixed models according to intention to treat, and multiple imputations were used for missing data.

Results Ninety children (50% girls) with a mean (SD) age of 9.7 (1.2) years and body mass index 28.7 (3.9) kg/ m² were included in the analyses. Summer camp children had an estimated mean (95% Cl) of 5.3 (0.4 to 10.1) points greater improvement in adiposity-specific HRQoL score at 2 years compared with the lifestyle school children, and this improvement was even larger in the parent proxy-report, where mean difference was 7.3 (95% Cl 2.3 to 12.2). Corresponding effect sizes were 0.33 and 0.44. Generic HRQoL questionnaires revealed no significant differences between treatment groups in either children or parents from baseline to 2 years.

Conclusions A 2-year family camp-based immersion obesity treatment programme had significantly larger effects on obesity-specific HRQoL in children's self-report and parent proxy-reports in children with obesity compared with an outpatient family-based treatment programme.

Trial registration number NCT01110096.

INTRODUCTION

Both psychological and physical health are negatively affected by obesity.^{1 2} Accordingly, childhood obesity treatment also aims to improve psychosocial well-being and health-related quality of life (HRQoL).³ However, there is conflicting evidence regarding the effect

What is already known on this topic?

- Children and adults with obesity often have reduced generic and obesity-specific health-related quality of life (HRQoL) compared with normal-weight peers.
- Both children and adults report improvement in HRQoL after intensive lifestyle treatment for obesity.
- Previous camp-based studies of HRQoL in children treated for obesity were not randomised, only one included a control group and none reported parents' HRQoL.

What this study hopes to add?

- Summer camp children had larger improvements in obesity-specific HRQoL compared with lifestyle school children, despite no significant differences in body mass index SD score at the end of treatment.
- There were no statistically significant differences in HRQoL between parents in the camp-based programme and parents in the outpatient treatment programme at 2 years.

of non-surgical multidisciplinary weight loss intervention programmes on HRQoL.³ ⁴ This might be due to the fact that most treatments only yielded no or modest weight loss.⁵ Furthermore, although camp-based treatment of childhood obesity has shown promising results,⁶ only a few non-randomised studies included HRQoL.⁷⁻⁹

It has been suggested that targeting both parent and child may enhance treatment effectiveness compared with child-only interventions.^{10 11} To our knowledge, no study has assessed the effect on HRQoL of including both child and parent with obesity in the camp-based treatment.

Previously, we reported results of a 2-year randomised controlled trial (RCT) of a family summer camp treatment compared with an outpatient lifestyle intervention, finding no significant between-group differences after 2years for primary outcomes (age-adjusted and sex-adjusted body mass index [BMI] SD score [BMI-SDS] for children's and parents' BMI).¹² However, these treatment options may still affect HRQoL differently.

The aim of the present study was therefore to assess the effect of the interventions on HRQoL, a prespecified secondary outcome. We hypothesised greater improvements in both general and obesity-specific HRQoL in both children and parents undergoing summer camp treatment versus those receiving outpatient lifestyle treatment.

PATIENTS AND METHODS

Study design and setting

The Family based intervention in childhood obesitY was a pragmatic two-armed RCT conducted at two tertiary care centres in Norway. Data collection occurred between April 2010 and June 2013. Details of the trial have been published previously.¹² Patients were not directly involved in the design of this study.

Participants

Families with at least one child with obesity (International Obesity Task Force),¹³ aged 7–12 years and at least one parent with obesity (BMI $\geq 30 \text{ m/kg}^2$) were recruited from primary healthcare nurses and general practitioners (>75%), as well as from media and regular referrals in 2010 (n=39) and 2011 (n=55). Exclusion criteria were syndromal obesity, other medical conditions associated with weight gain or inability to participate in either of the treatment programmes. Written informed consent was provided from all participants, and the study was performed in accordance with the Declaration of Helsinki.

