

Archives of
Disease in Childhood

HEALTH IN OVERWEIGHT CHILDREN.TWO-YEAR FOLLOW-UP OF FINNMARK ACTIVITY SCHOOL.A randomised trial

Journal:	<i>Archives of Disease in Childhood</i>
Manuscript ID:	Draft
Article Type:	Original article
Edition:	not in use
Date Submitted by the Author:	n/a
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Keywords:	Obesity, Child Psychology, Outcomes research, Comm Child Health, School Health

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5 **FINNMARK ACTIVITY SCHOOL. A randomised trial**
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42 Running title: Two-year outcome in Finnmark Activity School (RCT)
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44 Key words: Child, obesity, overweight, treatment, primary care
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47 Main text word count: 2490
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52 The trial is registered at www.clinicaltrials.gov (NCT00872807)
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ABSTRACT

Objective: To compare a comprehensive lifestyle intervention for overweight children performed in groups of families with a conventional single-family treatment. Two-year follow-up data on anthropometric and psychological outcome is presented.

Design: Overweight and obese children aged 6-12 years with BMI corresponding to $\geq 27.5 \text{ kg/m}^2$ in adults were randomised to multiple-family or single-family intervention in a parallel design. Multiple-family intervention comprised a 3-day inpatient programme with other families and a multidisciplinary team, follow-up visits in their hometown, weekly physical activity and a family camp after six months. Single-family intervention included counselling by paediatric nurse, paediatric consultant and nutritionist at the hospital and follow-up by a community public health nurse. Primary outcome measures were change in BMI kg/m^2 and BMI SD score after two years.

Results: BMI increased by 1.29 kg/m^2 in the multiple-family intervention compared to 2.02 kg/m^2 in the single-family intervention ($p=0.075$). BMI SD score decreased by 0.20 units in the multiple-family group and 0.09 units in the single-family intervention group ($p=0.058$). A between-group difference of 2.4 cm in waist circumference in favour of the multiple-family intervention, ($p=0.038$) was detected. Pooled data from both treatment groups showed a significant decrease in BMI SD score of 0.14 units and a significant decrease in parent and self-reported Strength and Difficulty Questionnaire Total Score of 1.9 units.

Conclusion: Two-year outcome showed a between-group effect in waist circumference favouring multiple family intervention, but no differences in BMI measures. Pooled data showed an overall improvement in psychological outcome measures and BMI SD score.

INTRODUCTION

Obesity is a considerable threat to children's physical and mental health. [1 2] Family based life style programmes focusing on nutrition, physical activity and behaviour change can reduce the level of overweight. [3-5] Data on effectiveness of treatment programmes beyond one year is however limited. There is little high-quality evidence to recommend one treatment over another and cost-effective programmes applicable to primary care have been requested. [3 5 6] There is further a lack of data on psychological outcomes in intervention studies[3] and this trial aims to address some of these shortcomings.

Consequences of childhood obesity including risk factors of type 2 diabetes and cardiovascular disease are well documented.[1] Anxiety, depression and behaviour problems are the most frequently reported psychological symptoms among obese children and adolescents. [2 7 8] Childhood obesity is also associated with reduced self esteem and impaired quality of life.[9-11] Weight based stigmatisation and teasing as well as weight and shape concerns are suggested as mediators for how obesity affects psychological health. [2 12 13] Parents participating in treatment for their child's obesity considered children's improved self-esteem and confidence a key outcome, even more important than weight change.[14]

The northernmost county of Norway, Finnmark, has a high prevalence of childhood obesity.[15] Long travelling distances and limited hospital resources stimulated new treatment strategies for childhood obesity based on collaboration between specialised and primary health care, a shared care approach.[16] Group based management of childhood obesity may contribute to interaction between group facilitator and group members towards behavioural change and is considered cost-effective.[17] Group approach may also affect obese youngsters' psychological health and is to our knowledge not well studied.

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3 The objective of the Finnmark Activity School trial was to compare a new comprehensive
4 multidisciplinary approach comprising meeting with other families in groups (multiple family
5 intervention, MUFI) with a more conventional single-family intervention (SIFI) with respect
6 to primary outcome parameters (BMI kg/m² and BMI SD score) and secondary outcome
7 parameters (anthropometrical, physical activity, metabolic and psychological measures) in a
8 randomised controlled trial (RCT). Methods are fully described in a previous paper. [16] This
9 paper presents 24 months anthropometrical and psychological outcomes of two treatment
10 programmes for childhood obesity.
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20 21 **MATERIAL AND METHODS**

22 23 **Participants and settings**

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25 Altogether 97 overweight and obese children aged 6-12 years with BMI corresponding to \geq
26 27.5 kg/m² in adults[16 18] were in 2009-2013 included in a RCT conducted at the Paediatric
27 Department at Hammerfest Hospital in collaboration with the University Hospital of North
28 Norway (UNN) and UiT the Arctic University of Norway. Participants were randomised to
29 multiple-family intervention (MUFI) or single-family intervention (SIFI) in a parallel design.
30 The trial is designed, conducted and reported in accordance with Consolidated Standards of
31 Reporting Trials (CONSORT) guidelines.[19] Recruitment was performed in two cycles to
32 obtain sufficient number of participants.
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44 45 **Interventions**

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47 MUFI comprised a 3-day inpatient programme at the hospital with other families and a
48 multidisciplinary team, individual and group-based follow-up visits in their hometown,
49 weekly group-based physical activity and a 4-day family camp. (Table 1) SIFI comprised
50 clinical examination and individual counselling by paediatric nurse, paediatric consultant,
51 nutritionist at the hospital and follow-up by a local public health nurse.
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3 Both intervention programmes focused on the families' own resources and aimed to reduce
4 sedentary activity, increase physical activity and increase the intake of healthy food according
5 to national guidelines. Principles from Solution-Focused Brief Therapy, Standardized Obesity
6 Family Therapy and elements from motivational interviewing were applied in both
7 interventions. [20-22]
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10 11 12 13 14 15 **Outcomes and blinding**

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17 Prescheduled hospital visits at baseline and at 3, 12, 24 and 36 months of follow-up included
18 anthropometric measurements, blood samples, bioelectrical impedance analysis, clinical
19 examinations and questionnaires. Mental health and well-being was also assessed by
20 questionnaires completed at home after six months of intervention. Height, weight, waist-
21 circumference, skin fold thickness and body composition were measured as described
22 previously. [16] Nurses blinded to group allocation performed primary outcome measures.
23 BMI kg/m² was calculated and BMI standard deviation score (BMI SD score) extracted from
24 an obesity calculator based on British reference data.[23]
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36 **Mental health** was measured by the validated Norwegian version of Strengths and
37 Difficulties Questionnaire (SDQ).[24] Teacher, parents and children ≥ 11 years of age
38 completed the questionnaire. Data were not collected from younger children.
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44 **Self esteem** was measured using the Norwegian version of Self-Perception Profile for
45 Children, (SPPC). [25] The questionnaire was completed by all children, with parents
46 interviewing their smaller children.
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51 **Quality of life** was measured using the Norwegian version of the parent-and self reported
52 "Kinder Lebensqualität Fragebogen" (KINDL) with separate forms for the 8-12 and 13-16
53 years age groups. [26]
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Sample size and randomisation

The study was powered to detect a between-group difference in mean change of 0.5 kg/m² BMI with standard deviation of 0.8 from baseline to two years with two-sided α - level of 0.05 and 80 % power. A sample size of 50 families in each group was needed given an expected withdrawal of 20 %. Personnel involved in the computer generated randomisation did not take any further part in the study.

Statistical methods

Differences between intervention groups at baseline were assessed by two sample t-test and Pearson chi square tests. All data were analysed by the intention-to-treat principle. Linear mixed models [27] were used to compare time trends in BMI kg/m² (and secondary anthropometrical outcomes) between the two groups over four time points. The independent variables were: Group, time (as three indicator variables) and cross product terms between each indicator variable of time with group. A significant group- by-time interaction indicated different time trends between the intervention groups. In secondary analyses we adjusted for random differences at baseline. All analyses were performed using Stata version 12.1(StataCorp 4905 Lakeway Drive College Station, TX, USA). Two-sided $p < 0.05$ was considered statistically significant.

Ethics and approval

The Regional Committee for Medical and Health Research Ethics approved the study. The families gave written informed consent signed by parents and all children ≥ 12 years. The Norwegian Social Science Data Services consented to the privacy protection in the study.

