Evaluation of therapy for overweight children and adolescents in Switzerland: Therapy in multiprofessional group programs – Part 2 of KIDSSTEP°°, collection and analysis of data, Final report February 12th, 2014

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°° KIDSSTEP = Kinder-Adipositas in der Schweiz - Studie zur Therapie-Evaluation von Programmen in Gruppen

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3 Abstract

Objective: The aim of this pilot project is to disseminate multiprofessional group programs (MGP) for therapy of the estimated 119'140 overweight/obese children in Switzerland. Family-based behavioral MGPs have been implemented from 2009 to 2013 to determine changes of health and family behaviours, after the intensive phase (T1), at 1 and 2 years after start (T2, T3).

Methods: MGP costs are reimbursed in Switzerland: 1) if 116 sessions are provided by experts in physical activity, nutrition and psychology; 2) if parents are included and if their adherence is higher than 85%. In the nationwide KIDSSTEP[1] study, multiple psychosocial and physical parameters were assessed at T0, T2 and T3. Out of 33 certified centers, 25 were active and only 19 were re-certified in 2013/2014.

Results: Out of 3482 patients referred, only 36% started in MGPs, while 30% were treated for co-morbidities in an individual setting. The return rate for MGP data was 1162 (87.3%), 682 (87.5%) and 354 patients (50.8 %) at T0, T2 and T3, respectively. At baseline, the mean age was 12.2±2.5 years (46 % non-Swiss origin, 54% girls) while the onset of obesity was at 6 years. There were 78.6% of children with extreme obesity (BMI>P.99.5), 16.6% with obesity (97 < P.< 99.5) and 4.6% with overweight (P.90-P.97).

After therapy, the BMI standard deviation score (BMI-SDS) was significantly reduced by -0.23 at T2 and -0.31 at T3, or in 70.5% and 70.2% of participants, respectively. Systolic blood pressure, physical capacities and fitness, family lifestyle and child's eating disorders significantly improved over time. At T0, quality of life was poor and major co-morbidities such as orthopaedic (68%) or mental disorders (45%) were present. All improved during therapy. A better outcome at T2 was predicted by age below 12 years and normal scores for mental health, quality of life or eating disorders. The drop out at T1 was predicted by high BMI-SDS and non-Swiss parents.

Conclusion: Obese children suffer from major co-morbidities and therefore, only one third of referred patients can be treated in MGPs and their beneficial effects on obesity as well as physical and mental health outcomes are sustained over 2 years. There is an urgent need to improve the programs financial support, the regional dissemination, the follow-up phase, and also the quality of care for obese children who cannot participate in group therapy.

[1] funded by the FOPH Grant / decree # 09.004211/204.0001/-629,
Methods assessed: family origin and eating & activity habits, body mass index standard deviation score (BMI-SDS), waist circumference (WC), blood pressure (BP), physical capacity (Eurofit Test), quality of life (Kidscreen 52), eating disorders (AD-EVA) and mental health problems (SDQ)

4 Executive Summary

Established Facts

- Childhood obesity represents a critical public health burden, due to the premature development of co-morbidities and association with physical incapacity.
- In Switzerland, approximately 20% of children are overweight and approximately 5% are obese. Early interventions are needed to prevent the progression of the disease into adulthood and the development of multiple health complications.
- For the reasons mentioned below, childhood obesity treatment is not available for the majority of children in Switzerland. Only 1251 obese children out of the 119'140 estimated can have access to multiprofessional group programs, evaluated by KIDSSTEP study.
- It is well-known, that the recruitment of patients for obesity therapy may be difficult; first, this is due to the fact that until 2013, only 2 forms of therapy were available: usual medical care, provided by physicians or, since 2009, the group programs within an evaluation project.
  Second, recruitment is hampered by the presence of contraindications, e.g. invalidity, psychiatric disease, or by the occupation of parents, or insufficient family resources.
- In addition, wide-spread regional availability of specific obesity therapy is limited due to a lack of specialized healthcare personal and centres, a poor coordination between health services, as well as insufficient financial support.
- In Switzerland, childhood obesity care depends essentially of non-governmental organizations (Fachverband Adipositas im Kinder- und Jugendalter akj, Schweizerische Gesellschaft für Pädiatrie SGP, Fondation Sportsmile).
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Novel insights

- The establishment of a good quality nationwide network and register is feasible in paediatric obesity care.
- The KIDSSTEP study demonstrates severe impairments in mental health, quality of life and physical capacities in obese children
- The multiprofessional group therapy is effective to reduce the degree of overweight, associated complications, improve physical capacities, as well as preclinical eating disorders. It does not induce side effects.
- Good quality of life and mental health are however prerequisites to maintain healthier weight and lifestyle.
- The effects of therapy are sustained at 2 years in children who benefit from a follow-up phase. Therefore, longer term care should be warranted, similarly to other chronic diseases such as arterial hypertension or diabetes.
- The health status rapidly improves in young obese children

Recommendations

- Group therapy and additional forms of multiprofessional care should be delivered to all obese children in Switzerland. The access to care should be ensured in all regions to decrease the inequality of opportunities.

- Multiprofessional therapy and the maintenance of care at long term should be imbedded into a national tertiary prevention plan for non-transmissible chronic diseases.
- Multiprofessional individual therapy directed by primary care providers appears to be a promising approach to complement the group therapy programs in Switzerland.
- Screening for early onset of childhood obesity, as a precursor of other non-transmissible diseases, is necessary to reduce cases and costs of subsequent co-morbidities.
- The quality of care should be warranted in Switzerland by the establishment of a coordination and information platform, as well as a benchmarking system.
- The accessibility and efficiency of health services should be dramatically improved in order to treat 119'140 obese and overweight children.

5 Introduction

In Switzerland approximately 185'000 children are overweight and 51'500 obese and need interventions to prevent progress of disease into adulthood.
In March 2007, Swiss Society of Paediatrics, represented by Dr. Laimbacher as head of the Swiss paediatric obesity working group, submitted an application for reimbursement of new medical procedures to the Federal Commission for General Health Insurance Benefits and Principles (ELGK), asking for several types of multiprofessional family based outpatient therapy for children and adolescents with overweight and obesity:

1. Multiprofessional Group Programs (MGP) in an outpatient setting
2. Multiprofessional Group Programs in a Modular group and individual setting (MGPM) and
3. Multiprofessional Programs in the Medical Practice (MPMP) in an individual setting.

As efficacy and sustained effects up to 10 years had been clearly demonstrated by randomized controlled trials for multiprofessional family-based group programs (Epstein et al 1994b; Oude Luttikhuis et al 2009), Swiss Department of the Interior (EDI), by the ordinance of November 21st, 2007, proposed a pilot phase of 5 years to evaluate only multiprofessional group therapy of overweight children and adolescents (MGP), being reimbursed by health insurances under the condition that the patients participate in an evaluation study analysing outcomes. At the same time, paediatric obesity was recognized as a disease. It was evident from studies in other countries that less than 40% of children and adolescents can participate in a MGP, because they are too obese or suffer from psychosocial problems (Wiegand et al 2005). Till present, nutritional counselling or physiotherapy of obese children with a body mass index (BMI) below 30kg/m2 are not reimbursed by health insurances, if diagnosis is "obesity" only.

A research project was granted by the Federal Office of Public Health FOPH on November 22nd, 2007 with the following aims:

-1. To set up programs for the treatment of obese children and adolescents in Switzerland that will be reimbursed by health insurances, and

-2. To develop instruments and procedures allowing to assess the quality of therapeutic programs in Switzerland,

-3. to evaluate individual changes of physical activity, nutrition, behaviours, quality of life, co-morbidities and adiposity during therapy until 2 years of follow-up and to identify predictors of positive or negative changes.

Negotiations on quantities and costs of therapy with Santésuisse were difficult and resulted in a tariff contract with a fixed structure of quantity on October 29th, 2008, and first programs could start in 2009 only. Therefore, research project was divided in 2 parts: in the 1st part, granted by the sections "Fundamentals" and "Nutrition & Physical Activity" on November 22nd, 2007, contract # 08.004938, the first two aims were approached. On January 20th, 2009, the final report of the first part documented the development of certified multi-professional group therapy programs for paediatric obesity and established a procedure for evaluation of outcomes in a national multicentre project, approved by all relevant ethical commissions in Switzerland. Since causes of obesity are complex and therapy has been proven difficult and often frustrating also in children, we conceived a prospective explorative cohort study using multiple questionnaires to find out predictors of outcomes. Yearly reports so far could show stable data on inclusion of about 200 – 250 children per year, as calculated in advance, and improved somatic and mental health outcomes.

To study longer term follow up until 3 years after start (T4) of therapy and to deepen psychological evaluation of eating disorders, additional grant was provided by Swiss

Foundation for the Health of Children and Adolescents on April 13th, 2010, "Prevention of relapse after obesity therapy in children and adolescents. Explorative study to assess psychosocial determinants of long term healthy weight control, a sub-study of the Swiss national evaluation project".

The present preliminary version of the final report of part 2 is based on the 1st final report, mentioned above, as well as on previous milestone reports 4 to 7 of 2009 to 2012. It presents the evaluation of paediatric obesity therapy in multiprofessional group programs in Switzerland, according to the decree # 09.004211 / 204.0001/-629 of the Federal Office of Public Health (FOPH) from July 24th, 2009**,** § 3.2 und 3.3. The 2-year evolution of overweight and obese children and adolescents included in the national multicentre project is described, comprising changes of physical and psychological health parameters, drop-out rate and data on parent's obesity and socioeconomic background.

The set-up of an active nationwide network for therapy of paediatric obesity is unique and it will be shown that the risk for the development of chronic non-transmissible diseases can be decreased and quality of life improved. Therefore chapter 6 comprehensively describes the establishment and quality control from this kind of healthcare delivery.

6 Methods

6.1 Diagnosis and Management of overweight in children and adolescents in Switzerland

6.1.1 Diagnosis of obesity in childhood

During growth and between age 5 to 18 years, body mass index (BMI) is steadily increasing and obesity has to be defined according to BMI references centiles for age and gender. In Switzerland, reference data of WHO are used as recommended by SGP (Jenni et al 2011). To compare the degree of overweight of girls and boys at different ages within one study, BMI was expressed as standard deviation score (SDS)[2]. A cut off ≥1.28 SDS (90th centile) was applied to classify overweight, a cut off ≥ 1.88 SDS (97th centile) to classify obesity, and a cut-off ≥ 2.58 SDS (99.5th centile) to classify extreme obesity. As BMI is only an indirect measure of adiposity, because it is composed of both fat and fat free mass, obesity is also defined by increased waist circumference (WC) or elevated fat mass according to Swiss guidelines (l'Allemand et al 2006).

In addition, since BMI is a measure to define the degree rather than the distribution of obesity, waist circumference as an index of body fat distribution is increasingly applied to define associated risk factors in obese adolescents, such as impaired glucose metabolism (Caprio et al 1996;Maffeis et al 2008). WC was also expressed as SDS values, using the Dutch data as reference parameters (Fredriks et al 2005) or as waist-to-height ratio (WtHR).