Interventions and outcomes

Summer camp participants underwent an initial 2-week programme at a private rehabilitation institution with four follow-up weekends (2 days at 6, 12, 18 and 24 months). The lifestyle school group attended 4 days (23 hours) in the outpatient clinic over a period of 4 weeks. All participants were offered monthly primary care follow-up for 2 years by a public health nurse. All interventions focused on healthy choices in terms of nutrition and physical activity and were based on behavioural techniques.^{14–16} Details of both treatment programmes have been described previously.¹²

At baseline, demographic information was obtained in semistructured interviews, and clinical examinations were performed. Anthropometric characteristics were recorded at baseline, at 1 year (only children) and at 2 years. HRQoL questionnaires were completed at baseline and at 2 years.

HRQoL measures

Age-specific self-report and parent proxy versions of the 'KINDer Lebensqualitätsfragebogen' (KINDL) bmjpo: first published as 10.1136/bmjpo-2018-000413 on 3 April 2019. Downloaded from http://bmjpaedsopen.bmj.com/ on September 6, 2019 at Oslo Universitetssykehus HF, Medisinsk Bibliotek. Protected by copyright.

questionnaire^{17 18} and its obesity-specific module¹⁹ were completed by children and parents. The KINDL is a 24-item generic HRQoL instrument representing six dimensions of HRQoL (physical well-being, emotional well-being, self-esteem, family, friends and school). A total score and subscale scores were calculated. The KINDL obesity-specific disease module contains 15 items, 12 of which are used to calculate an adiposity scale. All scales are transformed into ranges from 0 to 100; higher scores indicate better HRQoL. The KINDL is a reliable and valid instrument for measuring HRQoL.¹⁸ The KINDL adiposity scale has a Cronbach's alpha of 0.77.²⁰

Parents completed two adult, self-report obesity-specific questionnaires, Obesity and Weight Loss Quality of Life^{21 22} and Weight Related Symptom Measure (WRSM),²¹ ²² plus the generic Short-Form 36-item Health Survey (SF-36)²³ at baseline and the 2-year visit. The 17-item OWLOOL measures behaviours and feelings that are associated with overweight/obesity and weight loss. A score of 0 indicates the greatest adverse impact, and a score of 100 indicates the lowest impact, thus increasing OWLQOL scores imply better HRQoL. The WRSM is a 20-item instrument assessing the presence and bothersomeness of symptoms. Scores range from 0 to 120, with higher scores indicating a higher symptom burden. The SF-36 measures an individual's general health status across eight subscales (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health). Two summary measures-the physical component summary and the mental component summary-are calculated from the eight scales using different weightings. Lower scores represent more impaired health status, with a score of 50 being the mean for the US general population. Results are presented as correlated oblique physical and mental health factor summary scores.²⁴ The scores were transformed in accordance with the specific instructions from the authors of the different questionnaires.

Sample size and randomisation

The sample size was calculated based on the primary outcome measure (BMI SDS) for the children.¹² After inclusion of each consecutive family, study personnel contacted technical staff at the randomisation centre. Block randomisation (block sizes of four and five participants) stratified by the treatment centre was computer generated by technical staff using an internet-based device. Randomisation was performed 2 days after the baseline measurements. The participants (families) were randomly assigned to one of the two parallel groups in a 1:1 ratio. Allocation was concealed from both participants and triallists. Blinding of study participants or healthcare professionals was not possible due to the nature of the interventions.

Statistical analyses

Baseline data are presented as means and SDs or counts (percentages). Crude differences between pairs

the

Changes in HRQoL Compared with the lifestyle school group, summer camp group showed significantly greater improvement from baseline to 2 years on the KINDL adiposity module scores, both when self-reported and parent proxy reported (table 2, figure 2). Children's self-report and parent proxy-report revealed estimated mean differences (95% CIs) in the obesity-specific scores of 5.3 (0.4 to 10.1) points and 7.3 (2.3 to 12.2), respectively. Corresponding ESs were 0.33 and 0.44. A sensitivity analysis using the same linear mixed model without replacing missing values showed similar results (supplementary table 2).

Generic HRQoL measures did not reveal any significant differences between the two treatment groups regarding changes from baseline to 2years for either children or parents (table 2, figure 2), neither did the obesity-specific HROoL measures for the parents.

