APPENDIX

Camp-based Family Treatment of Childhood Obesity - Randomised Controlled Trial

CONTENTS

- P. 2: **Table A1.** Within-group changes and between group differences in biochemical characteristics of children from baseline to follow-up
- P. 3: **Table A2.** Baseline demographic, clinical and biochemical characteristics of the 89 parents included in the analysis
- P. 4: **Table A3.** Within-group changes and between group differences in clinical outcomes of parents from baseline to 2 year follow-up
- P. 5: Table A4. Coefficients of variation and methods of biochemical analyses
- Pp. 6-8: Interventions Additional details

Table A1. Within-group changes and between group differences in biochemical characteristics of children from baseline to follow-up

	Within-group change		Between-group difference	
Outcome	Summer Camp (n=39)	Lifestyle School (n=33)	Difference baseline to 2 years	P-value (group*time)
Glucose (mmol/L)	0.1 (0.04, 0.2)*	0.1 (-0.1, 0.2)	-0.05 (-0.2, 0.1)	0.46
HOMA-IR	1.1 (0.3, 1.9)*	2.4 (-0.2, 4.9)	-2.5 (-4.4, -0.7)*	0.35
Cholesterol (mmol/L)				
Total	-0.3 (-0.5, -0.1)*	-0.3 (-0.6, -0.1)*	-0.1 (-0.4, 0.2)	0.99
HDL	-0.04 (-0.1, 0.03)	-0.1 (-0.2, -0.1)*	0.2 (0.02, 0.3)*	0.10
LDL	-0.3 (-0.5, -0.2)**	-0.4 (-0.6, -0.2)**	-0.1 (-0.4, 0.2)	0.68
Triglycerides (mmol/L)	0.1 (-0.1, 0.3)	0.4 (0.1, 0.7)*	-0.3 (-0.6, -0.02)*	0.05
Aspartate aminotransferase, AST (U/L)	-3 (-6, -1)*	-3 (-5, -1)*	2 (-1, 5)	0.86
Alanine aminotransferase, ALT (U/L)	0 (-4, 5)	-1 (-4, 3)	1 (-4, 6)	0.88
Gamma glutamyl transferase, GGT (U/L)	3 (-2, 8)	-1 (-3, 1)	0 (-4, 4)	0.17
High-sensitivity C-reactive protein (mg/L)	-1.3 (-2.7, 0.1)	-0.7 (-3.1, 1.7)	-0.3 (-1.8, 1.1)	0.36

Abbreviations: B, Baseline; 2y, 2 year follow-up; HOMA-IR, the homeostasis model assessment of insulin resistance; HDL, high-density lipoprotein; LDL: low-density lipoprotein.

Values are presented as estimated means (95% CIs). At two year follow-up, n=34 SC-group and n= 28 LS-group. * P<0.05, ** P<0.001.

Table A2. Baseline demographic, clinical and biochemical characteristics of the 89 parents included in the analysis

Characteristics	All parents	Family summer	Family lifestyle	<i>P</i> -value
	(n=89)	camp (n=46)	school (n=43)	. = .
Age (years)	40.7 (5.0)	40.9 (4.8)	40.6 (5.2)	0.78
Gender, female (%)	69 (78)	31 (67)	38 (88)	0.023*
Weight and anthropometric measures				
Weight (kg)	105.3 (15.9)	108.2 (17.2)	102.3 (14.0)	0.12
Height (cm)	168.8 (7.4)	170.9 (7.8)	166.5 (6.4)	0.006*
Body mass index (kg/m ²)	37.0 (4.6)	37.0 (4.4)	36.9 (4.9)	0.90
Waist (cm)	115.1 (14.8)	117.1 (17.1)	112.9 (11.5)	0.32
Hip (cm)	121.9 (11.6)	123.5 (12.3)	120.2 (10.6)	0.41
Waist to hip ratio	0.95 (0.10)	0.95 (0.09)	0.94 (0.10)	0.84
Body fat (%)	40.8 (6.9)	39.5 (7.4)	42.2 (6.2)	0.07
Fat mass (kg)	43.1 (10.7)	42.7 (10.8)	43.5 (10.7)	0.75
Skeletal muscle mass (kg)	62.2 (11.5)	65.6 (13.5)	58.8 (7.8)	0.05
Systolic blood pressure (mmHg)	121 (15)	123 (17)	119 (12)	0.20
Diastolic blood pressure (mmHg)	75 (11)	76 (13)	75 (9)	0.59
Physical capacity				
6 minutes walking distance (m)	569 (64)	583 (65)	555 (60)	0.038
Biochemical analysis		n=38	n=32	
Glucose (mmol/L)	5.6 (2.0)	5.4 (1.2)	5.7 (2.7)	0.53
HOMA-IR	4.7 (3.2)	4.2 (2.8)	5.3 (3.6)	0.23
Cholesterol (mmol/L)	` ,	` '	` ,	
Total	5.2 (0.8)	5.1 (0.8)	5.3 (0.7)	0.34
HDL	1.3 (0.3)	1.3 (0.3)	1.2 (0.4)	0.10
LDL	3.2 (0.7)	3.2 (0.6)	3.3 (0.8)	0.79
Triglycerides (mmol/L)	1.4 (53.1)	115.0 (44.2)	132.7 (61.9)	0.15
Aspartate aminotransferase, AST	26 (9)	27 (11)	25 (7)	0.64
(U/L)				
Alanine aminotransferase, ALT (U/L)	28 (17)	29 (20)	27 (12)	0.51
Gamma glutamyl transferase, GGT (U/L)	32 (21)	28 (17)	37 (23)	0.006*
High sensitivity C-reactive protein (mg/L)	4.7 (4.8)	3.2 (3.5)	6.4 (5.6)	0.006*