WHtR >0.5 is considered as a convenient index to identify a high metabolic risk in overweight children at least as useful in public health to describe morbidity as BMI, but without need for age- related adjustments (Maffeis, Banzato, & Talamini 2008).

6.1.2 Management of obesity care in Switzerland

According to most recent population and public health data, out of 235'914 obese and overweight children in Switzerland, about 116'773 children are believed to be healthy and may benefit from measures of prevention of public health. There is no transparency on treatment of overweight and obesity provided in primary care, namely by paediatricians and family physicians or of overweight addressed in prevention programs e.g. of "Gesundheitsförderung Schweiz".

About 119'140 children under 18 years are obese (51'438) or overweight with co-morbidities (67'702), thus qualifying for therapy according to guidelines and the ordinance of medical procedures (Figure 1) and need adequate treatment. Until December 31st, 2013, the specific multiprofessional treatment as recommended by the professional association SGP could not be offered on an individual basis for those with BMI below 30 kg/m2 or without co-morbidities. Therefore, apart from bariatric surgery that rarely is indicated in youth, the only intervention for paediatric obesity covered by health insurances was group therapy which was performed in 1251 children and adolescents 8 to 18 years in the last 5 years.

Some programs were designed for younger children but had to stop because their structure with less lections for children did not comply with the quantitative structure prescribed in the tariff contract.

Paediatric multiprofessional group programs include also parents and are evidence-based (Epstein, Valoski, Wing, & McCurley 1994b; Oude Luttikhuis, Baur, Jansen, Shrewsbury, O'Malley, Stolk, & Summerbell 2009); therapy is provided by specialists in nutrition, physical

[2] The degree of overweight was quantified using Cole's Box Cox-transformation, normalizing the BMI skewed distribution in childhood and expressing BMI as a standard deviation score (SDS).

activity and psychology conducted by a specialized physician. Some programs are being organized outside tariff contract and were not included into KIDSSTEP evaluation (refer to Table 1, list of certified and other programs).

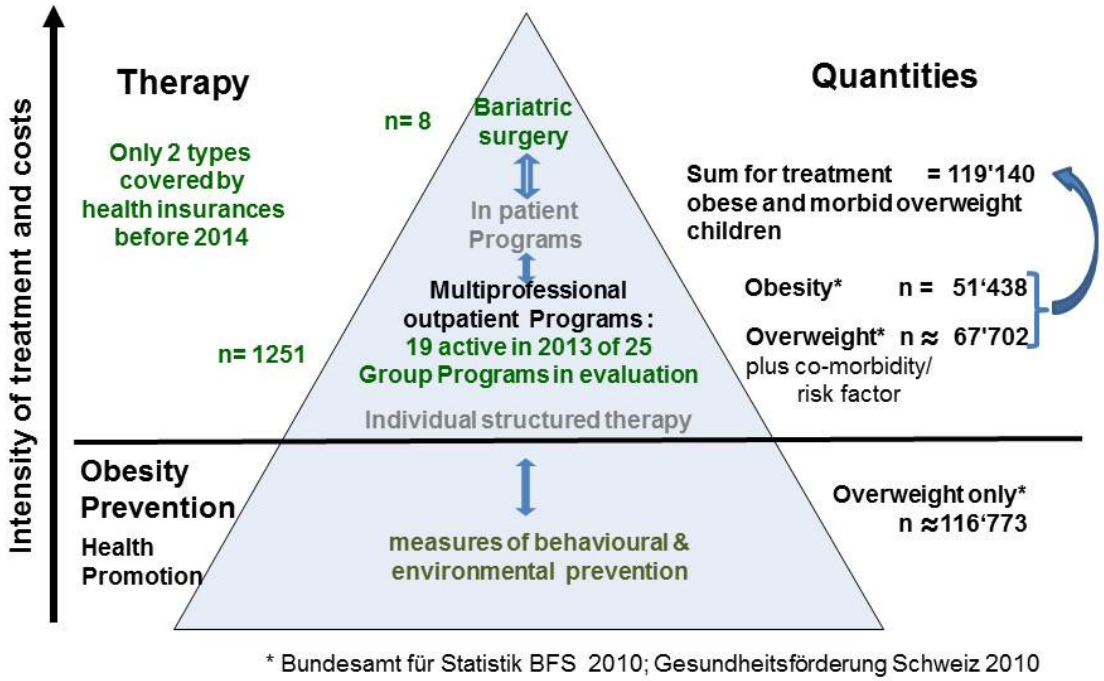


Figure 1: Pyramid of interventions in overweight children in Switzerland 2009-2013, revealing quantities of patients and forms of interventions according to Public Health Statistics(*)

In a unique system in Switzerland, the non-governmental organisation akj, Schweizerischer Fachverband Adipositas im Kindes- und Jugendalter, in accordance with the paediatric professional organisation SGP, is offering a central information system on obesity programs providers, supports health professionals in establishing qualified therapy services and gives free advice to patients seeking for therapy (www.akj-ch.ch). The evaluation of KIDSSTEP data (Figure 2) and formation of professionals is organised by akj, as well as the support in certification of programs.

Thus, in contrast to therapy programs offered for obese adults, paediatric obesity care is managed in a central and transparent way, combined with a system of quality control and information on all Swiss regions. During the pilot phase of group program evaluation 2009 to 2013, this work was in part supported by the FOPH grant for KIDSSTEP, but in future, governmental funding is no longer planned.

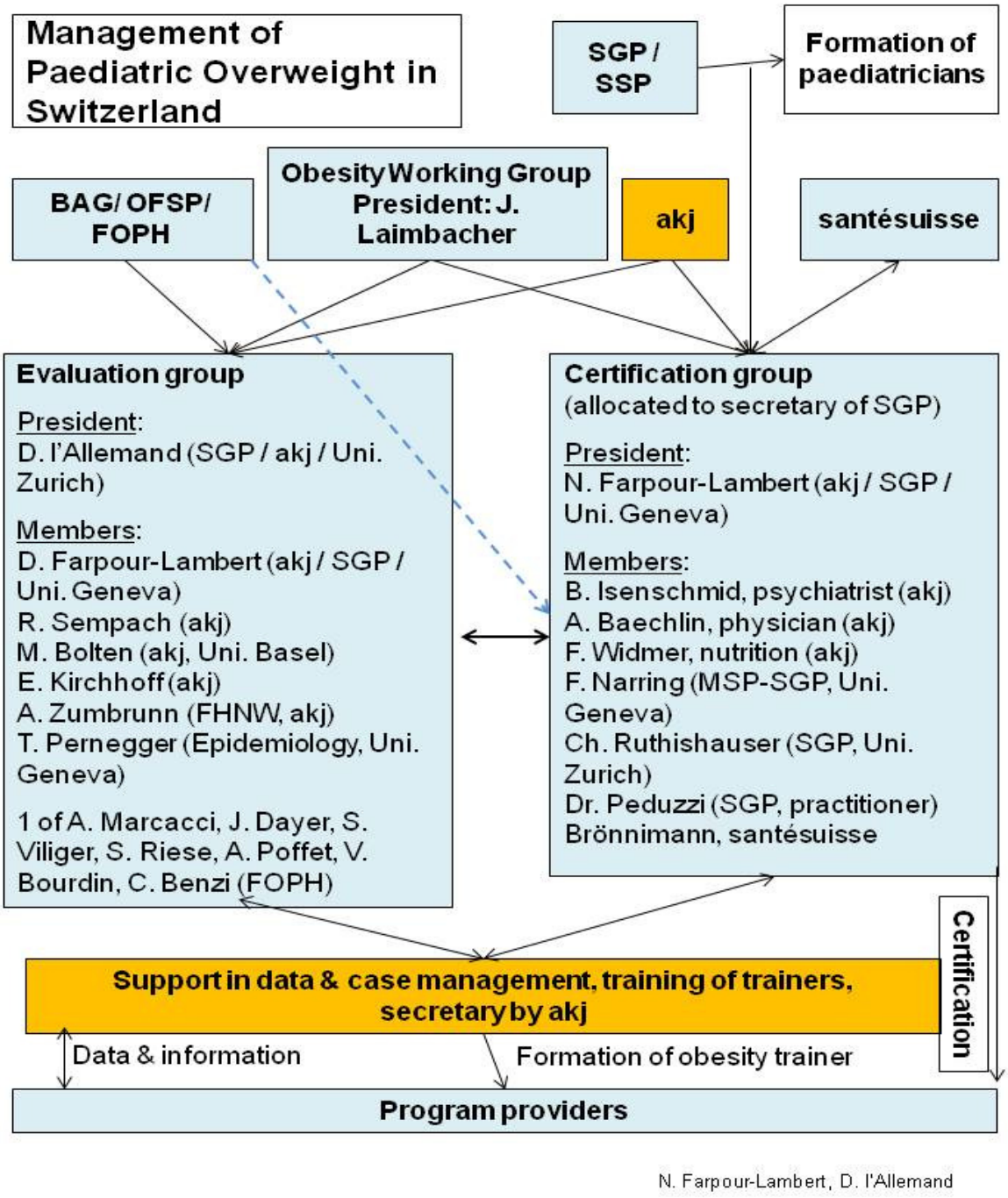


Figure 2: Flowsheet of organisation of obesity care in children and adolescents in Switzerland

Legend: SGP / SSP = Schweizerische Gesellschaft für Pädiatrie / Swiss Society of Paediatrics; BAG/ OFSP/ FOPH = Bundesamt für Gesundheit / Office fédéral de la santé publique / Federal Office of Public Health; akj = Fachverband Adipositas im Kindes- und Jugendalter. FNHW = Fachhochschule Nordwestschweiz; MSP = Société Suisse des Médecins Spécialistes en Prévention.

6.1.3 Tariff contract with santésuisse

On October 29th, 2008, tariff contract with santésuisse then representing all Swiss health insurers, was signed after negotiations with SGP and akj. Initially, the fixed structure of quantity including nutritionists, masters of sports and psychologists, had been designed for adolescents only and has proven its value during the pilot phase for this group. However, other modular therapy systems, e.g. shorter programs for younger children, were not accepted by santésuisse. Therefore, special therapy for young children with more active inclusion of parents cannot be provided in contrast to paediatric recommendations.

Duration of therapy and number of sessions are prescribed by the tariff contract and the quantitative guidelines, see enclosure 2. The adherence to the quantitative structure (112*45 min. in group and 4*60 min. in individual) is closely controlled by health insurances, represented by a member of santésuisse in the certification commission (Figure 2). Annual certification and re-certification procedures ensure quality and maintenance of standards as requested in the certification rules.

A novel accounting system, under guidance of a physician, was created for the flat rate of paediatric obesity group programs. The payment of the lump sum of 4200,- SFr. per patient and course, divided in 3 equal parts is only reimbursed by health insurances, if presence of a parent and the child in more than 90% of the courses is confirmed by the physician responsible of the program. The system applied of "Tiers Garant" (patient has to pay the costs of medical services and will be reimbursed by the health insurances) is difficult to manage by small program providers, as approximately 5% of patients did not pay the costs of the program, especially those dropping out.