RESULTS

Figure 1 shows participant flow from recruitment to 24 months' follow up. Altogether 97 families were randomised and 91 children provided baseline data. Anthropometrical data after 24 months was collected from 69 children. Additionally height/weight data from 10 children was reported from local child healthcare centre, adding up to 81% retention for primary end points. No between-group differences in baseline variables were detected (Table 2).

Anthropometrical outcome data are summarised in Table 3. At two-years follow-up, BMI had increased by 1.29 kg/m² in the MUFI group and by 2.02 kg/m² in the SIFI group, $p = 0.075$ (Figure 2). Mean decrease in BMI SD score was 0.20 units in the MUFI group and 0.08 units in the SIFI group ($p = 0.046$) and $p = 0.058$ when adjusted for baseline data (Figure 2). Waist circumference increased by 0.21 cm in the MUFI group and 2.60 cm in the SIFI group ($p = 0.038$) (Figure 3). Adjustment for baseline values did not change results and waist to height ratio showed a corresponding between-group difference ($p = 0.029$). No between-group difference was observed for skin fold or body fat. Pooled data from both treatment groups showed a significant decrease in BMI SD score of 0.14 units.

There was no between-group difference in **mental health** as measured by Strength and Difficulty Questionnaire from baseline to 24 months (Table A1 and A2, Appendices Web only files). However, pooled data from both intervention groups showed a significant decrease in parent and self-reported total difficulty score of 1.9 units (Figure 4) with a significant change in the emotional symptoms (Figure A1) and peer problem scale (Figure A2).

There was no difference in domain specific and global **self worth** subscales of self perception between the two intervention groups (Table A3) Pooled data from both intervention groups showed a significant increase in athletic competence, social acceptance and behavioural

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3 conduct after 12 months, a significant increase in athletic competence was sustained after 24
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5 months (Figure A3).
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8 The self -and parent reported **quality of life** data showed no difference between the
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10 intervention groups at any time point (Table A4). Pooled data showed a significant increase in
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12 self-reported total score after 12 months but improvement waned after 24 months. There was
13
14 no overall change in self-reported and parent reported total score of quality of life from
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16 baseline to 24 months.
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18 19 20 **DISCUSSION**

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23 Two year follow-up data from this child obesity trial showed a significant between-group
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25 difference in waist circumference in favour of the MUFI intervention. No between-group
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27 differences were observed for BMI kg/m² (raw), BMI SD score adjusted for baseline values,
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29 or psychological outcome measures. Pooled data from both intervention groups showed a
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31 significant decrease in parent and self-reported SDQ problem scale and an increase in self-
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33 reported athletic competence as well as an overall decrease in BMI SD score.
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36 37 **Anthropometrical outcomes**

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40 Evidence of long term effects in family based treatment of childhood obesity was early
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42 observed by Epstein and colleagues.[28] However few recent randomised life style
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44 interventions reported between-group difference in BMI or BMI SD score between new
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46 comprehensive approaches and control groups (conventional, self help or no treatment), [29
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48 30] whereas other trials showed no between-group differences after two years. [31 32]
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50 Authors evaluating obesity interventions have put forward social facilitation, increased
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52 contact and longer duration of treatment combined with a considerate reduction in adiposity
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54 during first months of intervention as approaches for improving long-term results.[31] These
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56 elements are present in the current trial and might explain the modest between-group effects.
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3 Mean treatment effect in the MUF1 group did not reach ≥ 0.25 BMI SD score reduction,
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5 which is necessary to improve cardiovascular risk factors in obese adolescents according to a
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7 British study. [33]. Waist circumference is considered a good marker of visceral adipose
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9 tissue in children and is associated with cardiovascular risk factors. [34] A significant
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11 between-group difference in waist circumference as seen in this trial may indicate a
12
13 favourable development in risk profile.
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17 The findings in this trial may be considered promising compared to other interventions
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19 performed in primary care. [35] Explanation for the modest group effect might be the fairly
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21 high-intensive programme. A review evaluating interventions relevant for primary care
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23 pointed out in an association between hours of contact and treatment effect.[6]
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27 On the other hand, the small improvement in the SIFI group (-0.09 in BMI SD score) in spite
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29 of very few hours of contact (8 hours first year and 2.5 hours second year) is interesting and
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31 we might speculate that the shared care approach in both treatment arms based on
32
33 collaboration between primary and specialised care has contributed to this finding.
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36 **Psychological outcomes**

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39 There were no between-group effects in measures of mental health and well-being in the
40
41 current study. Two obesity trials involving group interventions involving children and
42
43 adolescents reported on improvement in self-esteem and quality of life in the intervention
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45 group compared to control. [36 37] To the best of our knowledge, psychological outcomes in
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47 other group based trials addressing childhood obesity are lacking.
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51 Authors have raised the concern that too much focus on weight is not only ineffective in order
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53 to control obesity, but could also have negative effects on mental health and well-being. [38]
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56 We did not observe adverse effects in psychological outcomes in either intervention group
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58 after two years. Pooled data from both intervention groups showed an overall improvement in
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3 mental health rated by children and parents, as well as a significant improvement in self-
4 reported athletic competence. This finding corresponds with reviews concluding that weight
5 management programmes are not psychologically harmful in children. [3 12]
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10 Only a few child obesity trials reported on mental health outcome while some studies
11 reported on self-esteem and quality of life.[36 37] An overall improvement in these
12 parameters post-treatment was observed in most studies, but long-term effects beyond one
13 year are lacking. We applied principles from solution focused brief method, with non-
14 claiming /neutral therapeutic position, assumptions of motivation and focus on solutions
15 beyond problems.[21] This may have contributed to improved provider/ family interaction,
16 stronger retention and favourable anthropometrical and psychological long term results in
17 both treatment groups.
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21 Beneficial psychosocial effect of physical activity is thoroughly documented.[39] Provided
22 that the participating children managed to increase their activity levels, this favourable change
23 may have affected their mental health and well-being. The self reported improvement in
24 athletic competence could imply such a mechanism.
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28 29 30 31 32 33 34 35 36 37 38 **Strengths and limitations**

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41 Strengths of this study include the randomised design, blinding of the primary outcome
42 assessors, clearly specified hypothesis including primary and secondary outcome parameters,
43 sample size determined from power calculation achieved, appropriate statistical methods
44 including intention to treat analysis and linear mixed models applied, moderate withdrawal
45 and reporting according to CONSORT guidelines. In addition an appropriate pilot study was
46 performed.
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56 Limitations include a lower study power than anticipated because of a larger variability in
57 BMI than expected. The pragmatic inclusion criterion corresponding to adult BMI ≥ 27.5
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3 kg /m² and the fact that nurses measuring waist circumference were not blinded to group
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5 allocation was discussed previously.[16]
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8 The primary outcome parameter BMI SD score has limitations related to evaluation of
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10 treatment trials. Different reference populations for the calculation of BMI SD score make
11
12 comparisons between studies challenging and variability of BMI SD score depends on the
13
14 child's level of adiposity.[40]
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18 Performing a clinical trial in small municipalities is challenging because of high risk of
19
20 contamination between treatment groups. SIFI and MUFI appointments were scheduled at
21
22 different days to minimise contact between groups, but causal meetings between families was
23
24 inevitable. Due to the small municipalities and shortage of personnel, the same providers were
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26 employed in both treatment arms. As a consequence the outreached guidance and courses for
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28 providers, reached the SIFI as well as the MUFI groups. This strategy might have attenuated
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30 group differences.
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34 In order to assess the natural course of adiposity and psychological outcome in obese children,
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36 a true control group would be optimal. However, it is for ethical reasons impossible in long-
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38 term studies to randomise obese children to "no intervention" or a waiting list.
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41 **Implications**

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44 The modest difference between the two treatment groups after two years raises the question
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46 whether the cost of the MUFI approach can be justified. The between-group effect in waist
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48 circumference and effect on cardiovascular risk factors needs further investigation.
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52 The overall significant decrease in BMI SD score in both groups suggests that increased
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54 awareness and minimal support is sufficient to succeed with life style changes for some
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56 families. Future studies should examine subgroup effects. Obesity interventions in children
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3 and adolescents should examine health in broad perspective and evaluate mental health and
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5 well-being in addition to other health outcomes. The current shared care model can be
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7 applicable to other regions and settings.
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10 **Conclusion**

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12 Two-year results from this trial showed no between-group difference for BMI or
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14 psychological outcomes. There was a significant between-group difference in waist-
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16 circumference in favour of the MUFİ approach. Pooled results from both treatment arms
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18 showed a significant improvement in parent and self-reported mental health combined with a
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20 significant decrease in BMI SD score of 0.14.
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24 **Acknowledgements**