Considering the fraction of missing information, relative increase in variance and relative efficiency, the imputed data-sets were comparable with the original data-set (data not shown).

All scales in the parent proxy version of KINDL had satisfactory reliability (Cronbach's alpha values >0.70), except for the subscales of physical well-being and school. The children's version of KINDL had satisfactory total score reliability, but all subscales had Cronbach's alpha values <0.70. The child and parent proxy version of the KINDL adiposity-specific module and all adult HROoL questionnaires had Cronbach's alpha values >0.80 (online supplementary table 3.)

DISCUSSION

This RCT of families affected by obesity compared the 2-year effect of a family camp-based treatment programme (summer camp) with the effect of an outpatient treatment programme (lifestyle school) on HRQoL. This is the first RCT to explore the long-term effects of a campbased intervention in both children and parents. Children receiving camp-based treatment had significantly greater improvements in the obesity-specific measures of HRQoL, both using self-report and parent proxy, than children in the lifestyle school group. Corresponding ESs were small to medium. In contrast, generic HRQoL measures showed no significant between-group differences from baseline to 2 years for either children or parents, nor did the obesity-specific HRQoL measures for the parents. The finding of between-group differences on obesity-specific HRQoL, but not on generic measures of HRQoL, is not unusual. Disease-specific measures of HRQoL are generally more responsive to intervention than generic measures.²⁷

It is noteworthy that 2-year improvements in obesity-specific HRQoL were demonstrated for summer camp participants compared with lifestyle-school participants, both on self-report and parent proxy-report, despite there being no differences in BMI-SDS.¹² This

of continuous and categorical variables were assessed using independent samples t-test, Mann-Whitney U test, Wilcoxon signed rank test or Fisher's exact test as appropriate.

All individuals were analysed according to the intention-to-treat principle. To account for repeated measures on the same individuals, data were analysed using a linear mixed model,²⁵ with an unstructured covariance matrix. Fixed effects were treatment group, time and time*treatment group interaction. After applying Little's test of randomness of missing data (p=0.909), missing values on the KINDL (children and parents) and adult HRQoL (parents) scales at baseline and 2 years were imputed using multiple imputation. The multiple imputation was performed using a fully conditional specification model, applying linear regression as the prediction method for scale variables and two-way interactions for categorical variables. We generated five complete datasets with 10 iterations per dataset. Statistical analyses were performed on each imputed dataset, and thereafter the results were combined to arrive to single estimates. The combined estimates are presented.

We estimated mean changes in HRQoL from baseline to 2years, and results are presented as estimated mean difference between the treatment groups with 95% CIs. The standardised Cohen's d (effect sizes [ESs]) of the outcomes were calculated.²⁶ In addition, to test the robustness of the results, we performed a sensitivity analysis, using the same linear mixed model with all available data but without imputation of missing variables. We tested reliability of the sub- and total scales of the guestionnaires calculating Cronbach's alpha coefficient.

All tests were two sided. P values <0.05 were considered statistically significant. All analyses were performed with SPSS V.25.0.

RESULTS

Participant flow is depicted in figure 1. Table 1 shows baseline demographic and clinical characteristics of the 90 children and 89 parents that were available for the intention-to-treat analysis.¹² Online supplementary table 1 shows the numbers of valid questionnaires for each time point.

Values are reported as mean (SD) or number (%). Statistics were independent samples t-test for normally distributed continuous data, Mann-Whitney U test for non-normally distributed continuous data or Fisher's exact test for categorical data.

With a few exceptions, baseline demographics, clinical characteristics and HRQoL scores did not differ significantly between the groups (tables 1 and 2). There was, however, a higher percentage of female parents in the lifestyle school group (88% vs 76%) than in the summer camp group (table 1) and a small imbalance in the school domain of the parent proxy-report version of KINDL (table 2).