Abbreviations: HOMA-IR, the homeostasis model assessment of insulin resistance; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

Values are presented as mean (SD) or number (%). * P<0.05.

Table A3. Within-group changes and between group differences in clinical outcomes of parents from baseline to 2 year follow-up

	Within-group	mean change	Between-group	Between-group difference	
Outcome	Summer Camp Group (n=46)	Lifestyle School Group (n=41)	Mean adjusted difference (95% CI)	P-value (group*time)	
			<u> </u>		
Weight and anthropometr	ric measures				
Weight (kg)	-2.8 (-5.6, 0.1)	-2.1 (-5.6, 1.4)	6.3 (-0.3, 13.0)	0.96	
Body mass index	-0.9 (-1.8, -0.03)*	-0.8 (-2.1, 0.4)	0.3 (-1.7, 2.2)	0.97	
(kg/m^2)	, , ,	, , ,	, , ,		
Waist (cm)	-2.7 (-5.1, -0.4)*	-2.0 (-6.9, 2.9)	3.6 (-2.6, 9.8)	0.71	
Hip (cm)	-5.1 (-7.4, -2.9)**	-4.6 (-8.2, -1.0)*	4.1 (-0.9, 9.1)	0.98	
Waist:hip ratio	0.02 (-0.001, 0.04)	0.02 (-0.03, 0.08)	-0.01 (-0.05, 0.04)	0.79	
Body fat (%)	-0.8 (-1.7, 0.2)	-0.2 (-2.1, 1.6)	-0.3 (-2.3, 1.7)	0.75	
Fat mass (kg)	-1.6 (-3.6, 0.4)	-1.0 (-4.3, 2.2)	-0.3 (-4.9, 4.3)	0.92	
Skeletal muscle mass	-1.2 (-2.2, -0.2)*	-1.0 (-2.0, -0.1)*	6.7 (1.9, 11.5)*	0.80	
(kg)	·- (, · ·)	(,)	()		
Systolic blood pressure	1 (-3, 6)	2 (-2, 7)	4 (-2, 9)	0.83	
(mmHg)	- (- , -)	_ (_, , ,	. (–, - /	*****	
Diastolic blood pressure	-1 (-4, 2)	0 (-5, 4)	1 (-3, 5)	0.81	
(mmHg)	- (-, -)	(2, 1)	- (-, - /	****	
Physical capacity					
6 minutes walking	47 (30, 65)**	9 (-22, 40)	45 (17, 74)*	0.017*	
distance (m)					
Biochemical variables	n=38	n=30			
Glucose (mmol/L)	0.4 (-0.3, 1.1)	0.1 (-0.6, 0.8)	-0.1 (-1.3, 1.0)	0.54	
HOMA-IR	-0.3 (-1.2, 0.8)	0.3 (-0.1, 0.2)	-1.2 (-2.6, 0.2)	0.78	
Cholesterol (mmol/L)					
Total	-0.4 (-0.6, -0.2)*	-0.1 (-0.5, 0.2)	-0.3 (-0.7, 0.1)	0.20	
HDL	0.0 (-0.1, 0.1)	0.1 (-0.02, 0.2)	0.01 (-0.2, 0.2)	0.27	
LDL	-0.4 (-0.6, -0.2)**	-0.1 (-0.4, 0.3)	-0.2 (-0.5, 0.1)	0.07	
Triglycerides (mmol/L)	-0.01 (-0.2, 0.2)	0.04 (-0.2, 0.3)	-0.2 (-0.5, 0.1)	0.70	
Aspartat	-1 (-4, 1)	-1 (-3, 2)	3 (-1, 7)	0.80	
aminotransferase, AST					
(U/L)					
Alanin	-3 (-8, 3)	-1 (-6, 3)	3 (-4, 10)	0.82	
aminotransferase,					
ALAT (U/L)					
Gamma glutamyl	-3 (-6, 1)	-3 (-12, 7)	-10 (-17, -1)*	0.93	
transferase, GGT (U/L)					
High sensitivity C-	0.5 (-0.6, 1.6)	1.1 (-3.4, 5.5)	-3.5 (-5.8, -1.1)*	0.79	
reactive protein (mg/L)					