25
26 We want to thank all the participating families, and primary and secondary health care
27
28 personnel involved in the Finnmark Activity School trial. We also want to thank the families
29
30 participating in the pilot project, Professor Lars Bo Andersen University of Southern
31
32 Denmark, Professor John A Rønning, University of Tromsø, participants in the early Activity
33
34 School Reference Group, representatives from Finnmark County Authority, County Governor
35
36 of Finnmark and Finnmark Sport Council who all contributed with valuable support in the
37
38 development of this project. The authors thank Professor Tom Wilsgaard for advice and
39
40 quality assurance of the statistical analysis.
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46 **Contributors**

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48 **AK** designed the study, conducted the study, analysed and interpreted the data and wrote the
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50 original manuscript. **SG** designed the study, involved in conducting the study, data
51
52 interpretation and edited the manuscript. **SS** analysed psychological outcome measures,
53
54 interpreted data and edited the manuscript. **TF** designed the study and was involved in
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3 conducting the study, data interpretation and edited the manuscript. IN designed the study and
4
5 was involved in conducting the study, interpretation of data and editing the manuscript in
6
7 addition to statistical advices. All authors have read and approved the final manuscript.
8
9

10 **Funding**

11
12
13 The trial has been supported by Finnmark Hospital Trust, Northern Norway Regional Health
14
15 Authority, Norwegian Foundation for Health and Rehabilitation and The Norwegian
16
17 Directorate of Health. Contributions have also been made by the University of Tromsø, the
18
19 Ministry of Health and Care Services, SpareBank 1 Nord-Norge and Odd Berg Fund.
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23 **Competing interests:** None disclosed
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26 **What is already known on this topic?**

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- 29 • Childhood obesity represents a threat to children's health and comprehensive
30 treatment programmes can reduce the level of overweight one year from baseline.
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 - 33 • There is a need for evidence of long-term effects of childhood obesity interventions, to
34 recommend cost-effective treatment strategies applicable for primary care.
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 - 37 • Psychological consequences of obesity can be evident at young age, but few
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56 **What this study adds:**

- 57 • Two-year outcome of a comprehensive multiple-family intervention did not show any
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- Pooled data showed significant improvement in overweight and psychological outcome measures after completion of two generally applicable programmes performed in shared care.

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FIGURES AND TABLES

Table 1 Characteristics of the two intervention programmes. Finnmark Activity School

Content of the intervention	Single-family intervention	Multiple-family intervention
Who is the target	Parents and child	Parents and child
Responsible for the intervention	Community and hospital	Community and hospital
Start	Outpatient clinic 1 day	Inpatient clinic stay for 3 days
Who delivers the intervention	Project nurse, paediatrician and nutritionist at the hospital. Public health nurse in the municipality.	Multidisciplinary team at the hospital. Public health nurse, physiotherapist and coach in the municipality.
How	Every family individually	Families both individually and in groups
Physical activity for children	Not arranged	2 hours a week in groups
Camp for families	No camp	4 days 6-8 months from baseline
Solution focused counselling	Yes	Yes
Follow up intervals	1,2,3,5,7,10,12,18,24,36 months	Equal intervals as the single-family group
Hours of contact first 12 months	8	36
Organised physical activity first 12 months	0	38
Hours of contact 12-24 months	2.5	6.5
Organised physical activity 12-24 months	0	38

Table 2 Baseline characteristics Finnmark Activity School

Characteristics	Single family intervention	Multiple family intervention	Between group P
Age in years	10.5 ± 1.7	10.1 ± 1.7	0.24
Female/male	22/24	27/18	0.24
BMI kg/m ²	27.6 ± 4.3	26.9 ± 4.2	0.42
BMI SD score *	2.81 ± 0.60	2.76 ± 0.58	0.70
Obesity at baseline †	36 (78)	34 (76)	0.76
Waist circumference (cm)	89.2 ± 11.9	87.9 ± 12.0	0.62
Waist to height ratio	0.61 ± 0.06	0.61 ± 0.06	0.91
Mother BMI kg/m ² (n)	29.8 ± 6.8 (43)	29.9 ± 8.1 (41)	0.95
Father BMI kg/m ² (n)	29.5 ± 4.3 (20)	30.3 ± 5.5 (21)	0.63
SDQ ‡ Total score self report	11.9 ± 6.1	11.5 ± 6.2	0.85
SDQ Total score parent report	10.2 ± 5.6	9.98 ± 6.0	0.9
SSPPC § Physical appearance	2.6 ± 0.9	2.6 ± 0.7	0.97
SPPC Athletic competence	2.4 ± 0.7	2.5 ± 0.6	0.68
Quality of life self-report KINDL	70.2 ± 13.8	70.4 ± 10.3	0.94
Quality of life parent-report KINDL	72.1 ± 10.8	70.7 ± 9.3	0.53
Proportion mothers with higher education level / n ^α	16/42 (38)	11/41 (27)	0.2
Proportion fathers with higher education level / n ^α	8/39 (21)	10/40 (25)	0.9

Baseline characteristics are presented as mean ± standard deviation for continuous variables and number (percent) for binary variables.

*BMI SD score according to British reference (23)

†Obesity according to Cole 2000 (18)

‡Strength and Difficulty Questionnaire (24)

§Self Perception Profile for children (25)

|| Kinder Lebensqualität Fragebogen (26)

^α Academy, college, university education; ≥ 13 years of education

Table 3 Changes in BMI, BMI SD score and secondary anthropometrical outcomes through 24 months; by treatment group. Finnmark Activity School

	Difference (95 % confidence intervals) at follow up		Between group difference	P value group by time
	Single-family intervention	Multiple-family intervention	Koef (95% confidens interval)	
BMI				
3 months	$\dot{-}0.09(-0.47 \text{ to } 0.65)$	$\dot{-}0.28(-0.83 \text{ to } 0.28)$	$\dot{-}0.37(-1.15 \text{ to } 0.42)$	0.358
12 months	$\dot{-}0.78(0.21 \text{ to } 1.35)$	$\dot{-}0.37(-0.18 \text{ to } 0.91)$	$\dot{-}0.41(-1.20 \text{ to } 0.38)$	0.308
24 months	$\dot{-}2.02(1.44 \text{ to } 2.60)$	$\dot{-}1.29(0.74 \text{ to } 1.84)$	$\dot{-}0.73(-1.53 \text{ to } 0.07)$	0.075
BMI SDS				
3 months	$\dot{-}0.05(-0.14 \text{ to } 0.03)$	$\dot{-}0.13(-0.21 \text{ to } -0.05)$	$\dot{-}0.08(-0.20 \text{ to } 0.04)$	0.196
12 months	$\dot{-}0.07(-0.16 \text{ to } 0.01)$	$\dot{-}0.15(-0.23 \text{ to } -0.07)$	$\dot{-}0.08(-0.17 \text{ to } 0.01)$	0.188
24 months	$\dot{-}0.08(-0.17 \text{ to } 0.01)$	$\dot{-}0.20(-0.29 \text{ to } -0.12)$	$\dot{-}0.12(-0.24 \text{ to } 0.00)$	0.046
BMI SDS adjusted				
3 months	$\dot{-}0.05(-0.14 \text{ to } 0.03)$	$\dot{-}0.13(-0.21 \text{ to } -0.05)$	$\dot{-}0.08(-0.19 \text{ to } 0.04)$	0.209
12 months	$\dot{-}0.08(-0.16 \text{ to } 0.01)$	$\dot{-}0.15(-0.23 \text{ to } -0.07)$	$\dot{-}0.07(-0.19 \text{ to } 0.04)$	0.213
24 months	$\dot{-}0.09(-0.17 \text{ to } -0.02)$	$\dot{-}0.20(-0.29 \text{ to } -0.12)$	$\dot{-}0.11(-0.23 \text{ to } 0.00)$	0.058
Waist circumference				
3 months	$\dot{-}0.03(-1.51 \text{ to } 1.45)$	$\dot{-}1.44(-2.90 \text{ to } 0.03)$	$\dot{-}1.41(-3.49 \text{ to } 0.67)$	0.184
12 months	$\dot{-}0.96(-0.56 \text{ to } 2.48)$	$\dot{-}0.96(-2.45 \text{ to } 0.52)$	$\dot{-}1.92(-4.05 \text{ to } 0.20)$	0.076
24 months	$\dot{-}2.60(0.95 \text{ to } 4.26)$	$\dot{-}0.21(-1.32 \text{ to } 1.74)$	$\dot{-}2.39(-4.64 \text{ to } -0.14)$	0.038
Waist to height ratio				
3 months	$\dot{-}0.01(-0.02 \text{ to } 0.00)$	$\dot{-}0.02(-0.03 \text{ to } -0.01)$	$\dot{-}0.01(-0.02 \text{ to } 0.00)$	0.194
12 months	$\dot{-}0.02(-0.03 \text{ to } -0.01)$	$\dot{-}0.03(-0.04 \text{ to } -0.02)$	$\dot{-}0.01(-0.03 \text{ to } 0.00)$	0.057
24 months	$\dot{-}0.03(-0.04 \text{ to } -0.02)$	$\dot{-}0.04(-0.05 \text{ to } -0.03)$	$\dot{-}0.02(-0.03 \text{ to } 0.00)$	0.029
Skinfold				
3 months	$\dot{-}1.5(-2.4 \text{ to } -0.6)$	$\dot{-}3.00(-3.91 \text{ to } -2.20)$	$\dot{-}1.5(-2.8 \text{ to } -0.3)$	0.013
12 months	$\dot{-}4.0(-4.9 \text{ to } -3.1)$	$\dot{-}4.5(-5.38 \text{ to } -3.63)$	$\dot{-}0.5(-1.8 \text{ to } 0.7)$	0.404
24 months	$\dot{-}6.2(-7.1 \text{ to } -5.2)$	$\dot{-}6.5(-7.43 \text{ to } -5.64)$	$\dot{-}0.4(-1.7 \text{ to } 0.9)$	0.577
Body fat				
3 months	$\dot{-}0.51(-0.89 \text{ to } 1.90)$	$\dot{-}0.35(-1.73 \text{ to } 1.03)$	$\dot{-}0.85(-2.82 \text{ to } 1.11)$	0.393
12 months	$\dot{-}0.39(-1.04 \text{ to } 1.83)$	$\dot{-}0.05(-1.45 \text{ to } 1.36)$	$\dot{-}0.44(-2.45 \text{ to } 1.56)$	0.665
24 months	$\dot{-}1.87(0.31 \text{ to } 3.42)$	$\dot{-}0.76(-0.67 \text{ to } 2.19)$	$\dot{-}1.11(-3.22 \text{ to } 1.01)$	0.304
Pooled effects BMI SDS				
	Both treatment groups pooled(95% KI)		P value -change from baseline	
3 months	$\dot{-}0.09(-0.15 \text{ to } -0.03)$		0.002	
12 months	$\dot{-}0.11(-0.17 \text{ to } -0.05)$		0.000	
24 months	$\dot{-}0.14(-0.21 \text{ to } -0.08)$		0.000	