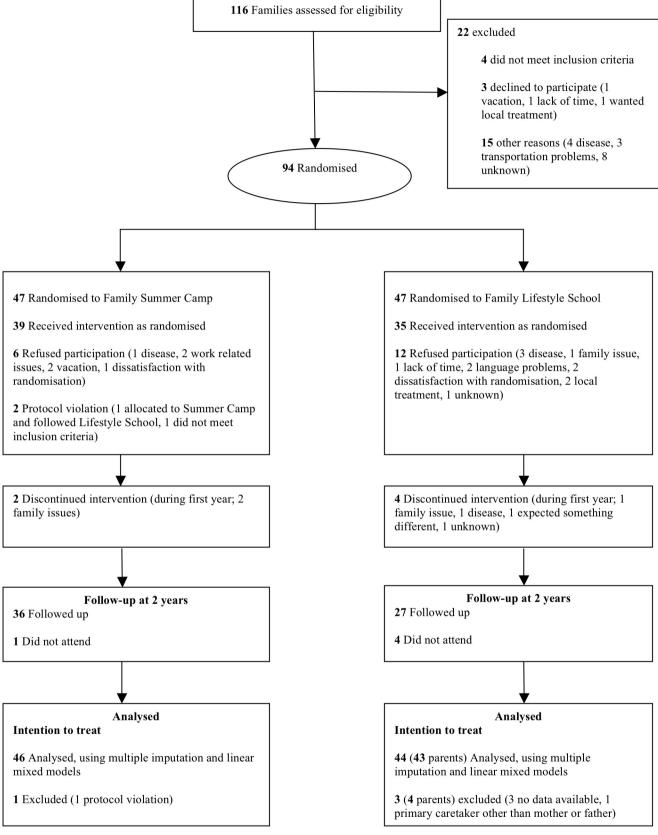


Figure 1 Participant flow: families with obesity assessed for eligibility, randomisation, intervention and follow-up.

is encouraging, as it suggests that the feelings, physical challenges and complaints associated with obesity may improve after comprehensive treatment for obesity even in the absence of significant weight loss. Given that poor self-image, bullying and bodily pain are prevalent in youth with obesity in clinical populations,¹ any change

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Table 1	Baseline demographic and clinical characteristics
of the 90	children and 89 parents included in the analyses

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	All	Family summer camp	Family lifestyle school
Children	n=90	n=46	n=44
Gender, female (%)	45 (50)	20 (44)	25 (57)
Ethnicity, European white (%)	77 (86)	41 (89)	36 (82)
Age (years)	9.7 (1.2)	9.6 (1.1)	9.7 (1.2)
BMI (kg/m ²)	28.7 (3.9)	28.2 (4.1)	29.3 (3.7)
BMI SDS	3.46 (0.75)	3.41 (0.79)	3.51 (0.71)
Parents	n=89	n=46	n=43
Gender, female (%)	69 (78)	31 (67)	38 (88)
Age (years)	40.7 (5.0)	40.9 (4.8)	40.6 (5.2)
BMI (kg/m²)	37.0 (4.6)	37.0 (4.4)	36.9 (4.9)

BMI SDS; body mass index SD score.

in HRQoL is likely to be perceived as a recognisable improvement for these children. Scores between 4 and 5 points on a scale from 0 to 100 have been considered to be minimal clinically meaningful differences previously.⁴ Our results are in accordance with previous studies that have reported improved psychosocial functioning even after controlling for BMI change. For example, Quinlan *et al*⁸ found improved social functioning, physical functioning, weight and eating efficacy, after controlling for BMI change in a camp-based treatment programme.

Camp-based treatment can be considered to be 'immersion treatment', which has been described as treatment in a 'therapeutic and educational environment for extended periods of time, thereby removing participants from obesogenic environments'.^b In the present study, children in the camp-based group were immersed in a non-obesogenic environment, initially for 2weeks, followed by four follow-up weekends. Early success achieved through immersion treatment may improve self-efficacy, attitudes and moods, which in turn may enhance long-term commitment.⁶ In addition, the children participating in the summer camp group might have experienced an increase in social support from their participating peers,²⁸ which could have led to higher self-acceptance and increased HRQoL.²⁹ This in turn could have affected both their motivation for treatment and their self-efficacy.²⁸