6.1.4 Certification procedure

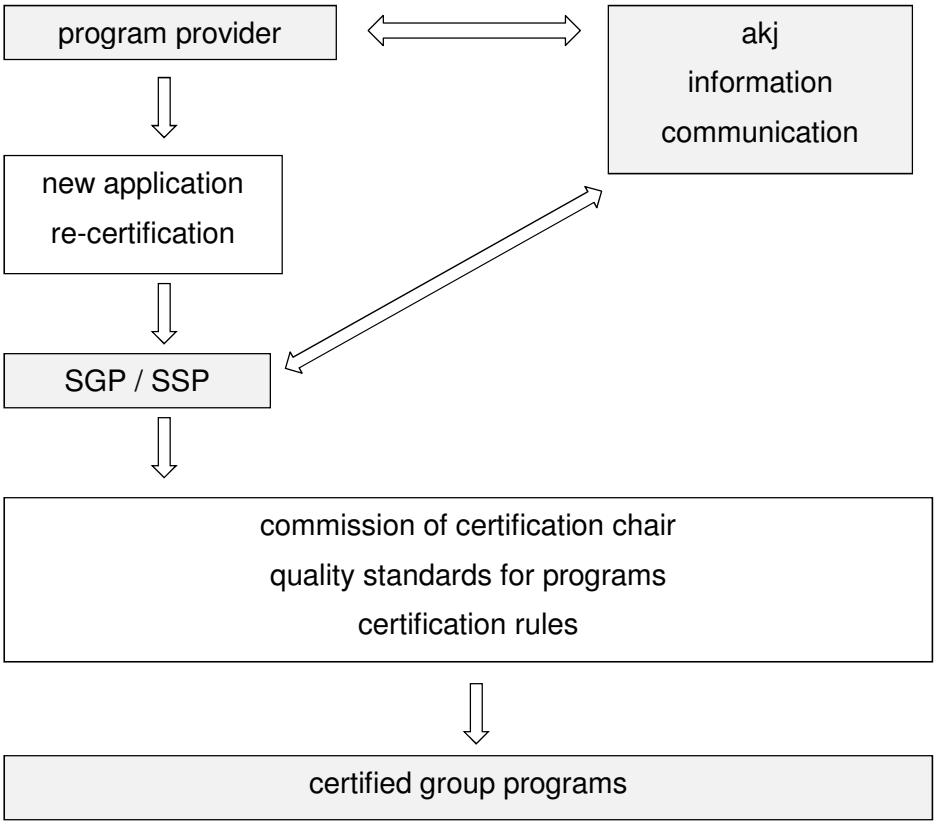


Figure 3: Certification procedure of paediatric obesity group programs

The implementation of certified group therapies in Switzerland (Figure 2, Figure 3, Figure 4) was described in milestone reports 2 to 6, 2008 – 2010 and the certification rules and documents can be downloaded from the SGP and akj websites (http://www.akj-ch.ch/fachpersonen/zertifizierung-mgp.html). The certification of paediatric obesity group therapy programs depends on continuous supply of patient's data and compliance with guidelines and certification rules (see http://www.akj-ch.ch/fachpersonen/zertifizierung-mgp.html), as convened by the Swiss Society of Paediatrics and the Fachverband Adipositas im Kindes- und Jugendalter (akj) according to the ordinance of the Swiss Department of the Interior (EDI) approved November 21st, 2007.

The certification is checked yearly, or after any change in the content of the program or in the professional team, by the national Certification Commission. It is composed by specialists in the field of childhood obesity. Currently, the new certification costs 1600.- CHF and the annual re-certification costs 200.- CHF. The procedure is directed by the SGP secretariat.

6.1.5 Paediatric obesity centres, providers of certified programs

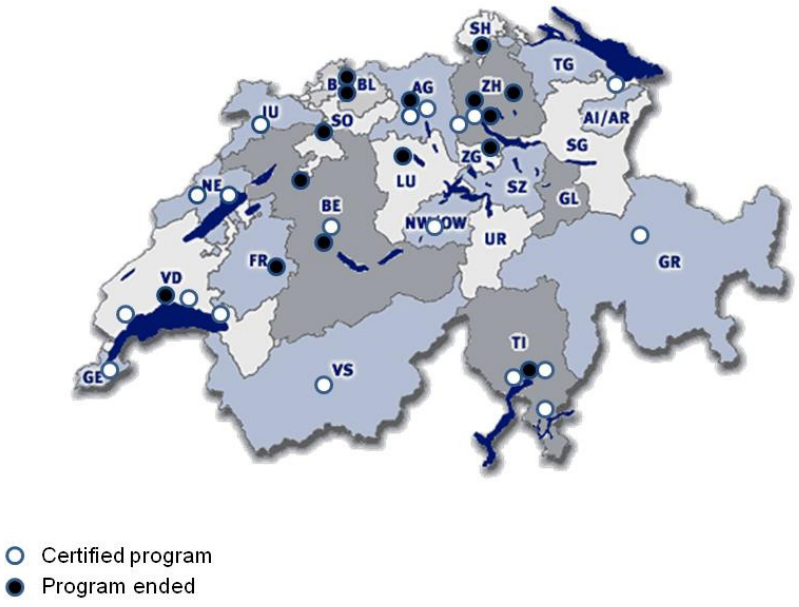


Figure 4: Group Programs in Switzerland in 2013/2014

The present study evaluates multiprofessional group therapy conducted in certified centres. Figure 4 and Table 1 show the 19 centres that are actually active. Hence, since 2009, 25 programs have been active within the tariff contract with santésuisse:

- 14 programs in the German speaking part , out of them 6 stopped working during 2011/12 and only 1 new opened,
- 7 in French speaking part, mostly in large centres adjoined to hospitals, 1 new program was opened in 12/2013,
- 3 in the Italian speaking part, 1 new was opened in 1/2012 and
- 1 in the Rhaeto-Romanic part.

Unfortunately, in the Eastern and central Southern part of Switzerland, no multiprofessional therapy programs can be offered to patients.

Though 33 programs were certified initially, only 25 of them could start one or more group therapy since 2009 (Figure 4). Only 19 out of 33 programs (58%) are re-certified and 17 have been active in 2013 (Table 1; for interpretation of these numbers, refer to discussion).

The reasons for 6 institutes in the German part to stop running programs was the lack of organizational and financial support by governmental health system; with admittance of tariff contract, cantonal and other funding had been withdrawn. The main problem of the program providers consists in an insufficient covering of the effective costs by the flat rate reimbursed by health insurances, in combination with the absence of payment by patients with low socioeconomic level. The cost-effectiveness can only be reached if the group size is at least 12 children, as there is at least 1 patient dropping out per group (death/ illness in the family, loss of employment, change in family situation,….).

Table 1: List of certified and re-certified group programs in March 2013 (refer to attachment 1)

Other reasons limiting the establishment of group therapies include:

1) the effort and time needed to organise and coordinate programs;
2) high personnel costs (qualified and experienced therapists are needed) without regular employment and;
3) difficulties in recruiting patients and families due to insufficient local availability, as shown in Figure 4.

Many programs cannot recruit more than 6 families per year for this comprehensive form of treatment, demanding a high involvement of the whole family, and so far were not able to start group therapy.

6.1.6 Formation of professionals

As described in the flow sheet, Figure 2, training of health care professionals to qualify for providing treatment in a paediatric obesity group program, , as described below and elsewhere (www.akj-ch.ch), is part of a post-professional formation and was offered by different providers, namely private organisations (in the German part of Switzerland):

- akj and "minufit" training programs
- Contrepoids training programs in the French part and
- KIDSSTEP training workshops during 2009 and 2012
- KIG-training centre workshop of the Euregio Bodensee project.

Curricula of these training courses were adapted from international standards (Stachow 2006; Epstein 1996; Golan 2006; Graf 2003) and their supervision was provided by the certification procedure (http://www.akj-ch.ch/fachpersonen/zertifizierung-mgp.html).
In the future, primary care providers will be actively encouraged to train in paediatric obesity care, as it is intended by a research project at the Institute of "Hausarztmedizin" in Bern (BIHAM for general practitioners in the cantons Bern and Fribourg).

This kind of formation is paid by professionals themselves and in part supported by sponsoring (Migros Kulturprozent,) or EU funding for KIG Euregio or by cantonal means for Contrepoids. It is planned that formation will be pre-requisite of certification for specialised care programs for overweight and obese children (Application at FOPH for Funding of MGP, Multiprofessionelle Gruppentherapieprograme, and MSIT, Multiprofessionelle strukturierte Individual-Therapie für übergewichtige und adipöse Kinder und Jugendliche).

6.2 Recruitment of patients and motivational analysis

Patients with BMI, fat mass or waist circumference above the 97th percentile, or a BMI above the 90th percentile plus a co-morbidity qualify for obesity therapy are referred to a program provider by their physician. All paediatricians in Switzerland, through the website and the journal of their professional association as well as all members of akj were informed on group programs for therapy pf obese children. Thus, the recruitment was nationwide and should have included all youth ready for therapy.

	Obesity manifestation	(as from anamnestic readings)	6.1 ± 3.7 years of age
Study population	Registration for therapy	n = 3482	12.2 ± 2.5 years of age
	[Motivational analysis	*n = 1771*	*(attrition rate > 17%)]*
	Medical and psychological examination	n = 3126	Contraindication in 60%
	Admittance to group therapy	n = 1251	36% admitted of referral
	Evaluation at start (T0) 53% female, 46% non-Swiss mother	n = 1013	(Completeness of data assessment = 87.3%)
	Evaluation at 1 y. (T2)	n = 682	Declared drop-out 6.0% (completeness of assessment = 87.5%)

Figure 5: Procedure of allocation to group programs for overweight children and adolescents 2009 - 2013

This referral process was delayed on average by 6 years after the manifestation of obesity (Figure **5**) according to present data. Yet, individual therapy had been started already by families in non-medical settings, namely 14.7% of children had psychotherapy, compared to an average of 7% in Swiss children, or nutrition counselling in 11 % or physiotherapy in 3% only, though orthopaedic problems were found about 70% of children (refer to chapter 7.2.1) or in 3% psychomotor therapy.
In multiprofessional group programs, children together with their parents will be enrolled in an intensive group program with 1- to 2-weekly sessions for 6 to 9 months, with 3 to15 months of follow up within the tariff contract. As in every chronic disease, follow up by physician is warranted at least 6 monthly, as long as overweight has not yet been normalized and co-morbidities resolved, usually, 2 to 5 years of follow up are recommended.