Data based on mixed models analysis with single-family intervention as reference group.

*Analysis adjusted for values at baseline

[†]BMI SD score according to British reference (23)

[‡]P value for equality between groups, group-by- time effect

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3 **Figure 1 Flow of participants* through 24 months of treatment. Finnmark Activity**
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5 **School**
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8 *Siblings are not included in the analysis
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10 †Longitudinal analyses include all available data from every subject through withdrawal or
11 study completion
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14 **Figure 2 BMI kg/m² and BMI SD score. Finnmark Activity School**
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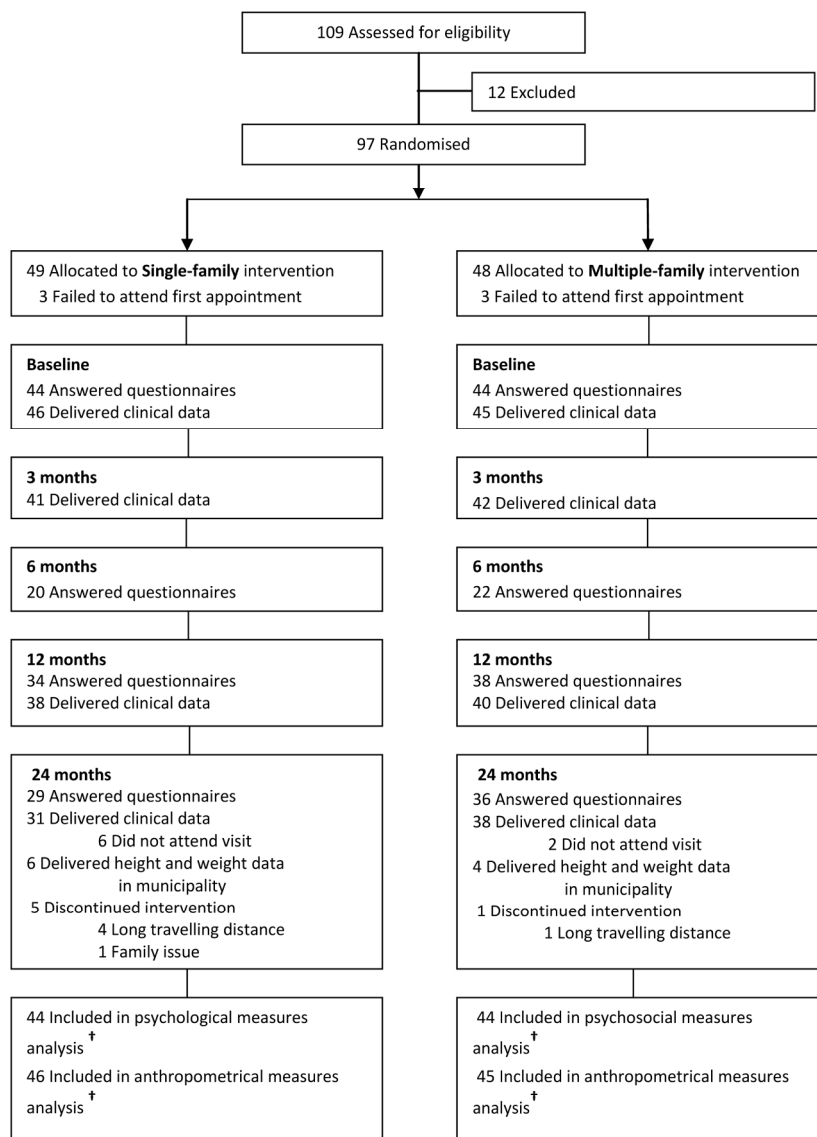
16
17 Mean (95% CI) changes in body mass index and BMI SD score from baseline to 24- months'
18 follow- up by intervention group.
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21 **Figure 3 Waist circumference. Finnmark Activity School**
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23 Mean (95% CI) changes in waist circumference from baseline to 24- months follow up by
24 intervention group.
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27 **Figure 4 Parent and self- reported mental health (SDQ) total score. Finnmark Activity**
28 **School**