Abbreviations: B, baseline; 2y, 2 year follow-up; BMI, body mass index; BP, blood pressure; HOMA-IR, the homeostasis model assessment of insulin resistance; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

Values are presented as estimated means (95% CI). At two year follow-up, n=37 SC-group and n=24 LS-group delivered clinical data and n=30 (SC) and n=25 (LS) delivered blood samples. * P<0.05, ** P<0.001.

Table A4. Coefficients of variation and methods of biochemical analyses

Variable	Coefficient of variation (CV_{at})	Method of analysis
Glucose (mg/dL)	$\frac{(c + at)}{2.0}$	a
Insulin (pmol/L)	4.0	Immunoassay method (ECLIA kit, Roche Diagnostics, Mannheim, Germany), The Hormone Laboratory, Oslo University Hospital Aker, Norway
Cholesterol (mg/dL)		
Total	1.8	a
HDL	3.0	a
LDL	3.0	a
Triglycerides (mg/dL)	3.0	a
Aspartat aminotransferase, AST (U/L)	4.0	a
Alanin aminotransferase, ALT (U/L)	6.0	a
Gamma glutamyl transferase, GGT (U/L)	3.5	a
High-sensitivity C-reactive protein (mg/L)	6.0	a

Abbreviations: CV_{at}, Analytical coefficient of variation; HDL, high-density lipoprotein; LDL: low-density lipoprotein

a: Performed by the Vestfold Hospital Trust laboratory using standard analysing methods used routinely, layered dry-slide chemical methods with photometric reflection and potentiometric detection principles (Vitros®Microslide Technology, Ortho-Clinical Diagnostics, UK).

INTERVENTIONS – ADDITIONAL DETAILS

Intervention commonalities

All family members were invited to participate in the interventions in order to assure that the changes in lifestyle were adopted by the family as a whole and that the family members would provide support to each other. Each family had a local coordinator, acting as the family's "coach" in the local community. The role of the coordinator was to offer monthly consultations (either in person or by telephone) in order to both provide more concrete goals and methods which could assist in the implementation of each family's goals. Both the local coordinator and the family's primary physician were informed in written form about their goals and the anthropometric measurements from the other institutions involved.

At their baseline visit the families stayed at the hospital for a day (7 hours). They were informed about the purpose and the design of the study and measurements were taken from both children and parents. They signed consent forms after being given information in a written and oral presentation. A group session on childhood obesity (4 hours) was held – in which the local coordinator was also invited to participate. The group session included nutritional and physical activity; reduce or avoid sugary drinks, limit screen time to ≤ 2 hours a day, eat breakfast, eat at home, eat ≥ 5 portions of fruit or vegetables a day, whole grain products, fish, lean meats, sharing at least 5-6 family meals a week, self-regulation of meals, engage in > 1 hour of physical activity a day, reduce sedentary time. A paediatrician, a physical therapist, a public health nurse and a nurse were present during this first day. All interventions implemented behavioural techniques for achieving and maintaining changes based on elements of dynamic group therapy, [1] motivational interviewing [2] and Parent Management Training – Oregon (PMTO).[3] Participant measurements were taken in the hospitals at baseline, one-year visit and two-year visit. On these measurement-taking days participants also attended lectures about nutrition and physical activity, exchanging personal experiences in order to boost motivation.