Table 2: Descriptive statistics on patients with or without allocation to group programs and drop-outs during the 1st year of therapy, 5 years of KIDSSTEP-Obesity

	Region			CH	
2009 - 2013	**German Part**	**French Part**	**Ticino & Grisons**	**Total**	**2013 only**
Program Provider (n)	14	7*	4	**25**	17
Total patients at referral (n)	1214	2050	218	**3482**	554
Total patients for examination (n) (% of referral)	961 (79.2%)	1968 (96.0%)	196 (89.9%)	**3126** **(89.8%)**	506 (91.3%)
Contra-indication for group program / not allocated (n) (% of examinations)	446 (46.1%)	1405 (71.4%)	19 (9.7%)	**1870** **(59.8%)**	294 (58.1%)
Group therapy participants (n) (% of referral)	511 (42.1%)	563 (27.5%)	177 (81.2%)	**1251** **(35.9%)**	224 (40.4%)
Dropouts (n) (% of participants)	42 (7.7%)	17 (3.4%)	13 (7.7%)	**72** **(6.1%)**	10 (4.5%)
patients per group (n)	12.2	9.4	12.6	**10.8**	11.9
Individual Therapy (n) (% of referral)	273 (22.5%)	764 (37.3%)	4 (1.8%)	**1041** **(29.9%)**	451 (81.4%)

(*1 new 2013)

As shown in Table 2, at least 10 % of patients referred retire before first medical examination by the specialist, but assessment of such data is impossible in this setting, which is not population based, but relied on referrals by physicians. In addition, Swiss health care system is based on individual responsibility; therapy is not based on public health care, but rather on private organisations, in this case 33 program providers of obesity therapy which makes nationwide assessments difficult. In centres, where data on referrals, motivation and resources are closely monitored, this primary attrition rate is 25%. This means that up to one quarter of families sent by their physician is not ready for any obesity therapy, mostly due to constraints by work load and a variety of psychosocial and motivational problems that cannot be analysed because patients did not answer to questionnaires and letters.
In a further step, inclusion criteria for group programs are checked by medical examination and psychological interview and, depending on the specialization of the centre, between 0% and 91%, on average 60% of patients cannot be allocated to group programs due to invalidity, psychosocial problems, occupation of parents (work, other family duties, illness …) or other limitations. Altogether, about 35% of patients referred finally participate in group

programs. Fortunately, the rate of patients offered a therapy in an individual setting in large centres, mainly for co-morbidities, did increase to 29.9% of all referrals in Switzerland.

The differences between centres in French and Germanic parts of Switzerland, namely that in the first, half the number of centres care for a double number of patients, can be explained by the cantonal or university's support in the Vaud and Geneva cantons, respectively, making it possible that program provider receive further support for recruitment and care of patients and can offer several groups per year and per centre for the treatment of obese children. In German parts, more private institutions offer programs with single groups and large hospitals are less interested in obesity group programs, because the costs for organisation are not covered by the actual reimbursement sum of 4200 CHF.

Before start of group treatment, insurer's approval to assume the costs has to be obtained and patients and parents sign a contract with program providers to guarantee regular participation and to assume the costs not covered by health insurances.

This rigorous procedure of recruitment for group programs is deemed necessary to find out problems of individual families that would interfere with their commitment before start of therapy and to keep the attrition rate as low as possible.

During the KIDSSTEP evaluation project, patients and parents had to give informed consent for anonymous evaluation of data.

6.3 Design of KIDSSTEP study

To yield sustained effects, paediatric obesity therapy aims at lifestyle changes of the child and its family and to reinforce the self-efficacy of the patient. In the out-patient setting of paediatric group programs, in general, weight loss by itself is less important than the other aims mentioned in Table 3, in order to avoid dieting and weight cycling.

Table 3: Aims of obesity treatment in children and adolescents and the respective methods of their evaluation (refer to 6.5 for further description, references and meaning of the abbreviations).

Aims of childhood obesity therapy	Methods of evaluation
1. Improvement of overweight-related co-morbidities.	Blood pressure, orthopaedic diagnoses, mental health problems SDQ, eating disorders AD-EVA (Blood metabolic markers at T2 only if pathological, refer to Milestone 7)
2. Insight into the individual causes of overweight (lifestyle, behaviours, psycho-social, environment, hereditary factors)	Family eating and activity questionnaires FEAH Questionnaires, AD-EVA
3. Augmentation of physical activity and improvement of body perception, as well as reduction of sedentary activities e.g. television, computer and electronic games…	Eurofit Test FEAH, (Activity questionnaires)
4. Improvement of nutritional habits and behaviours in the family (food choice, preparation, portions, rhythm of meals).	FEAH Questionnaires, (Food Frequency List FFQ, refer to Milestone 7)
5. Increases of self-esteem, well-being and aptitude to manage conflicts	Quality of life KIDSCREEN-52, SDQ, AD-EVA
6. Reinforcement of parenting skills.	FEAH Questionnaires, (ZKE (Reitzle et al 2001) refer to Milestone 7)
7. Stabilisation or reduction of BMI, waist circumference or fat mass, as associated effects of the above mentioned improvements of lifestyle and behaviours.	BMI-SDS, Waist / Height-Ratio, Waist circumference-SDS

All patients treated were included into a longitudinal prospective cohort study to explore changes and identify associations between outcome measures of obesity and potential influences by other variables. The following table shows the chosen measurement time points:

Table 4: Study design: Measurement time points

Measurement time point	description
T0	before the start of intensive phase of therapy
T1	directly at the end of the intensive phase of therapy
T2	one year after the start of the therapy
T3	two years after the start of the therapy
T4	three years after the start of the therapy

As shown in Table 5 at start (T0), after 1 year (T2) and 2 years (T3), standardized questionnaires ("instruments") validated in Swiss or European children were used to document changes during and after therapy. They assess motivation, personal and family history (at T0 only), weight of parents at T0 to T3 and psychosocial parameter (Table 5) these methods are further described in section 6.5.

Anonymized data were recorded centrally in an electronic database (akj, X. Martin, Geneva), after controlling for completeness and plausibility.
To guarantee meaningful analyses, data of patients with complete evaluation (until T2) were included when they started therapy before July 2012.

Thereafter, therapy is being reimbursed, if a minimum of 9 parameters is provided to comply with quality control standards, as specified in paediatric recommendations (chapter 9) below.

Table 5: Study design and tests performed during KIDSSTEP study (for explanation refer to the final report of the first part of the study, l'Allemand et al. 2009)

		T0	**T1**	**T2**	**T3 & T4**
Instrument	**Nr.**	Start	End of intensive phase	1 year after start	2 & 3 years after start
Time after T0			6-9 months	12-13 months	23-26 months
Medical examination	04, 05	+	(+)	++	
Blood tests for obesity	05	+	-	(+)	(+)
Motivation questionnaires & interviews	06, 07, 08, 10 (09)	+	-	--	
Weight of parents	21	+	+	+	+
Eurofit-Test	11	+	+	+ (if Δ T1 > 3 months)	+
Questionnaires on quality of life, family habits, nutrition, physical activity, mental health, eating disorders, parenting skills	12-17 (child & parent)	+	-	+	+
Satisfaction with therapy	18, 19 (child & parent)	-	-	+	-

6.4 Structure of intervention and follow-up of MGPs included in the flat rate

Obesity is a complex disease, therefore many different forms of therapy have proven to be efficacious (Oude Luttikhuis, Baur, Jansen, Shrewsbury, O'Malley, Stolk, & Summerbell 2009), if including counselling on nutrition, healthy behaviour and physical activity. Usually, duration and intensity of therapy have to be adapted to the needs of the patient and his family.

Within the current pilot project, only one form of group therapy was approved (EDI decree and tariff contract) and reimbursed within the flat rate of 4200.- SFr. according to a time table strictly controlled by health insurances (Table 6):

Table 6: Structure of MGPs for children and adolescents in Switzerland according to tariff contract 2009

Group program total version, Tariff 2009 Amount of units with presence of child/adolescent and parents:					
Intensive phase of group therapy:					
	Number of meetings	amount	min	Total units	hours
Child/adolescent 35 units with 2 x 45 minutes	35	2	45	70	52.5
Parents 15 units with 2 x 45 minutes	15	2	45	30	22.5
Parents and child/adolescent together 6 units with 1 x 45 minutes	6	1	45	6	4.5
Individual therapy 3 units with 1 x 60 minutes	3	1	60	3	3
subtotal				**109**	**82.5**
Total follow up care / follow up meetings					
Child/adolescent 2 units with 1 x 45 minutes	2	1	45	2	1.5
Parents 2 units with 1 x 45 minutes	2	1	45	2	1.5
Parents and child/adolescent together 2 units with 1 x 45 minutes	2	1	45	2	1.5
Individual therapy 1 unit with 1 x 60 minutes	1	1	60	1	1
subtotal				**7**	**5.5**
Patient (incl. parents) total hours				***116***	***88***

The average duration of the intensive phase of therapy, measured as the time interval between Eurofit tests, performed at start and end of the intensive course (T0 and T1) was = 8.83 months (± 3.20 months).

The total duration of therapy including the follow-up phase was 13.72 ± 3.00 months (time interval between T0 and completion of questionnaires at T2).

6.5 Methods of evaluation

6.5.1 Medical history and somatic examination

Questionnaires on medical history were completed by parents before the first medical examination and amended by the physician. Weight and height were measured according to standardised procedures by physicians before start of therapy as described in the medical questionnaire attached (medical status). waist circumference (WC) was recommended to be

measured with a flexible, non-elastic band and defined as the smallest abdominal girth between the lowest rib and the upper anterior iliac spine (l'Allemand , Farpour-Lambert, & Laimbacher 2006). WtHR was calculated by the formula: waist circumference in centimetres divided by body height in centimetres. Pubertal stage was assessed according to Tanner, as depicted in the attachment. Tanner stages 1 and 2 were combined as pre-/early pubertal, stages 3 and 4 as pubertal, and stages 5 (and P6, if applicable) defined postpubertal development. Blood pressure was measured following standardised procedures, and reference values for height- and age-specific cut offs for blood pressure measurements were based on the recommendations of the American Heart Association (National Institutes of Health (U.S.) 2004). Hypertension was defined as blood pressure above 95th percentile.

Blood tests were performed in all children with obesity by the referring physician or before start of therapy and results were reported in interim reports. For ethical reasons, only abnormal levels were controlled at T1 to T3 and could not be evaluated systematically in all children during follow-up. It has been shown elsewhere that these parameter decrease during obesity therapy (refer to discussion).

6.5.2 Psychosocial interview and questionnaires

In order to identify relevant behavioural and mental health predictors of obesity as well as comorbidities and consequences, we used different standardised instruments.

Quality of life:

In the present study, health-related quality of life (HRQoL) was therefore measured by a standardized questionnaire (KIDSCREEN-52) which has been developed in international cooperation as self-report measure applicable for healthy and chronically ill children and adolescents and was validated in German Swiss children (Bisegger & Cloetta 2005). The instrument assesses in a comprehensive way physical, psychological, social, family and educational dimensions of well-being and functioning of children and adolescents (www.kidscreen.org, Ravens-Sieberer, U., & the European KIDSCREEN Group, 2006 (Ravens-Sieberer & The KIDSCREEN Group 2006).

Screening for psychological disorders

The Strengths and Difficulties Questionnaire (SDQ, (Goodman 1999)), is a brief behavioural screening questionnaire (25 questions) for parents (and teachers, but not in this study) that provide balanced coverage of children and young people's behaviours, emotions, and relationships. Clinical cut-off-levels are provided to define a likely disorder. It is available in German, French and Italian versions for baseline and follow-up investigations.