29 Mean (95% CI) changes in Strength and Difficulty Questionnaire Total score from baseline to
30 24- months' follow- up by intervention group.
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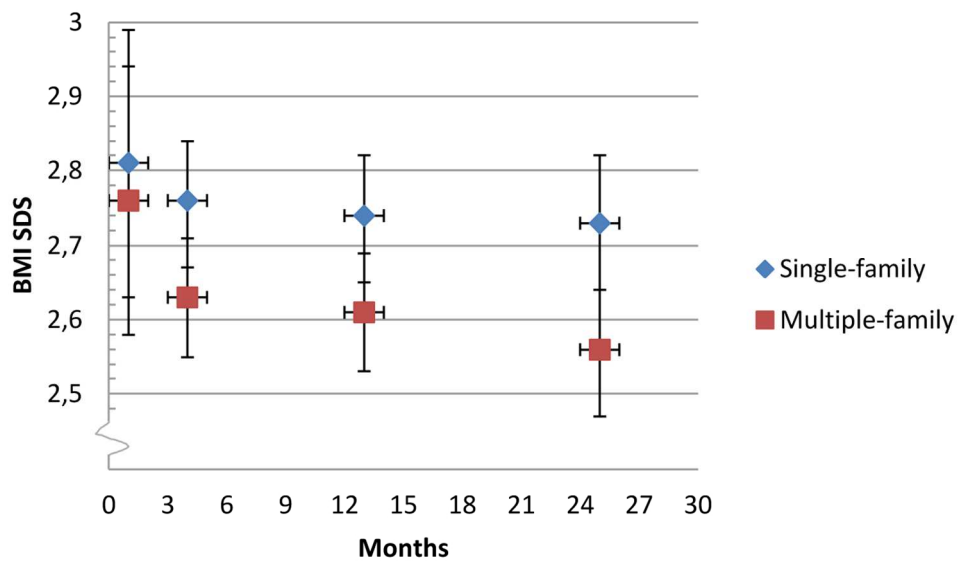
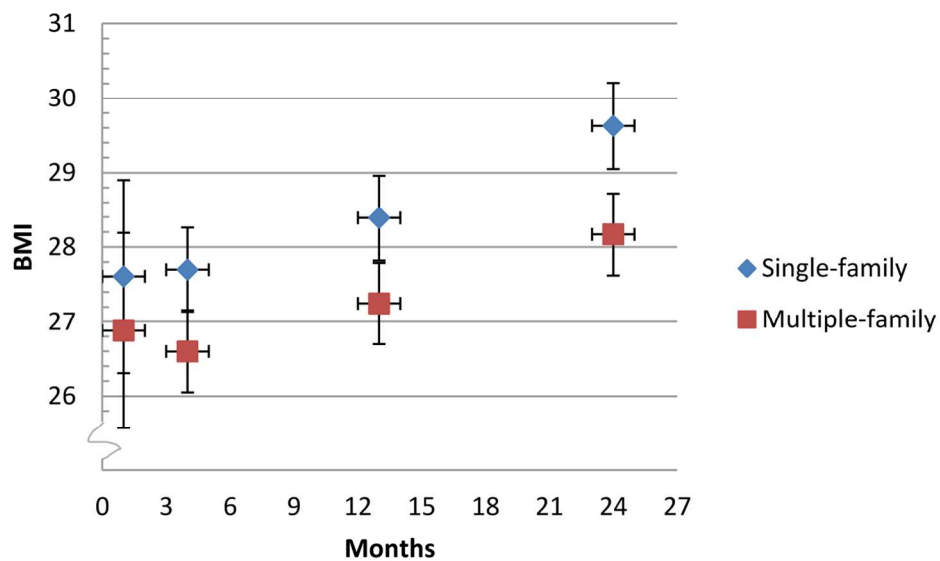


*Siblings are not included in the analysis

†Longitudinal analyses include all available data from every subject through withdrawal or study completion

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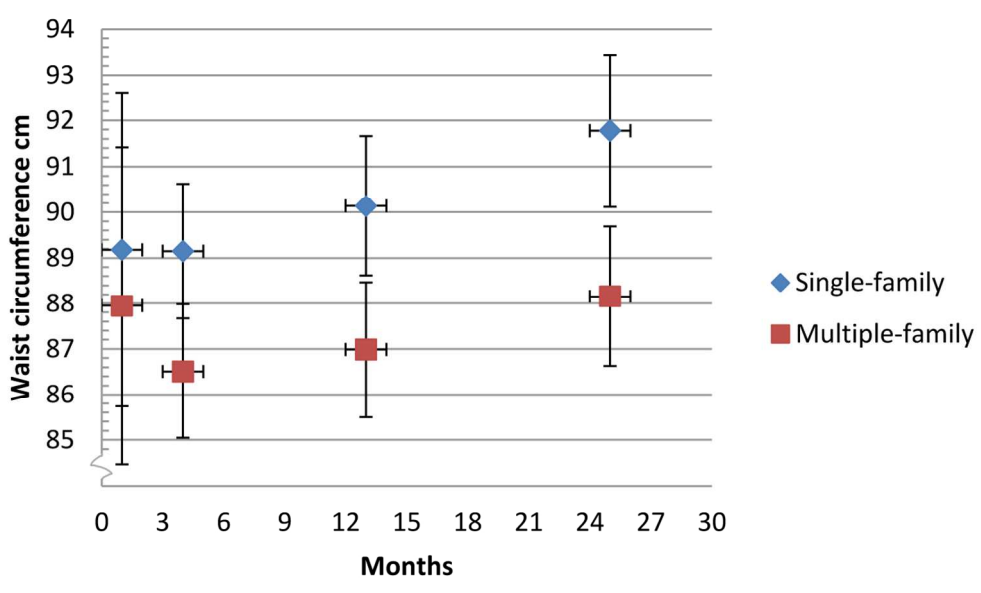


Mean (95% CI) changes in body mass index and BMI SD score from baseline to 24- months' follow- up by intervention group.

121x150mm (300 x 300 DPI)

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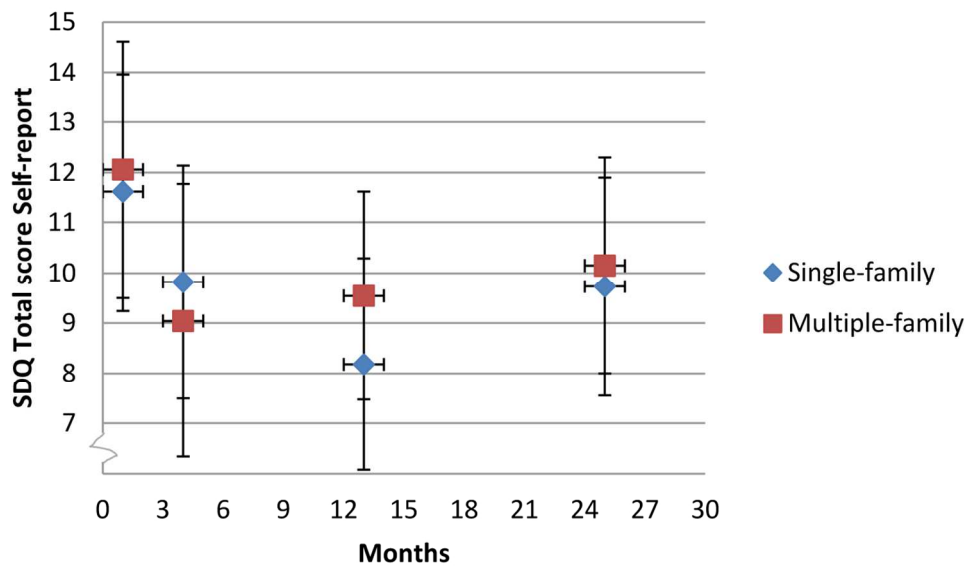
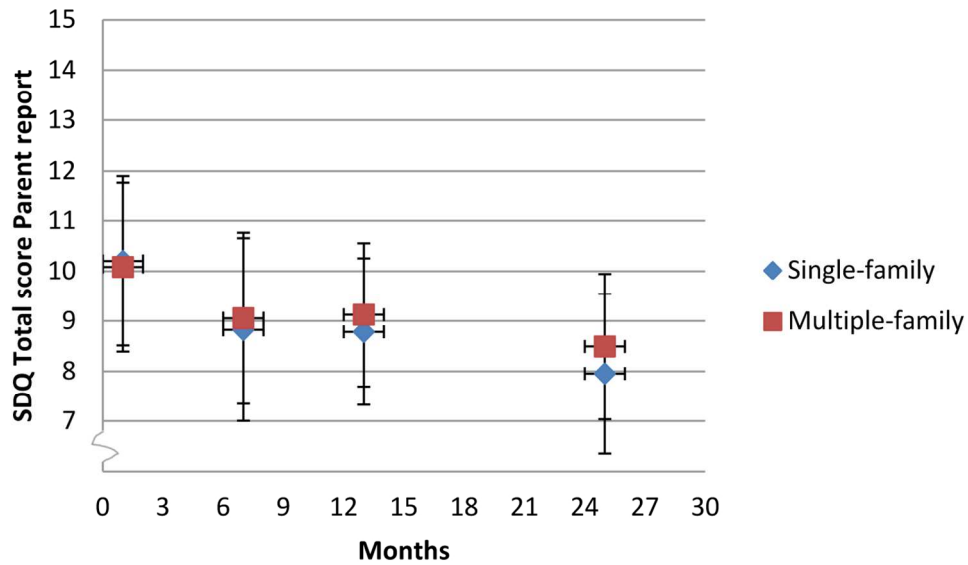
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Mean (95% CI) changes in waist circumference from baseline to 24- months follow up by intervention group.
122x73mm (300 x 300 DPI)

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Mean (95% CI) changes in Strength and Difficulty Questionnaire Total score from baseline to 24- months' follow- up by intervention group.