Summer camp intervention

The 2-week in-patient family summer camp was located at either Røros Rehabilitation Centre in Røros (Mid-Norway) or at the Evje clinic in Agder (South-Norway). The camp focused on the family unit, the role of the parents, nutrition and physical activity. Possible factors limiting lifestyle changes (i.e. factors within the family unit, social problems, financial problems, educational difficulties) were also explored. The goal of the camp was to help parents find the motivation to continue the process of adopting a healthier lifestyle at home, and to learn specific measures which could influence the functioning of the family unit and the lifestyle of the child. The focus during the family camp was exploring which specific means of change each specific family wanted to work on.

The overall teaching method was confluent education, in which the core idea is learning through experience. The children acquired knowledge through socialisation, play- and activity-based nutritional training in groups. The aim was to empower them such that they could make informed choices related to food and physical activity based on awareness of their bodily sensations associated with hunger and satiety, and by exploration of the thoughts and emotions connected to food, the function of food, physical activity, body and health. In addition, the families engaged in different forms of physical activity. The goal was that the

children should feel comfortable participating in physical activity, have fun, and be confident in their physiologic reactions to physical activity (i.e. heart rate, "hurts", sweat etc.)

The families participated in 4 follow-up weekends (each two days) at the rehabilitation centres. The first took place after approximately 3 months, then every sixth month. Before their departure from these visits each family had an individual consultation with staff members of the treatment centre. The family's goals for parent management, nutrition and physical activity were written on a form which they brought home as a reminder to continue the work.

The same healthcare providers (psychologist, public health nurse, psychiatric health nurse, nutritionist, physical therapist, health and training therapist, gymnastics teacher, physician, social worker) attended these visits.

Family lifestyle school

The lifestyle school took place in September 2010 and 2011 for the two cohorts, respectively, and the four days of education were given as two subsequent days twice with a four week interval, a total of 23 hours. This was an introductory course in lifestyle change for families with obesity at which their local coordinators were also present during the first day. The same medical professionals gave the LS-treatment at both hospitals; a dietist, a psychologist, a public health nurse, a physical therapist and a paediatrician. Parents and children attended sessions on healthy nutrition, physical activity and practical "shopping training". They also attended a day trip and the children made lunch one day together with a nutritionist. Parents attended lessons on parenting skills.

The lifestyle change process would continue through motivational and supportive meetings in the home municipality, in which the parents were empowered to help the family change in the desired direction by functioning as good role-models for their children. The goal was to educate parents and children about healthy choices regarding nutrition, physical activity and factors that influence motivation.

The approach was based on change focused counselling and group based tutoring with emphasis on the child's perspective. The focus was making changes in lifestyle, trying new physical activities, coping strategies, motivation and family dynamics.

The parents were helped to make two specific "family lifestyle change goals" in terms of nutrition and physical activity.

The local coordinators

The municipalities in which the families lived had to provide a local coordinator in order for the family to be eligible to participate. The coordinator offered monthly follow-up for the family, and could choose different ways to conduct these appointments (by phone call, by appointments at their office, by offering participation in a group.)

The community coordinators in the SC-group were offered the opportunity to participate on the first repetition weekend, and received monthly follow-up by telephone from the staff at the rehabilitation centre. The coordinators in the LS-group were offered the opportunity to participate on day 1 of the Lifestyle School. They did not receive any systematic follow-up from the specialist care.

All local coordinators were invited to the first day of information and baseline measurements for the possible participants, before randomisation. They had access to an internet based discussion forum. They were also offered the opportunity to participate in a "coordinator gathering" at 6 months and 18 months, where staff from the hospitals involved in the study provided lectures and could discuss their experiences so far. They were instructed to start following the families once a month, beginning one month after the initial treatment at the latest.

- 1. Poey K. Guidelines for the practice of brief, dynamic group therapy. *Int J Group Psychother* 1985;**35**(3):331-54.
- 2. Rollnick S, Kinnersley P, Stott N. Methods of helping patients with behaviour change. *Bmj* 1993;**307**(6897):188-90.
- 3. Ogden T, Hagen KA. Treatment effectiveness of Parent Management Training in Norway: a randomized controlled trial of children with conduct problems. *J Consult Clin Psychol* 2008;**76**(4):607-21.