Comparing our results directly with other camp-based immersion treatment studies proved challenging, as the few existing studies used different questionnaires for measuring HRQoL. Although previous camp-based studies did not include parents together with their children, Knöpfli *et al*⁷ gave parents practical and theoretical counselling in their multidisciplinary inpatient

programme, but they only focused on treatment of the children's obesity. They reported increased HRQoL for the children pretreatment to post-treatment over 8 weeks, as well as a large effect on weight. Nonetheless, they did not include a control group or a subsequent follow-up. A study of a combined inpatient (6 weeks) and outpatient (4.5 months) treatment programme included a waiting list control group, and it found an increase in obesity-specific HRQoL³⁰ in the treatment group compared with the control group.⁹ Improvements in both generic and weight-related quality of life immediately after a summer camp weight loss programme have been demonstrated for adolescents⁸ and children,³¹ although these studies did not include a control group or longer follow-up. A more recent observational study demonstrated improvements in both generic and weight-related HRQoL among children and adolescents (8-19 years) with severe obesity undergoing an intensive lifestyle treatment for 1 year despite partial weight regain from 1-year to 2-year measurements. The treatment included an inpatient period of either 2 or 6 months (immersion treatment) and then a 1-year follow-up.³² This study also found improvements in self-reported obesity-specific HRQoL comparable with the current study, of 8.9 (4.6 to 13.2) points, although using a different HRQoL instrument³³ (with scores ranging from 0 to 100, as in the KINDL). In the present study, the improvements in obesity-specific HRQoL scores were not accompanied by improvements in BMI SDS. This is in accordance with results from another study with 24-month follow-up after 4-6 weeks of inpatient treatment, which did not find an association between changes in HRQoL and changes in BMI but indicated a potential role of physical activity in improving HRQoL.³⁴

Strengths and limitations

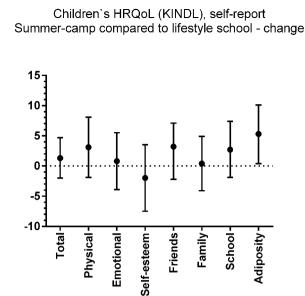
The relatively long follow-up is a strength in this study. Our findings might be generalisable to treatment-seeking families with obesity and applicable in similar healthcare settings engaged in childhood obesity treatment. In addition, we assessed HRQoL in both children and parents participating in the study and applied both self-reports and parent proxy-reports for the children. The use of disease-specific, in addition to generic, instruments to measure HRQoL is an advantage, as they are more responsive to effects of treatment.²⁷

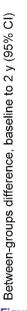
Limitations include the participation of mainly European white families and the lack of data on socioeconomic status and adherence to follow-up in the municipalities. Furthermore, neither of the interventions in this study represent the standard care treatment at the tertiary care centres. Weight inclusion criteria for the study was lower than criteria for specialist treatment. The sample size was calculated based on the primary outcome measure (BMI SDS) for the children, not on the HRQoL measures. We did not include measures of motivation or perceived social support. Another limitation is that reliability of the KINDL subscales for the children's version (all subscales)