Eating behaviour:

For eating behaviour and (pre)clinical eating disorders, parts of the "AD-EVA Interdisciplinary Test System for Diagnosis and Evaluation of Obesity and Other Diseases Influenceable through Eating and Exercise Behaviour" (Ardelt-Gattinger & Meindl 2010) were used, namely items on:

- salutogenic eating cognitions on healthy exercise and eating behaviour;
- pathogenic eating cognitions, i.e. the subscale on emotional eating;
- craving and addiction to overeating;
- preclinical eating disorders in 2 dimensions, namely,
  - preoccupation with weight and shape and
  - symptoms of (pre)clinical eating disorders (vomiting, purging and binge eating)

Questionnaires on motivation for therapy (developed by M. Bolten and R. Sempach), food frequency (FFQ)(Cavadini et al 1999), physical activity (Bringolf-Isler et al 2007) or satisfaction with therapy (Stachow et al 2004) were not filled in correctly or did not yield plausible answers, mainly due to unrealistic information or to please therapeutic team. Therefore, these data have not been included in the current evaluation.

6.5.3 Eurofit test and activity questionnaires

Modified Eurofit Test

Aerobic fitness, muscle strength, balance and coordination will be assessed using a modified "Eurofit" test (Narring et al 1999) which includes 6 tests: the "Flamingo" test (balance), the 50 plate taping (coordination), the standing long jump (legs strength and power), the sit-up test (abdominal muscular endurance), shuttle run 5x10m (speed and coordination), and the modified 20-meter shuttle test (according to Luc Léger, cardiorespiratory fitness). These tests have been widely used in sport education and research, validated in healthy children as well as adapted to obese children (l'Allemand, Sempach, Farpour.Lambert et al 2009).

Child and family lifestyle FEAH

The revised form of the Family Eating and Activity Habits Questionnaire - Revised- (FEAH, (Golan & Weizman 1998)) kindly provided by the authors was used to determine family lifestyle and nutrition. The 11-item questionnaire was validated in parents of normal and overweight children below 11 years in Israel.

6.6 Sample description

6.6.1 Return rate and completeness of examination

There was no significant difference in age, BMI and other somatic parameters, as displayed in Table 12 in the subgroup comprising data of 898 patients assessed between 2009 to 2012 as compared to the 1013 children of the total sample 2009 to 2013. Therefore, results on pycho-social background, co-morbidities and parents include data until 2012 only,

There were two methods to assess the total of patients included:

1. statistics of program providers, declaring the number of patients (n=1251) and drop-outs included in each program group before December, 31st, 2013 (Table 2) and
2. Patient's data, assessed by questionnaires returned before December 1st, 2013, n = 1161 (Table 12).

In response to several reminders, 1161 children or adolescents and their families returned at least one questionnaire before therapy and their data were entered into the database after intensive control of plausibility by each researcher in his field (Table 12). This corresponds to a response rate of 87.3% at T0. Missing of questionnaires was due to the fact that not all patients' data was transmitted to the study centre, though this was pre-requisite for reimbursement of therapy.
Out of 1161 patients included, 36 withdrew from therapy immediately before start.
In addition, data of most patients starting in 2013 were assessed by a simplified questionnaire and therefore, 112 BMI data were not included into this evaluation. Data of children starting therapy in 2013 will continue their program until end of 2014 and this simplified evaluation will be presented to the FOPH at the end of February 2014.

To calculate the return rate of follow-up data until the final inclusion date of December 31st, 2013 (Table 2), the number of patients continuing therapy after T0 was assumed, according to the provider's declaration, as follows:

At T0 2009-20013, total of patients with BMI n = 1013

After 1 year,T2, Expected, subtracting 224 new patients in 2013, minus 10 drop-outs
n = 779
T2, Measured n = 682 => 87.5% return.

After 2 years,T3, Expected, subtracting 276 new patients in 2012, 8 drop-outs and 13 normal weight children at T2 n = 697
T3, Measured n = 354 => 50.8% return.

After 3 years, T4, Expected, subtracting 225 new patients in 2011, 19 dropouts and 28 normal weight children at T3 n = 438
T4, Measured n = 53 => 12.1% return.

Since the declared drop out from therapy was around 6% and already considered and since reimbursement during the first year of therapy until T2 was dependent on documented presence of patients, the main reason for the incomplete return rate is not the drop-out from therapy during the first year. In contrast, the low return rate seems to be due to the fact that patients were not examined at T2 or data not transmitted by the physician.

Later, in the follow-up, a higher dropout rate could not be avoided within this real-life evaluation study. Completeness of examination or reporting was even lower for other parameter (blood pressure measured or reported only in 83.5% of BMIs assessed at T0 and in 69.5% only at T2; similarly for waist circumference).

6.6.2 Age, gender, puberty and other forms of obesity

The average age of patients in the analysed data set is 12.2 years, including 54.3 % of girls (Table 7). In accordance with age, a prepubertal or early pubertal (for boys) to mid-pubertal (for girls) stage of sexual maturation is present in about two thirds of patients. Therefore, most participants are 12 to 14 years old between T0 and T3, having to manage not only the change into the secondary school but also the peak of pubertal development.

Table 7: Description of patients before therapy

Patients 2009 - 2013	N total measured	T0 Mean ± SD, or proportion measured
Age (years)	1013	12.2 ± 2.5
Gender		54.3 % girls
Pubic hair stage ≥2 (= start of puberty, see enclosure) in %	613	62.1 %
Breast stage ≥2 in girls in %	403	73.0 %
Genital stage ≥2 in boys in %	308	55.8 %

Patients with secondary obesity were rare at T0 and T2:

- endocrine 3.0 % (e.g. Hypothyroidism with treatment) or
- iatrogenic 2.2 % (e.g. following glucocorticoid therapy)
- no patients with syndromal obesity and
- less than 2 % with dysmorphic signs.

6.6.3 Migration background

More than half of parents originated from Switzerland (see Table 8). The second most occurring origins were the Balkans and countries of Southern Europe. Other cultural/geographical parts of the world as Middle Europe, Middle East or Northern Africa built up a smaller part of the foreign parents.

Bearing in mind that we didn't have information from all parents, we may assume that the migration background is overrepresented in our sample, compared to Swiss statistical data (Table 8). This may be the case because children of migrated parents aren't reached by public health (primary prevention and health promotion) as wanted.

Table 8: Percentage of parents originating from Switzerland or foreign countries compared with permanent resident population of Switzerland in the age range of 20 to 64 years (end of year 2010) [3]

Data of 2009-2012	mothers		Swiss population (women)	fathers		Swiss population (men)
	n	%		n	%	
Switzerland	392	54.4%	75.9%	353	50.4%	72.6%
Total foreign	328	45.6%	24.1%	347	49.6%	27.4%
Balkans	120			124		
Southern Europe	79			105		
Other regions	129			118		
Total reported	720			700		

In the whole, the origin of 698 *couples* of parents is known: Within 294 couples (42.1%) both parents originated from Switzerland and the higher rate of families with migration background mirrors the higher rate of obesity in children of non-Swiss origin (refer to discussion in chapter 8.2). Within 261 couples (37.4%) both parents originated from foreign countries, whereas within 58 couples (8.3%) only the mother and within 85 couples (12.2%) only the father originated from foreign.

At T0, 360 parents (66.9% of 538 parents reporting their marital status) are married, additional 49 parents (9.1%) live in relationship (some of them after divorce); 129 of the parents completing the questionnaire reported to live without partner (24.0%). Compared with official information concerning household structure in Swiss households in the year 2010, where 15.2% of households with children were kept by single-parents, the quota of single-parents with children in our study is somewhat higher[4].

6.6.4 Socioeconomic status of parents

6.6.4.1 Education

Compared to the statistics of the population of Switzerland in 2010, parents of overweight children and adolescents included in this cohort were somewhat less educated, with higher

[3] See Swiss Federal Statistical Office, download 20th April 2012, http://www.bfs.admin.ch/bfs/portal/de/index/themen/01/02/blank/key/alter/nach_staatsangehoerigkeit.html, see Excel table „Altersmasszahlen der ständigen Wohnbevölkerung nach Staatsangehörigkeit und Geschlecht"

[4] See Swiss Federal Statistical Office, download 29th April 2012, http://www.bfs.admin.ch/bfs/portal/de/index/themen/01/04/blank/key/haushaltstypen.html, Excel table "Haushaltsstruktur"

proportions observed in the lowest level (no degree / compulsory school) and lower quota in the highest level (higher vocational education / university). Table 9 show the data for mothers and fathers in dependence of their origin. Comparing these two groups of origin, significant overrepresentations of levels of education are coloured in grey.

Table 9: Percentage of educational levels of mothers and fathers, separated for Swiss and foreign origin, compared with Swiss population (year 2010, age range of 25 to 64) [5,6]

a) Mothers[a]

Data of	Swiss		foreign		Swiss population
2009-2012	n	%	n	%	(women)
none	1	0.3%	**18**	**7.7%**	--
compulsory school	37	11.4%	**95**	**40.6%**	17.4%
vocational education	**209**	**64.5%**	53	22.6%	44.0%
"Maturität"	**19**	**5.9%**	22	9.4%	10.0%
higher vocat. education	46	14.2%	12	5.1%	7.7%
university	12	3.7%	34	14.5%	20.9%
total reported	324		234		

[a] $\chi^2 = 104.085$, $p < .001$

b) Fathers[b]

Data of	Swiss		foreign		Swiss population
2009-2012	n	%	n	%	(men)
none	0	0.0%	**9**	**4.1%**	--
compulsory school	25	9.5%	**87**	**39.7%**	11.1%
vocational education	**153**	**58.0%**	48	21.9%	40.9%
"Maturität"	**8**	**3.0%**	21	9.6%	6.2%
higher vocat. education	45	17.0%	15	6.8%	14.2%
university	33	12.5%	39	17.8%	27.6%
total reported	264		219		

[b] $\chi^2 = 79.321$, $p < .001$

6.6.4.2 Employment

The workload out of home was reported by 534 mothers and 461 fathers (56.7% and 49.0% of the T0 sample of patients). Differences of workload in dependence of origin of parents are presented in Table 10 (lower sample size due to missing data); comparing these two groups of origin, significant overrepresentations of levels of workload are coloured in grey.

[5] See Swiss Federal Statistical Office, download 20th April 2012, for population with age of 25 to 64 years, http://www.bfs.admin.ch/bfs/portal/de/index/themen/15/01/key/blank/01.html

[6] Chi^2 tests were performed for differences of education between Swiss and foreign parents, separating 3 levels of education: compulsory school (incl. no degree) vs. secondary level (vocational education / "Maturität") vs. tertiary level (higher vocational education / university). Highlighted & **bold** = significant overrepresentation of one group of origin, compared to the other group.