123x149mm (300 x 300 DPI)



Table 3 Changes in BMI, BMI SD score and secondary anthropometrical outcomes through 24 months; by treatment group. Finnmark Activity School

	Difference (95 % confidence intervals) at follow up			P value ‡ group by time
	Single-family intervention	Multiple-family intervention	Between group difference Koef (95% confidens interval)	
BMI				
3 months	0.09(-0.47 to 0.65)	-0.28 (-0.83 to 0.28)	-0.37 (-1.15 to 0.42)	0.358
12 months	0.78 (0.21 to 1.35)	0.37 (-0.18 to 0.91)	-0.41 (-1.20 to 0.38)	0.308
24 months	2.02 (1.44 to 2.60)	1.29 (0.74 to 1.84)	-0.73 (-1.53 to 0.07)	0.075
BMI SDS[†]				
3 months	-0.05 (-0.14 to 0.03)	-0.13 (-0.21 to -0.05)	-0.08 (-0.20 to 0.04)	0.196
12 months	-0.07 (-0.16 to 0.01)	-0.15(-0.23 to -0.07)	-0.08 (-0.17 to 0.01)	0.188
24 months	-0.08 (-0.17 to 0.01)	-0.20 (-0.29 to -0.12)	-0.12 (-0.24 to 0.00)	0.046
BMI SDS adjusted*				
3 months	-0.05(-0.14 to 0.03)	-0.13(-0.21 to -0.05)	0.08(-0.19 to 0.04)	0.209
12 months	-0.08 (-0.16 to 0.01)	-0.15 (-0.23 to -0.07)	-0.07 (-0.19 to 0.04)	0.213
24 months	-0.09(-0.17 to -0.02)	-0.20 (-0.29 to -0.12)	-0.11 (-0.23 to 0.00)	0.058
Waist circumference				
3 months	-0.03 (-1.51 to 1.45)	-1.44(-2.90 to 0.03)	-1.41 (-3.49 to 0.67)	0.184
12 months	0.96 (-0.56 to 2.48)	-0.96(-2.45 to 0.52)	-1.92 (-4.05 to 0.20)	0.076
24 months	2.60 (0.95 to 4.26)	0.21 (-1.32 to 1.74)	-2.39 (-4.64 to -0.14)	0.038
Waist to height ratio				
3 months	-0.01 (-0.02 to 0.00)	-0.02 (-0.03 to -0.01)	-0.01 (-0.02 to 0.00)	0.194
12 months	-0.02 (-0.03 to -0.01)	-0.03(-0.04 to -0.02)	-0.01 (-0.03 to 0.00)	0.057
24 months	-0.03 (-0.04 to -0.02)	-0.04 (-0.05 to -0.03)	-0.02 (-0.03 to 0.00)	0.029
Skinfold				
3 months	-1.5(-2.4 to -0.6)	-3.00 (-3.91 to -2.20)	-1.5 (-2.8 to -0.3)	0.013

12 months	-4.0 (-4.9 to -3.1)	-4.5 (-5.38 to - 3.63)	-0.5 (-1.8 to 0.7)	0.404
24 months	-6.2 (-7.1 to -5.2)	-6.5 (-7.43 to - 5.64)	-0.4 (-1.7 to 0.9)	0.577
Body fat				
3 months	0.51 (-0.89 to 1.90)	-0.35(-1.73 to 1.03)	-0.85 (-2.82 to 1.11)	0.393
12 months	0.39 (-1.04 to 1.83)	-0.05(-1.45 to 1.36)	-0.44 (-2.45 to 1.56)	0.665
24 months	1.87 (0.31 to 3.42)	0.76(-0.67 to 2.19)	-1.11 (-3.22 to 1.01)	0.304
Pooled effects BMI SDS		Both treatment groups pooled(95% KI)	P value - change from baseline	
3 months		-0.09 (-0.15 to - 0.03)	0.002	
12 months		-0.11 (-0.17 to - 0.05)	0.000	
24 months		-0.14 (-0.21 to -0.08)	0.000	

Data based on mixed models analysis with single-family intervention as reference group.

*Analysis adjusted for values at baseline

[†]BMI SD score according to British reference (23)

P value for equality between groups, group-by- time effect

Table A1 Changes in self reported mental health (SDQ) through 24 months; by treatment group and pooled. Finnmark Activity School

Self reported SDQ score*	Change at follow up(95 % CI) Single-family intervention	Change at follow up (95% CI) Multiple-family intervention	Between group difference (95% CI)	P value group by time [†]
Prosocial behaviour				
6 months	0.12 (-0.83 to 1.06)	0.08 (-0.95 to 1.11)	-0.04 (-1.43 to 1.37)	0.958
12 months	0.16 (-0.68 to 0.99)	0.51(-0.33 to 1.35)	0.35 (0.84 to 1.53)	0.564
24 months	-0.60 (-1.45 to 0.26)	0.01(-0.85 to 0.87)	0.61 (-0.60 to 1.82)	0.324
Hyperactivity-inattention				
6 months	0,1 (-0,9 to 1,1)	-0.48 (-1.61 to 0.65)	-0,58 (-2,10 to 0,93)	0.452
12 months	-0.28(-1.18 to 0.62)	-0.32 (-1.22 to 0.58)	0,03 (-1,31 to 1,24)	0.959
24 months	-0,16 (-1,08 to 0,76)	0,12 (-0,8 to 1,05)	0,28 (-1,02 to 1,59)	0.670
Emotional symptoms				
6 months	-0.68(-1.62 to 0.27)	-0.85 (-1.92 to 0.22)	-0.18 (-1.6 to 1.25)	0.810
12 months	-1.13(-1.99 to -0.28)	-0.97 (-1.81 to -0.13)	0.16 (-1.04 to 1.36)	0.795
24 months	-0.74 (-1.62 to 0.14)	-0.60 (-1.47 to 0.27)	0.14 (-1.1 to 1.38)	0.828
Conduct problems				
6 months	-0.59 (-1.32 to 0.15)	-0.82 (-1.61 to -0.02)	-0.23 (-1.31 to 0.85)	0.671
12 months	-0.67 (-1.32 to -0.01)	-0.68 (-1.33 to -0.03)	-0.01 (-0.93 to 0.91)	0.979
24 months	-0.31 (-0.98 to 0.36)	-0.40 (-1.08 to 0.26)	-0.09 (-1.04 to 0.86)	0.848
Peer problems				
6 months	-0.68(-1.61 to 0.25)	-0.39 (-1.41 to 0.62)	0.29 ((-1.09 to 1.67)	0.681
12 months	-1.42 (-2.25 to -0.59)	-0.24 (-1.06 to 0.59)	1.19 (-1.05 to 1.36)	0.048
24 months	-0.82 (-1.67 to 0.03)	-0.67(-1.52 to 0.19)	0.15 (-1.05 to 1.36)	0.804
Total difficulties				
6 months	-1.78(-4.11 to 0.54)	-3.02(- 5.73 to -0.32)	-1.24 (-4.8 to 2.32)	0.495
12 months	-3.43 (-5.53 to -1.32)	-2.52 (-4.59 to -0.46)	0.90 (-2.05 to 3.85)	0.549
24 months	-1.87 (-4.05 to 3.85)	-1.91 (-4.07 to 0.23)	-0.04 (-3.1 to 3.01)	0.977

SDQ Child Total score	Both treatment groups pooled(95% KI)	P value -change from baseline
3 months	-2.27 (-4.02 to -0.53)	0.011
12 months	-2.94 (-4.40 to - 1.47)	0.000
24 months	-1.89 (-3.41 to -0.37)	0.015

Data based on mixed models analysis with single-family intervention as reference group.

* According to Norwegian version of Strength and Difficulty Questionnaire (23)

[†]P value for equality between groups, group-by-time effect

Table A2 Changes in parent reported mental health (SDQ) through 24 months by treatment group and pooled. Finnmark Activity

School.