		camp	Family lifestyle schoo	ool	Between-group difference	ifference	
Outcome	Baseline	2years	Baseline	2years	Mean difference	P value	Effect size
Child self-report, KINDL							
Total HRQoL	67.5 (64.5 to 70.6)	70.1 (67.3 to 72.8)	65.6 (62.4 to 68.7)	69.4 (66.6 to 72.2)	1.3 (-2.0 to 4.7)	0.44	0.12
Physical	67.8 (62.9 to 72.7)	75.6 (71.2 to 80.1)	66.1 (61.1 to 71.1)	71.2 (66.4 to 75.9)	3.1 (-1.9 to 8.1)	0.23	0.19
Emotional	76.4 (71.7 to 81.1)	80.5 (76.5 to 84.4)	73.6 (68.8 to 78.4)	81.7 (77.6 to 85.8)	0.8 (-3.9 to 5.5)	0.75	0.05
Self-esteem	68.3 (63.1 to 73.5)	68.8 (64.2 to 73.3)	70.2 (64.9 to 75.6)	70.8 (66.2 to 75.5)	-2.0 (-7.5 to 3.5)	0.48	0.11
Friends	78.6 (73.9 to 83.4)	82.0 (77.7 to 86.4)	76.1 (71.2 to 81.0)	78.2 (73.4 to 83.0)	3.2 (-2.2 to 7.1)	0.32	0.19
Family	77.7 (73.6 to 81.7)	78.6 (74.6 to 82.6)	76.2 (72.0 to 80.3)	79.4 (73.8 to 85.1)	0.4 (-4.1 to 4.9)	0.78	0.03
School	74.0 (69.4 to 78.5)	72.9 (68.2 to 77.6)	69.1 (64.4 to 73.8)	72.3 (67.7 to 76.9)	2.7 (-1.9 to 7.4)	0.27	0.17
Adiposity specific	73.9 (69.3 to 78.5)	78.3 (74.5 to 82.0)	68.8 (64.1 to 73.4)	72.9 (68.9 to 76.8)	5.3 (0.4 to 10.1)	0.03	0.33
Parent proxy-report, KINDL							
Total HRQoL	72.2 (68.8 to 75.6)	73.6 (71.1 to 76.2)	68.0 (64.5 to 71.6)	72.6 (69.9 to 75.3)	2.6 (-0.9 to 6.1)	0.15	0.22
Physical	67.9 (62.9 to 73.0)	75.5 (71.3 to 79.7)	65.9 (63.3 to 68.6)	72.3 (68.0 to 76.5)	2.6 (-2.8 to 8.0)	0.34	0.15
Emotional	75.9 (71.2 to 80.7)	74.1 (70.3 to 77.9)	69.7 (64.8 to 74.6)	74.6 (70.6 to 78.6)	2.9 (-2.0 to 7.7)	0.24	0.17
Self-esteem	67.7 (62.6 to 72.8)	66.5 (62.6 to 70.5)	59.1 (53.8 to 64.4)	65.5 (61.4 to 69.6)	4.8 (-0.4 to 9.9)	0.07	0.27
Friends	70.9 (66.2 to 75.6)	75.9 (71.9 to 79.9)	69.8 (64.9 to 74.6)	72.7 (68.5 to 76.9)	2.2 (–2.9 to 7.3)	0.40	0.13
Family	74.5 (70.3 to 78.8)	76.3 (72.8 to 79.7)	73.3 (68.9 to 77.7)	76.3 (72.3 to 80.4)	0.6 (-4.2 to 5.3)	0.81	0.04
School	76.4 (72.5 to 80.2)	73.5 (70.3 to 76.7)	70.3 (66.4 to 74.3)	74.2 (70.8 to 77.6)	2.7 (-1.1 to 6.5)	0.17	0.20
Adiposity specific	72.4 (67.7 to 77.1)	77.0 (72.9 to 81.0)	66.3 (61.4 to 71.2)	68.6 (64.2 to 73.0)	7.3 (2.3 to 12.2)	0.005	0.44
Parent self-report							
Physical dimension (SF-36)	40.0 (34.6 to 45.4)	47.2 (35.1 to 59.4)	39.8 (34.5 to 45.1)	48.8 (39.4 to 58.2)	-0.2 (-4.6 to 4.1)	0.49	0.02
Mental dimension (SF-36)	40.9 (31.9 to 49.8)	45.0 (38.0 to 52.1)	40.2 (35.5 to 44.9)	43.6 (27.9 to 59.4)	1.2 (–2.8 to 5.3)	0.36	0.10
Emotional dimension (OWQOL)	51.1 (44.2 to 57.8)	68.0 (57.7 to 78.3)	43.3 (36.2 to 50.3)	73.0 (53.4 to 92.7)	3.7 (-4.9 to 12.3)	0.41	0.16
Number of symptoms (WRSM)*	7.6 (6.2 to 8.9)	4.5 (3.3 to 5.8)	9.1 (7.8 to 10.5)	3.4 (2.1 to 4.7)	-0.1 (-1.5 to 1.3)	0.91	0.02
Symptom distress (WRSM)	25.1 (18.8 to 31.5)	13.4 (4.1 to 22.8)	34.0 (27.5 to 40.4)	11.3 (1.1 to 21.4)	-3.4 (-10.5 to 3.7)	0.37	0.16
Results are presented as estimated means for the treatment groups at baseline and 2 years and es presented by Cohen's d. HRQoL scores range from 0 to 100, higher values indicate better HRQoL.	ans for the treatment grou s range from 0 to 100, high	ps at baseline and 2 years ler values indicate better	s and estimated between- HRQoL.	baseline and 2 years and estimated between-group difference in change with 95% Cl (linear mixed model); effect size is Jues indicate better HRQoL.	je with 95% Cl (linear m	iixed model)	; effect size is