Table 10: Workload per week of mothers and fathers in % of total reported, separated for Swiss and foreign origin

	mothers (n=486)[a]				fathers (n=422)[b]			
Data of	Swiss		foreign		Swiss		foreign	
2009-2012	n	%	n	%	n	%	n	%
<10h	65	22.5%	52	26.4%	7	2.9%	**20**	**11.1%**
11-20h	**66**	**22.8%**	28	14.2%	2	0.8%	6	3.3%
21-30h	**77**	**26.6%**	37	18.8%	6	2.5%	5	2.8%
>30h	81	28.0%	**80**	**40.6%**	**227**	**93.8%**	149	82.8%
Total reported	289		197		242		180	

[a] within mothers, Chi^2-Test for workload and origin: $\chi^2 = 13.931$, p = .003
[b] within fathers, Chi^2-Test for workload and origin: $\chi^2 = 15.762$, p = .001

6.7 Statistical analyses

Statistical analyses were performed by specialists in each field being supervised by public health scientists. Statistical evaluation was performed using SPSS version 19. Categorical data are shown as number (n) and percentage (%), sometimes analysed for statistical significance of deviations by Chi^2 tests. Continuous data are presented as mean ± standard deviation (SD) if data were normally distributed, and median and minimum/maximum range if no normal distribution could be assumed. All measurement time points in focus were analysed descriptively with the total cross-sectional sample for cross-sectional results:

- T0 = before start of therapy,
- T1 = end of the intensive therapy
- T2 = one year after start of therapy,
- T3 = two years after start of therapy.

For some cross-sectional analyses, univariate ANOVA were used. Samples with longitudinally available data were analysed separately for tests of changes, using ANOVA (GLM) with repeated measures, including T0 – T2 - T3 data[7]. For all analyses, values were considered to be significant at the p≤0.05 level. Effect sizes were computed by eta square (η^2) with interpretation of the scores as following (Bortz 2005)[8]:

$\eta^2 < .06$ = low effect
$.06 <= \eta^2 <. 14$ = middle effect
$\eta^2 >= .14$ strong effect.

A special section of analyses focused the question if patients and families dropping out from program during the intensive phase of therapy (<T1) differed from patients finishing the therapy (≥T1). The base line data (T0) for these two groups were compared by univariate ANOVA or Chi^2 tests.

[7] Sometimes including T1 data, if T2 data were not available; especially done for BMI.
[8] The effect size (ES) measures the strength of the relationship between two variables, i.e. the magnitude of a treatment effect, by providing standard indices. Unlike significance tests, these indices are independent of sample size. ES measures are the common currency of meta-analysis studies that summarize the findings from a specific area of research.

6.8 Ethical votes

According to legal advice of FOPH, a positive ethical vote by the responsible cantonal ethical commission had to be obtained for each of the 24 programs delivering data, though the analysis of quantitative statistics was prescribed by EDI and pre-condition to be allocated to a group therapy program (see Table 11). Informed consent to participate in such an analysis was obtained by each patient and his parents or caregivers.

Table 11: Positive votes of cantonal ethical commissions – KIDSSTEP Obesity, unchanged since 29.4.2011

	Ethical commission	**fees**	**Date of positive vote**	**region**
1	Aargau	3000.- CHF	Jul 09	Aargau, Solothurn
2	St. Gallen	free of charge	Jul 08	Appenzell IR, St. Gallen
2	Appenzell	Emdedded in program of St. Gallen		Appenzell AR
3	Basel	1000.- CHF	Oct 09	Basel Stadt, Basel Land
4	Bern	2500.- CHF	Feb 11	Bern
5	Fribourg, Jura, Neuchàtel	No program		Fribourg, Jura, Neuchâtel
6	Genf	free of charge	Aug 09	Genf
7	Zürich	1000.- CHF	Sept 09	Glarus, Graubünden, Schaffhausen, Zürich
8	Luzern	500.- CHF	Feb 09	Luzern, Obwalden, Nidwalden, Schwyz, Uri, Zug
9	Thurgau	no program		Thurgau
10	Tessin	free of charge	Feb 11	Tessin
11	Wallis	500.- CHF	Sept 09	Wallis
12	Waadt	500.- CHF	Sept 09	Waadt

7 Results

7.1 Obesity

Table 12: Baseline somatic parameter of patients in the groups with and without therapy, 2009-2013. Data of the total group until 2012 for comparison (refer to Methods for explanation).

Parameter before therapy	2009 – 2013 Group Therapy						2009 – 2013 No Therapy						2009 – 2012 Total Group					
T0	n	**Mean**	SD	**Median**	min	max	n	**Mean**	SD	**Median**	min	max	n	**Mean**	SD	**Median**	min	max
Age (years)	1013	**12.2**	2.5	**12.2**	4.5	18.4	32	**11.8**	2.83	**11.8**	5.9	17.9	898	**12.1**	2.5	**12.2**	3.5	18.3
BMI_T0 (kg/m^2)	1013	**29.5**	5.2	**28.4**	19.6	55.9	31	**28.1**	4.5	**28.0**	20.7	37.8	898	**29.4**	5.2	**28.3**	19.6	55.9
BMI T0 (SDS)	1013	**2.88**	0.78	**2.76**	0.90	8.72	31	**2.75**	0.77	**2.86**	1.20	4.30	898	**2.88**	0.78	**2.76**	0.9	8.72
Waist circumference (cm)	899	**91.1**	11.9	**90.0**	58.0	140	30	**85.9**	12.1	**86.0**	63	128	727	**90.9**	12.2	**90.0**	58	140
Waist circumference (SDS)	835	**2.69**	0.53	**2.74**	0.14	4.53	30	**2.47**	0.64	**2.51**	0.80	3.90	726	**2.69**	0.5	**2.7**	0.1	4.5
Waist/Height ratio (cm/cm)	834	**0.59**	0.06	**0.58**	0.43	0.80	30	**0.57**	0.25	**0.57**	0.46	0.70	726	**0.59**	0.06	**0.58**	0.20	0.80
Waist/Hip ratio (cm/cm)	759	**0.91**	0.08	**0.90**	0.70	1.21	30	**0.90**	0.10	**0.87**	0.74	1.10	680	**0.91**	0.08	**0.9**	0.7	1.21
Waist/Hip ratio (SDS)	761	**1.49**	1.13	**1.45**	-1.75	5.40	30	**1.25**	1.39	**1.19**	-1.23	4.17	680	**1.5**	1.2	**1.4**	-2.1	5.4
Syst.Blood Press. (mmHg)	924	**115**	12	**114**	66	160	28	**113**	15	**110**	94	170	750	**115**	12	**115**	82	170
Dias.Blood Press.(mmHg)	923	**68**	10	**68**	40	110	29	**70**	9	**70**	58	90	750	**68**	10	**68**	40	110
Syst.Blood Press. (SDS)	924	**0.71**	1.08	**0.67**	-2.57	4.95	27	**0.56**	1.35	**0.38**	-1.31	5.51	739	**0.75**	1.07	**0.67**	-1.91	5.51
Dias.Blood Press. (SDS)	923	**0.44**	0.90	**0.43**	-2.19	4.05	28	**0.65**	0.78	**0.71**	-0.34	2.59	739	**0.45**	0.91	**0.43**	-2.19	4.05

The aim of the present study was to analyse the effects of Swiss group programs in overweight children. Nevertheless, it was possible to analyse also data of children not able to participate in this therapy setting. Data before start of therapy (table 1) show that children refraining from therapy before start are slightly, but not significantly younger and less obese than the children starting group therapy; other somatic parameter did not differ between both groups. In addition, the data added to the database in 2013 did not lead to significant changes. Therefore, all calculations of other parameters than BMI and waist circumference were made with the dataset of 2009 – 2012.

7.1.1 BMI

Table 13: Childrens' BMI classification 2009-2013

BMI class by percentile range adjusting for age & gender (kg/m^2 at medical or sports examination)	T0 (before therapy)		T1 (6-9 months)		T2 (12 months)		T3 (24 months)		T4 (36 months)	
	n	% total	n	% total	n	% total	n	% total	n	% total
0= Normal Weight P.<90	2	0.2	13	1.9	28	4.1	25	7.1	4	7.5
1= Overweight P.>90<97	47	4.6	91	13.6	85	12.5	49	13.8	9	17.0
2= Obesity P.> 97<99.5	168	16.6	133	19.9	131	19.2	62	17.5	7	13.2
3= Extreme OB >P.99.5	796	**78.6**	432	**64.6**	438	**64.2**	218	**61.6**	33	**62.3**
Total BMI class	1013	100.0	669	100.0	682	100.0	354	100.0	53	100.0

Nearly 80 % of children treated presented with an extreme obesity, corresponding to a BMI >40kg/m^2 in adults. During the intensive phase and directly after therapy, this percentage decreased to 64.% and remained stable at 62% after 2 and 3 years (Table 13). Though the incomplete assessment at T3 and T4 could give a wrongly beneficial outcome, the significant and constant decrease of BMI over time was also confirmed in the longitudinal sample (T0 – T3, Figure 7).

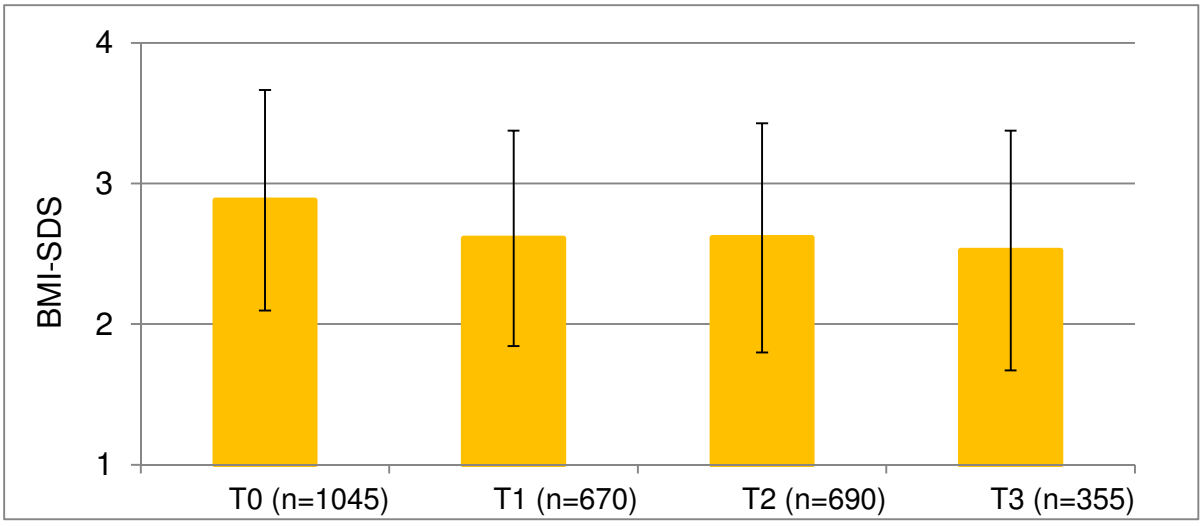


Figure 6: BMI-SDS 2009-2013, means and standard deviations for T0 to T3 (cross-sectional)

After all, 70.5% of children decreased their BMI-SDS (Table 13 as well as Figure 6 and Figure 7, and Table 14), as measured in 874 children after the end of therapy and 1 year after the end of therapy, at T3, 71.2 % or 354 children had decreased their BMI-SDS.