Parent reported SDQ score*	Change at follow up(95 % CI) Single-family intervention	Change at follow up(95 % CI) Multiple-family intervention	Between group difference (95% CI)	P value group by time [†]
Prosocial behaviour				
6 months	0.03 (-0.69 to 0.75)	0.25 (-0.43 to 0.93)	0.22 (-0.77 to 1.21)	0.661
12 months	-0.02 (-0.56 to 0.60)	0 (-0.57 to 0.57)	-0.02 (-0.83 to 0.80)	0.966
24 months	0.06 (-0.57 to 0.69)	0,39 (-0.19 to 0.97)	0.33 (-0.53 to 1.18)	0.450
Hyperactivity-inattention				
6 months	-0.1 (-0.78 to 0.58)	-0.07 (0.71 to 0.57)	0.03 (-0.91 to 0.96)	0.954
12 months	0.02 (-0.53 to 0.57)	-0.18 (-0.71 to 0.36)	-0.20 (-0.96 to 0.57)	0.611
24 months	-0.49 (-1.09 to 0.10)	-0.44 (-0.99 to 0.10)	0.05 (-0.75 to 0.86)	0.899
Emotional symptoms				
6 months	-0.42 (-1.23 to 0.38)	-0,82 (-1.58 to -0.06)	-0.39 (-1.5 to 0.71)	0.485
12 months	-0.80 (-1.45 to -0.15)	-0.63 (-1.27 to - 0.00)	0.16 (-0.74 to 1.07)	0.721
24 months	-0.76 (-1.47 to -0.06)	-0.77 (-1.41 to - 0.13)	0.0 (-0.96 to 0.95)	0.992
Conduct problems				

6 months	-0.46 (-1.02 to 0.09)	-0.11(-0.63 to 0.41)	0.35 (-0.4 to 1.11)	0.359
12 months	-0.11 (-0.56 to 0.33)	-0.09(-0.52 to 0.35)	0.03 (-0.59 to 0.65)	0.932
24 months	-0.21 (-0.70 to 0.27)	-0.06 (-0.50 to 0.38)	0.15 (-0.5 to 0.8)	0.654
Peer problems				
6 months	-0.11(-0.85 to-0.63)	-0.04 (-0.73 to 0.66)	0.07 (-0.95 to 1.09)	0.892
12 months	-0.33 (-0.92 to 0.27)	-0.12(-0.70 to 0.46)	0.21 (-0.62 to 1.04)	0.625
24 months	-0.54 (-1.19 to 0.10)	-0.36 (-0.95 to 0.23)	0.19 (-0.69 to 1.06)	0.678
Total difficulties				
6 months	-1.38(-3.20 to 0.45)	-1.03(-2.74 to 0.68)	0.35 (-2.16 to 2.85)	0.786
12 months	-1.42 (-2.88 to 0.05)	-0.96(- 2.39 to 0.47)	0.46 (-1.58 to2.51)	0.659
24 months	-2.25(-3.85 to -0.66)	-1.59 (- 3.05 to -0.14)	0.66 (-1.50 to 2.82)	0.550

SDQ Parents Total score	Both treatment groups pooled(95% KI)	P value -change from baseline
3 months	-1.20 (-2.44 to 0.04)	0.058
12 months	-1.18 (-2.19 to -0.16)	0.023
24 months	-1.89 (-2.96 to -0.83)	0.000

Data based on mixed models analysis with single-family intervention as reference group.

* According to Norwegian version of Strength and Difficulty Questionnaire (23)

†P value for equality between groups, group-by-time effect

Table A3 Changes in self perception profile for children through 24 months in Finnmark Activity School; by treatment group.

Self perception profile for children (SPPC) *	Change at follow up(95 % CI) Single-family intervention	Change at follow up(95 % CI) Multiple-family intervention	Between group difference (95% CI) Koeff (95% KI)	p value group by time [†]
School competence				
6 months	0.05(-0.18 to 0.28)	-0.01 (-0.24 to 0.22)	-0.06 (-0.38 to 0.27)	0.742
12 months	0.12 (-0.69 to 0.31)	-0.07 (-0.26 to 0.12)	-0.18 (-0.45 to 0.08)	0.165
24 months	-0.06 (-0.26 to 0.14)	-0.14 (-0.33 to 0.05)	-0.08(-0.35 to 0.20)	0.576
Social acceptance				
6 months	0.04(-0.20 to 0.29)	0.20 (-0.04 to 0.44)	0.16 (0.19 to 0.50)	0.370
12 months	0.17(-0.03 to 0.37)	0.14 (-0.06 to 0.33)	-0.03 (-0.31 to 0.24)	0.816
24 months	0.03 (-0.17 to 0.23)	-0.04 (-0.24 to 0.16)	0.07 (-0.35 to 0.22)	0.651
Athletic competence				
6 months	0.63(0.34 to 0.91)	0.64 (0.36 to 0.92)	0.01(-0.38 to 0.41)	0.946
12 months	0.71(0.48 to 0.94)	0.58 (0.35 to 0.81)	-0.13 (-0.45 to 0.20)	0.442
24 months	0.57 (0.33 to 0.81)	0.44(0.21 to 0.67)	-0.13 (-0.47 to 0.20)	0.439
Physical appearance				
6 months	0.20 (-0.6 to 0.46)	-0.07(-0.33 to 0.19)	-0.28 (-0.64 to 0.09)	0.144
12 months	0.17 (-0.04 to 0.38)	0.12(-0.10 to 0.33)	-0.06 (-0.35 to 0.24)	0.718
24 months	0.11 (-0.11 to 0.34)	-0.19 (-0.40 to 0.03)	-0.30 (-0.61 to 0.01)	0.056
Behavioural conduct				
6 months	0.03(-0.19 to 0.25)	0.13 (-0.09 to 0.36)	0.10(-0.21 to 0.42)	0.523
12 months	0.16 (-0.02 to 0.34)	0.17 (-0.01 to 0.35)	0.01 (-0.25 to 0.27)	0.945
24 months	-0.04 (-0.15 to 0.23)	0.03 (-0.15 to 0.21)	0.01 (-0.27 to 0.26)	0.968
Self worth				
6 months	-0.11(-0.32 to 0.10)	-0.11(-0.32 to 0.10)	0 (-0.30 to 0.30)	0.993
12 months	0.03 (-0.14 to 0.20)	0.06 (-0.11 to 0.23)	0.04 (-0.21 to 0.28)	0.770
24 months	-0.04 (-0.22 to 0.14)	-0.14 (-0.32 to 0.04)	-0.1 (-0.36 to 0.16)	0.448

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Data based on mixed models analysis with single-family intervention as reference group.

* According to Norwegian version of Harter Self- Perception Profile for Children (24)

[†]P value for equality between groups, group-by-time effect

Table A4 Changes in self reported and parent reported quality of life (KINDL) through 24 months by treatment group and pooled effects. Finnmark Activity School

Quality of life Self reported KINDL*	Change at follow up(95 % CI) Single-family intervention	Change at follow up(95 % CI) Multiple-family intervention	Between group difference (95% CI)	p value group by time [†]
Total				
6 months	0.20 (-5.14 to 5.54)	0.95(-4.41 to 6.31)	0.75 (-6.82 to 8.32)	0.846
12 months	4.43 (-0.21 to 9.07)	2.64(-1.48 to 6.75)	-1.80 (-8.00 to 4.41)	0.570
24 months	-0.68 (-5.31 to 3.96)	-1.45(-5.61 to 2.70)	-0.78 (-7.00 to 5.45)	0.807
Parent reported KINDL*				
Total				
6 months	-1.93 (-6.43 to 2.57)	3.01 (-0.79 to 6.80)	4.94 (-0.95 to 10.82)	0.100
12 months	0.32 (-3.05 to 3.68)	2.99 (-0.28 to 6.25)	2.67 (-2.02 to 7.36)	0.264
24 months	1.61 (-1.85 to 5.07)	2.27 (-0.95 to 5.48)	0.66 (-4.06 to 5.38)	0.784
Physical				
6 months	-3.47 (-11.72 to 4.79)	6.40 (-1.39 to 14.20)	9.87 (-1.48 to 21.23)	0.088
12 months	4.58 (-2.16 to 11.33)	3.05 (-3.57 to 9.67)	-1.53 (-10.98 to 7.92)	0.751
24 months	4.39 (-2.84 to 11.63)	1.84 (-4.87 to 8.56)	-2.55 (-12.42 to 7.32)	0.613
Emotions				
6 months	0.01 (-6.35 to 6.36)	5.49 (-0.10 to 11.08)	5.49 (-2.98 to 13.95)	0.204
12 months	1.06 (-3.83 to 5.94)	1.85 (-2.88 to 6.59)	0.80 (-6.01 to 7.60)	0.819
24 months	0.17 (-5.00 to 5.34)	5.30 (0.54 to 10.06)	5.13 (-1.90 to 12.16)	0.153
Self esteem				
6 months	-2.79 (-9.04 to 3.47)	2.13(-3.73 to 8.00)	4.92 (-3.66 to 13.50)	0.261
12 months	-1.36 (-6.49 to 3.78)	5.38(0.46 to 10.31)	6.74 (-0.37 to 13.85)	0.063
24 months	5.15 (-0.25 to 10.55)	1.27 (-3.63 to 6.17)	-3.88 (-11.18 to 3.41)	0.297