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Children's HRQoL (KINDL), parent proxy-report Summer-camp compared to lifestyle school - change

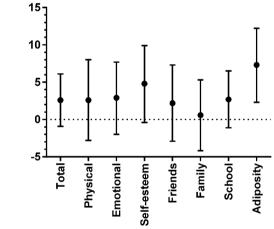


Figure 2 Estimated mean difference in change betweengroups (95% CI) in HRQoL scores for the children from baseline to 2 years, measured by KINDL self-reports (upper) and parent proxy-reports (bottom). The possible scale for HRQoL range from 0 to 100. HRQoL, health-related quality of life; KINDL, KINDer Lebensqualitätsfragebogen.

and some of the parent's proxy reports (physical wellbeing and school) were unsatisfactory. Similar values for reliability of the subscales of the KINDL have previously been shown by others.^{29 35}

CONCLUSION

A 2-year family camp-based immersion treatment programme for obesity resulted in significantly larger improvements in obesity-related HRQoL in children's self-reports and parent proxy-reports in children with obesity compared with an outpatient family-based

treatment programme despite no significant effects on BMI SDS.

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Acknowledgements We are grateful for the contributions of all healthcare professionals involved at the four centres and all the children and parents who participated in this study. We particularly wish to thank the former leader of the MOC pediatric section. MD Martin Handeland, study nurse Åshild Skulstad-Hansen and bioengineer Berit Mossing Bjørkås. Research relating to this article was funded by the Norwegian Ministry of Health and Care Services, the Norwegian Foundation for Health and Rehabilitation and GiensidigeStiftelsen. The first author has been funded by a public research grant from the South-Eastern Norway Regional Health Authority. Treatment in the Norwegian public healthcare system is nearly free of charge for patients.

Contributors BB carried out the analyses, drafted the initial manuscript. reviewed and revised the manuscript and approved the final manuscript as submitted. T-IK designed parts of the study protocol, carried out the multiple imputations, gave advice on the initial manuscript, reviewed and revised the manuscript and approved the final manuscript as submitted. MCS gave advice on the statistical analyses, reviewed and revised the manuscript and approved the final manuscript as submitted. SL coordinated and supervised parts of the data collection at one of the outpatient clinics, reviewed and revised the manuscript and approved the final manuscript as submitted. JKH gave advice on data preparation, contributed to discussion, reviewed and revised the manuscript and approved the final manuscript as submitted. SS contributed to discussion. reviewed and revised the manuscript and approved the final manuscript as submitted. RLK contributed to discussion, reviewed and revised the manuscript and approved the final manuscript as submitted. RAØ designed the study and wrote the protocol, coordinated and supervised data collection at one of the outpatient clinics, reviewed and revised the manuscript and approved the final manuscript as submitted. JH designed the study and wrote the protocol, reviewed the initial manuscript, reviewed and revised the manuscript and approved the final manuscript as submitted. All authors approved the final manuscript as submitted and are accountable for all aspects of the work.

Funding Research relating to this article was funded by the Norwegian Ministry of Health and Care Services, the Norwegian Foundation for Health and Rehabilitation and GjensidigeStiftelsen. The first author has been funded by a public research grant from the South-Eastern Norway Regional Health Authority.

Disclaimer None of the funding parties had a role in design or conduct of the study; collection, management, analysis or interpretation of the data; or preparation, review or approval of the manuscript.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The study was approved by the Regional Committee for Medical and Health Research Ethics (2009/176).

Provenance and peer review Not commissioned; externally peer reviewed.

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