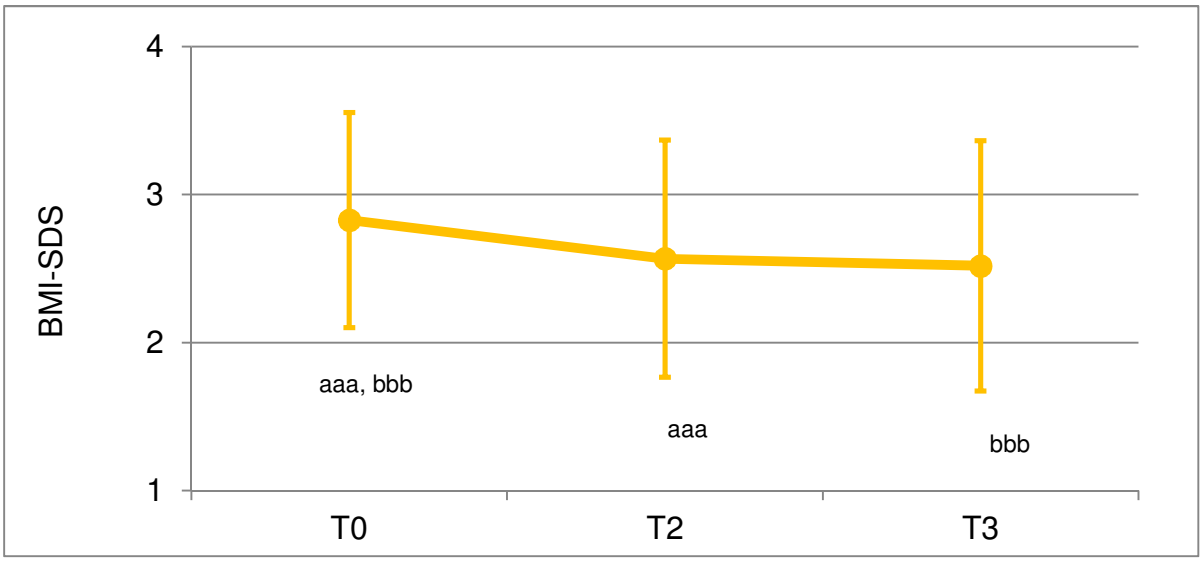


Figure 7: BMI-SDS 2009-2013, means and standard deviations for T0 to T3 (longitudinal, n = 344)
Legend: [aaa / bbb]: significant differences with p < .001 between same indices.

Also in the longitudinal sample, the decrease of both obesity parameters was highly significant, as shown in the previous tables and figures.

Out of 874 children after therapy (9-12 months),

- 47.5% decreased significantly their BMI by more than -0.2 SD,
- 23.0% showed smaller decrease between -0.01 and -0.2 SD and
- 18.9% decreased their BMI significantly by more than - 0.5 SD.

A clinically relevant decrease of BMI-SDS >0.5 is predicting significant changes in metabolic parameters as a decrease of insulin resistance (Reinehr & Andler 2004).

Table 14: Reduction of obesity during and after therapy (data of 2009-2013)

	TO	**T1-T0**	**T2-T0**	**T3-T0**	**T3-T2**	**T4-T0**
Delta BMI SDS	M± SEM n p η^2	**-0.21±0.01** 663 0.000 .25	**-0.23±0.02** 680 0.000 .21	**-0.31±0.3** 351 0.000 .30	-0.05±0.02 344 n.s. .30	-0.24±0.09 50 0.01 .13
Delta Waist/ Height (cm/cm)	M± SEM n η^2	**-.015±.002** 322 0.000 .11	**-.022±.002** 377 0.000 .19	**-.029±.005** 159 0.000 .30	-.001±.004 159 n.s. .30	-.022±.014 30 n.s. .08

Legend: Reduction was defined asdifferences (Delta) of BMI-SDS or WHtR between visits T0 –T2 – T3. SDS (Standard deviation score) adjusted for gender and age was normally distributed. (Statistical significance by ANOVA for repeated measures, p, and effect size η^2 refer to methods)

7.1.2 Waist circumference and Waist to Height ratio

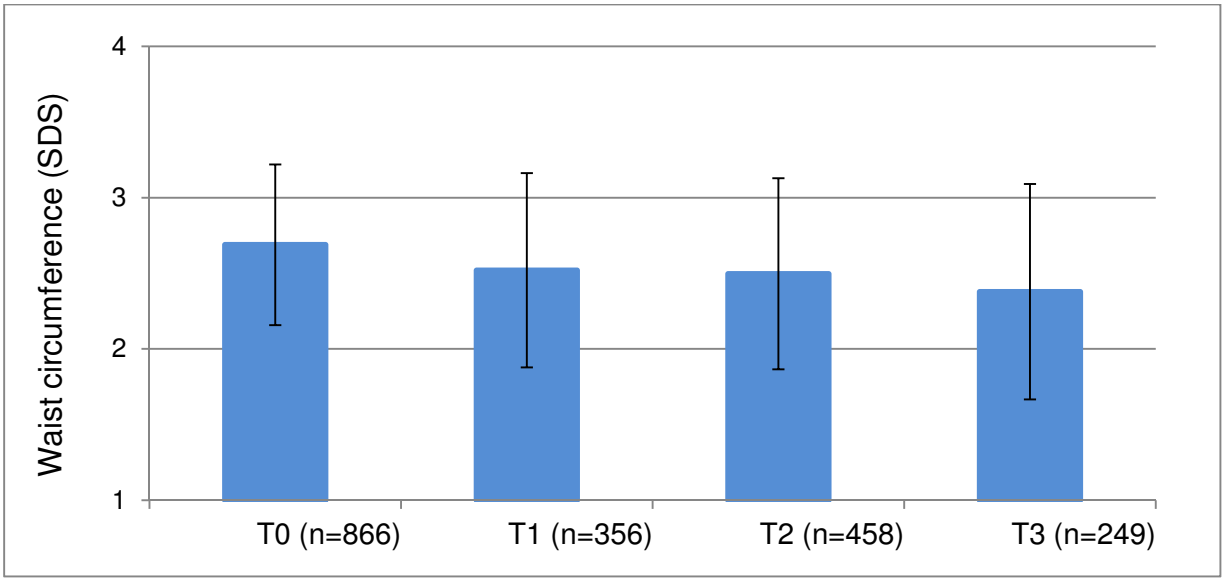


Figure 8: Waist circumference SDS, means and standard deviations for T0 to T3 (cross-sectional, 2009-2013)

Results for waist circumference SDS were similar to waist circumference–to-height-ratio (Figure 8 and Figure 9).

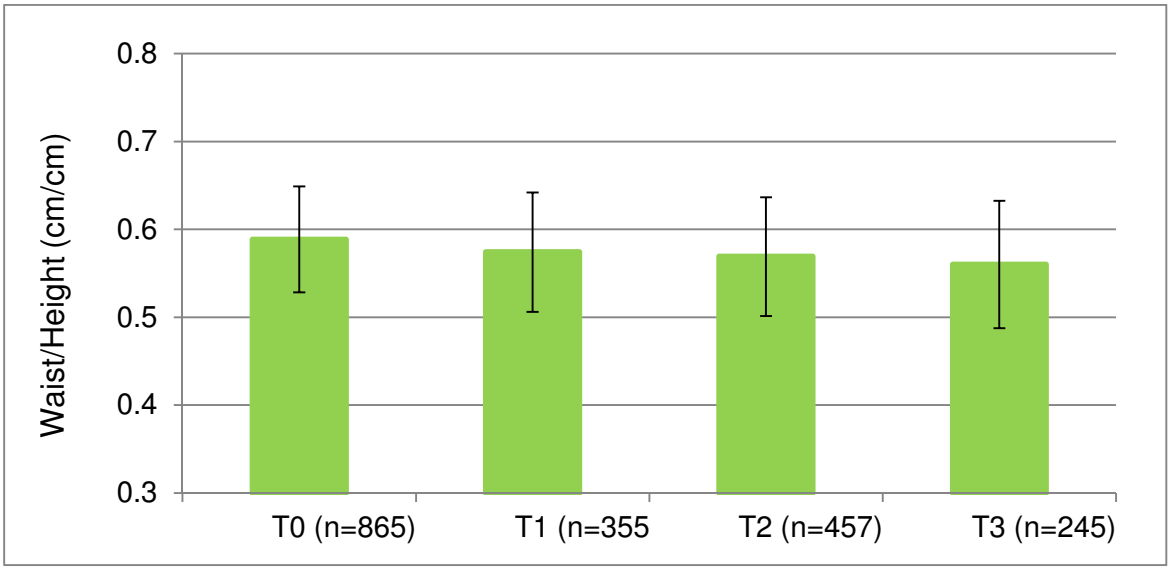


Figure 9: Waist to height ratio (cm/cm), means and standard deviations for T0 to T3 (cross-sectional, 2009-2013)

WHtR is easier to assess in medical examinations, because no percentile charts must be referred to. Therefore this measure was examined in the present study. WHtR decreased significantly during the intervention in 66.6% of patients and remained so following 1 year and 2 years after therapy (T3 and T4), still 63.2% -70% of children having a lower waist circumference than before therapy.

A normal waist circumference below 50% of height was found in 13.6 % of children 1 year after start of therapy, indication a normalization of fat distribution.

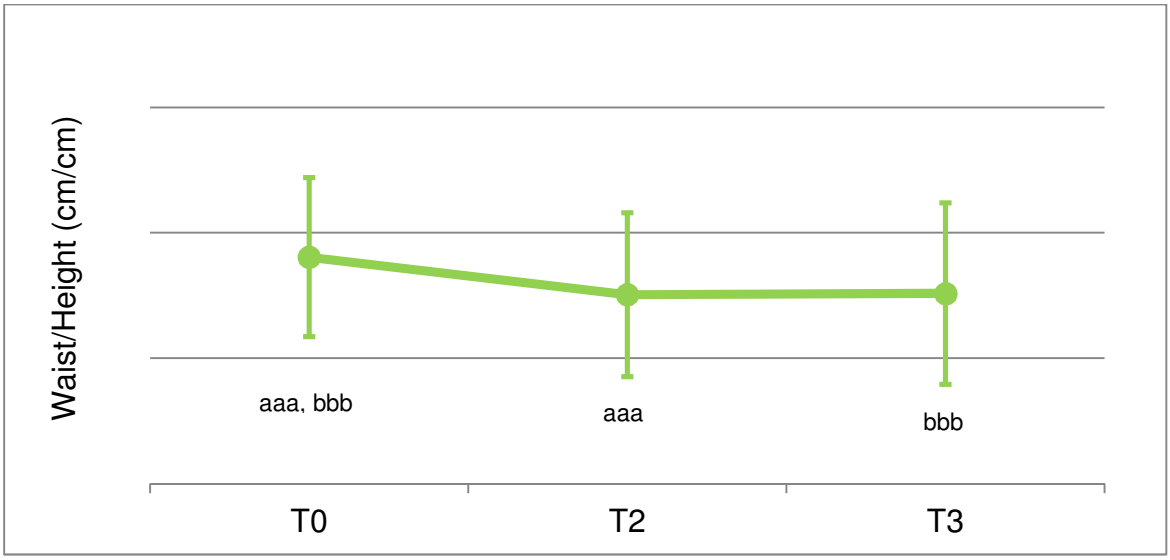


Figure 10: Waist to height ratio (cm/cm), means and standard deviations for T0 to T3 (longitudinal, n = 159, 2009-2013)
Legend: Same indices $^{aaa\ /\ bbb}$: significant differences with $p < .001$

7.1.3 Association of children's obesity with age, initial obesity grade and socioeconomic status of parents

7.1.3.1 Association of children's obesity with age or initial obesity grade

The extent of weight loss is significantly higher in younger children than in children older than 12 years (Figure 11). This difference is found immediately and 1 year after therapy (T0-T1 and T0-T2, resp.) as well as in the second year after therapy (T0-T3), so short and long term effects are age-dependant in this population.. The degree of obesity before therapy, comparing children with extreme obesity (OB class 3) with overweight and obese children (OB class 1&2), did not predict the decrease of BMI-SDS during therapy (T1 to T3).