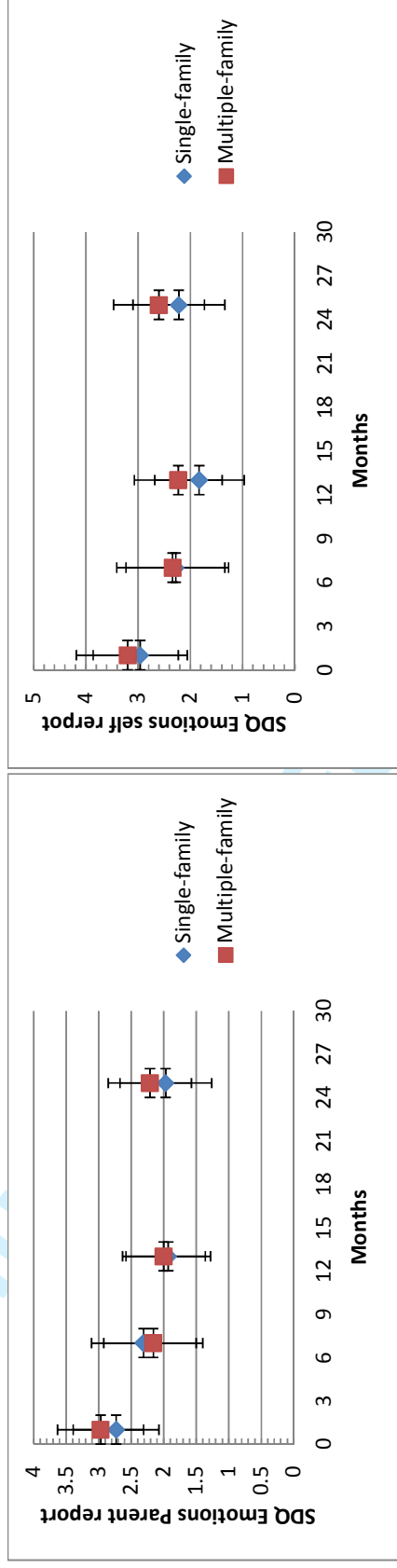
Family					
6 months	0.32(-5.02 to 5.65)	1.30 (-3.69 to 6.29)	0.99(-6.32 to 8.29)	0.791	
12 months	1.22 (-3.04 to 5.48)	0.71 (-3.55 to 4.97)	-0.51 (-6.54 to 5.51)	0.867	
24 months	-0.23 (-4.84 to 4.37)	2.23 (-2.01 to 6.48)	2.46 (-3.80 to 8.72)	0.441	
Friends					
6 months	-1.58 (-6.87 to 3.71)	3.13(-1.67 to 7.93)	4.70 (-2.44 to 11.85)	0.197	
12 months	0.41 (-3.78 to 4.61)	2.91(-1.21 to 7.02)	2.49 (-3.38 to 8.37)	0.406	
24 months	2.09 (-2.38 to 6.55)	1.35 (-2.75 to 5.46)	-0.73 (-6.80 to 5.34)	0.813	
School					
6 months	-1.22 (-6.65 to 4.21)	-2.21 (-7.19 to 2.77)	-0.99(-8.36 to 6.37)	0.792	
12 months	0.37 (-4.03 to 4.76)	3.63 (-0.66 to 7.92)	3.27 (-2.88 to 9.41)	0.297	
24 months	-0.57 (-5.10 to 3.96)	2.01 (-2.21 to 6.24)	2.58 (-3.61 to 8.78)	0.414	
KINDL Child Total score	Both treatment groups pooled (95% CI)	P value -change from baseline			
6 months	0.53 (-3.21 to 4.27)	0.781			
12 months	3.39 (0.34 to 6.43)	0.029			
24 months	-1.16 (-4.22 to 1.90)	0.457			
KINDL Parents Total score	Both treatment groups pooled (95% CI)	P value -change from baseline			
6 months	0.92 (-1.96 to 3.81)	0.531			
12 months	1.67 (-0.67 to 4.02)	0.161			
24 months	1.90 (-0.45 to 4.25)	0.113			

Data based on mixed models analysis with single-family intervention as reference group.

* According to Norwegian version of “Kinder Lebensqualität Fragebogen” KINDL (25)

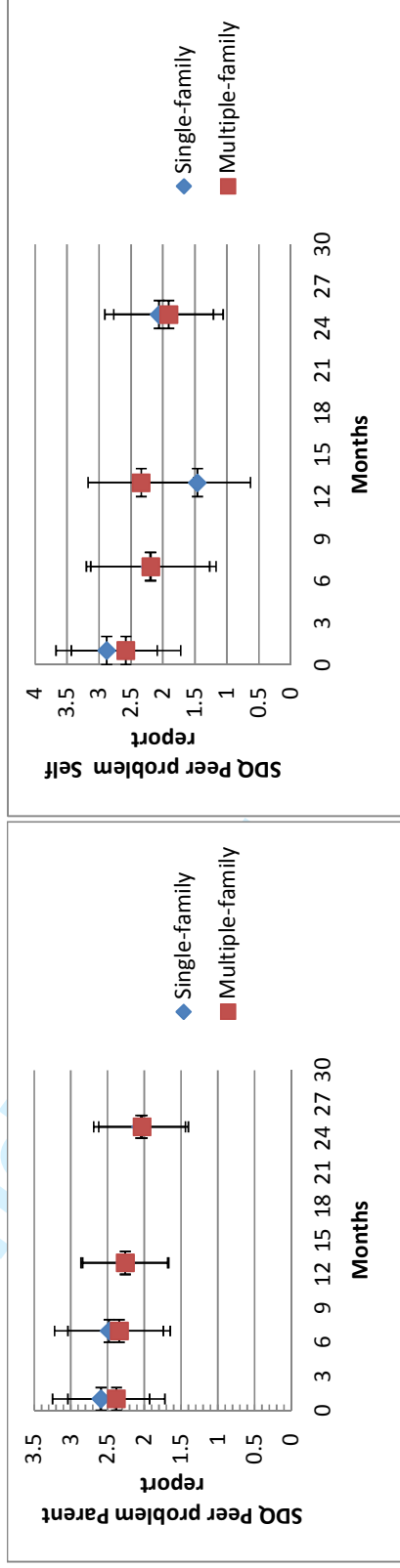
†P value for equality between groups, group-by-time effect

Figure A1 Parent and self-reported mental health (SDQ) emotional symptoms from baseline to 24 months by intervention group. Finnmark Activity School



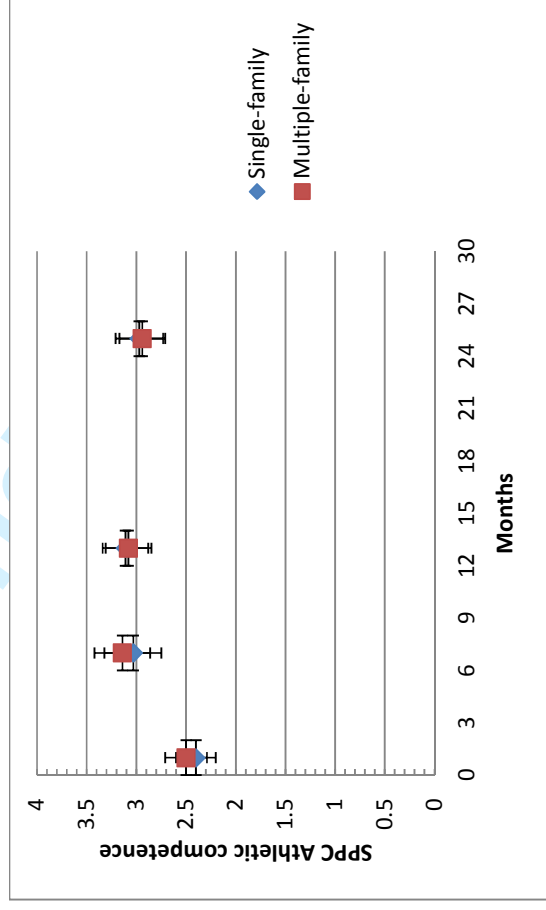
Mean (95% CI) changes in SDQ score emotional symptoms from baseline to 24- months follow up by intervention group.

Figure A2 Parent and self-reported mental health (SDQ) peer problem. Finnmark Activity School



Mean (95% CI) changes in SDQ score peer problem from baseline to 24- months follow up by intervention group.

Figure A 3 Self esteem, athletic competences. Finnmark Activity School



Mean (95% CI) changes in Self Perception Profile, athletic competence from baseline to 24- months follow -up by intervention group.