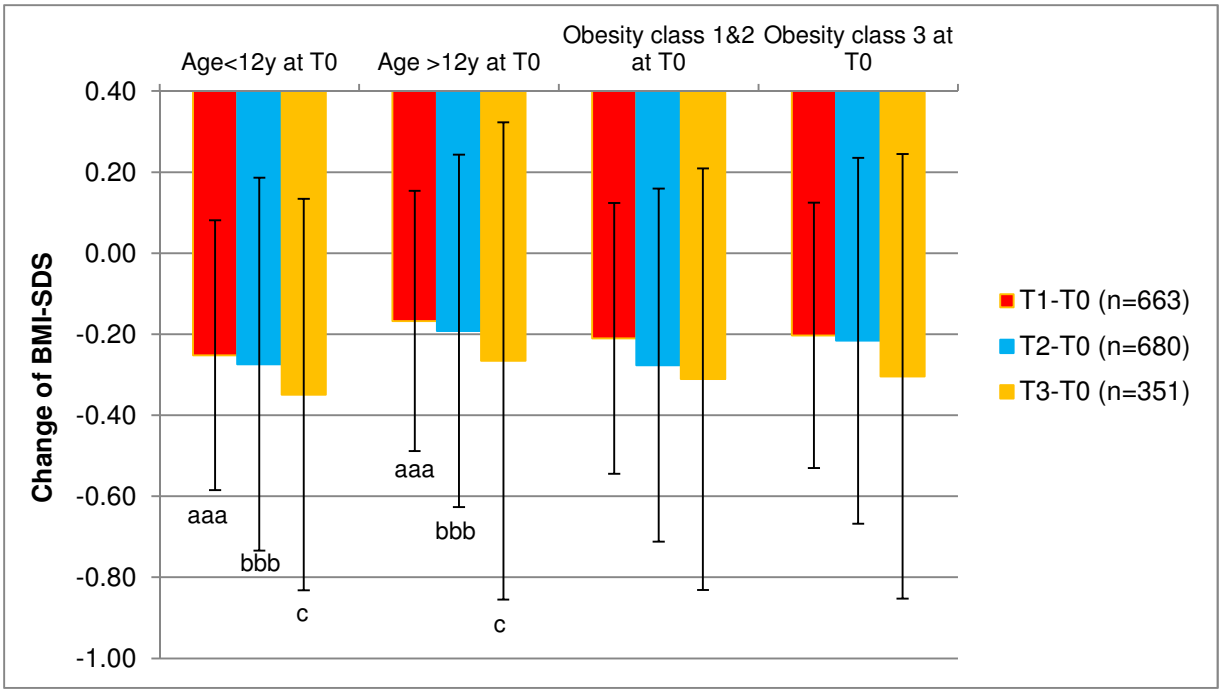


Figure 11: Changes of BMI-SDS during multiprofessional obesity therapy according to age group or initial BMI class, 2009-2013.
Legend: Same indices indicating significant differences between groups by Mann-Whitney U-Test, [aaa, bbb] $p<0.001$, [c] $p<0.05$.

7.1.3.2 Association between parents' origin, education and workload with their children's obesity

Before start of therapy (baseline T0), the degree of obesity of children (obesity class 1 and 2 vs. 3) was not systematically associated with the origin of their parents nor the workload of parents (Chi^2 tests n.s).

But differences occurred if the parental level of education was included: Compared to parents of children in BMI class 1 and 2, parents of severely obese children with BMI class 3 less often completed a tertiary level of education (higher vocational education / university), but more often completed only compulsory school or a secondary level (vocational education / "Maturität")[9].

Finally, in the longitudinal sample, the decrease of BMI-SDS of children during therapy until T2 was similar in all socioeconomic subgroups analysed; i.e. changes in children's obesity occurred independently from the family's origin or educational level or workload of their parents.

[9] respective Chi^2 tests for education and BMI-Classes of children: within mothers $\chi^2 = 7.684$, $p = .021$, within fathers $\chi^2 = 13.904$, $p = .001$.

7.2 Impact of obesity on co-morbidities, mental health and physical activity

7.2.1 Cardiovascular and orthopaedic disorders

Table 15: Frequency of elevated blood pressure levels at T0, T1 T2 and T3, 2009-2012

Pathology		**TO°**	**T1°**	**T2°**	**T3°**	**T0-T2-T3**	**η^2**	**T2-T0**	**T3-T0**
Systolic Hypertension	%	13.8	9.6	8.2	12.0	F=3.05, p<0.05	.015	*	*
Diastolic Hypertension	%	6.9	2.3	4.8	3.7	ns		ns	ns
	n	846	469	376	217	203			

°: means of cross-sectionals data; *: p<0.05 decrease after therapy

Arterial hypertension is found in 7 to 14 percent of patients before therapy (Table 15, T0). The rate of hypertension is much lower than described in other populations (25 – 35% of obese youth, During therapy, the prevalence of hypertension is decreasing slightly, but significantly, becoming significant for systolic hypertension one and two years after start of therapy (T2, T3). The putative systolic increase between T2 and T3 is not significant and due to small n.

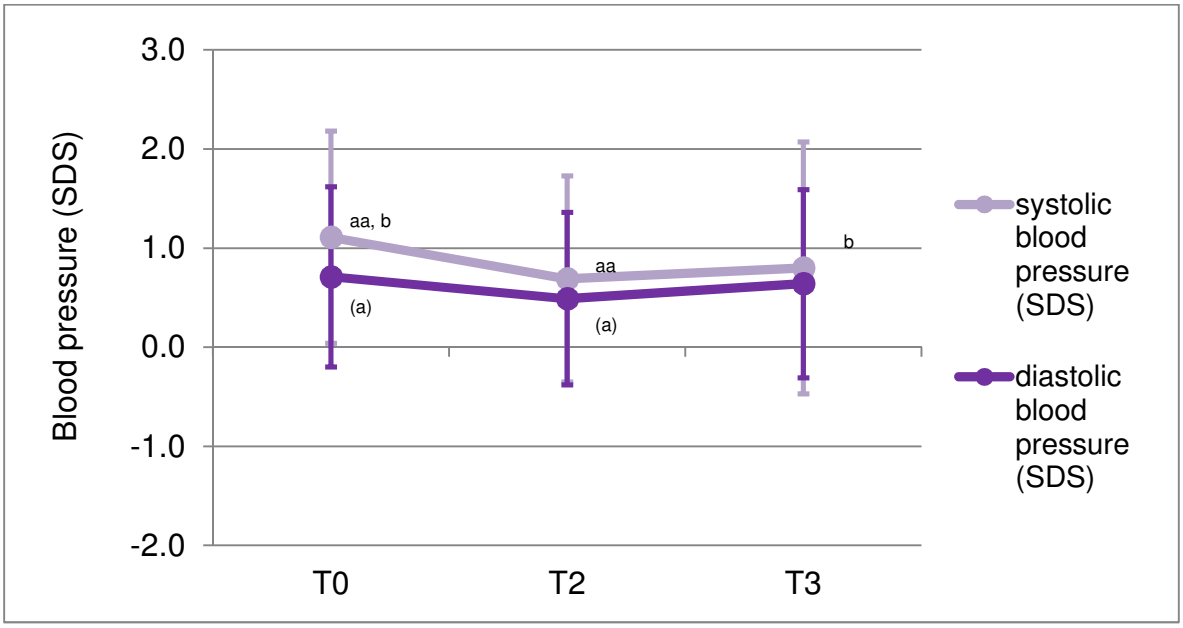


Figure 12: Systolic and diastolic blood pressure (SDS), means and standard deviations for T0 to T3 (longitudinal, n = 98, 2009-2012)
Legend: Same indices indicating significant differences between groups, [aa] p<0.01, [b] p < .05, [(a)] trend.

Similarly, in the longitudinal sample (Figure 12), **systolic blood pressure**, adjusted for gender and age, **decreased significantly until T2 and T3** and diastolic blood pressure remained unchanged. The putative systolic increase between T2 and T3 is not significant.

Table 16: Orthopaedic problems in overweight children, 2009-2012.

	T0	T1	T2	T3	T0-T2-T3	η^2	T2-T0
Total n	*817*	*436*	*523*	*177*	(longitudinal sample n=157)		
Any orthopaedic pathology (%/total)	***68.1***	***33.7***	***53.7***	***57.1***	**-**		
Total n	*816*	*436*	*517*	*169*			
Genua valga (%/total)	46.5	25.0	41.1	39.0	F=3.5, p<.03	0.21	p=.028
Hip motility (%/total)	3.4	0.7	1.6	3.6	n.s.		
Pes planus (%/total)	27.6	17.4	28.5	25.0	F=3.7, p<.05	0.26	p=.04
LWS hyperlordosis (%/total)	35.4	15.4	28.6	22.5	n.s.		

In cross-sectional examinations, orthopaedic problems are being recognized as most prevalent co-morbidities in this population, concerning 68% of obese children. Knock-knees are found in nearly half of patients and each one third show flat feet and / or hollow-back. In the longitudinal subset, feet and knee pathology seems to decrease significantly one and 2 years after therapy (Table 16).

7.2.2 Mental health assessed by SDQ

Psychological comorbidities of obesity are well recognized (White et al 2012). However, the role of childhood psychological problems in the etiology of obesity has been little studied.

Because of the facts that many obese children suffer from severe mental health problems and that comorbid psychiatric disorders are assumed to be relevant for treatment outcome, we were interested in the mental health status of our sample. Before starting the intervention (T0), we screened 637 children with a standardized questionnaire (Strength and Difficulties Questionnaire, SDQ; (Goodman 1999).

Figure 13 shows mental health problems assessed by the SDQ in our sample. Compared to a normative sample (Woerner et al 2002), our sample had much higher rates of emotional behavioural problems at T0. For instance, in the sample of Woerner et al.(Woerner, Becker, Friedrich, Klasen, Goodman, & Rothenberger 2002), only 10% of the 6-16-year-olds had a total difficulties' score in the clinical (suspisious) range, while in our sample nearly half (45.5%) of the assessed children and adolescents had a total SDQ score above the clinical cut-off. As shown in , 12.3 % of our patients had emotional problems (e.g. worries, unhappyness or fears) and 17% had problems with hyperactivity and inattention (e.g. restlessness, fidgety or distractiblity), 16.2% of the children reported peer problems (e.g. bullied, no good friends) and 4.4 % had conduct problems (e.g. tempers, fights or lies) at T0.

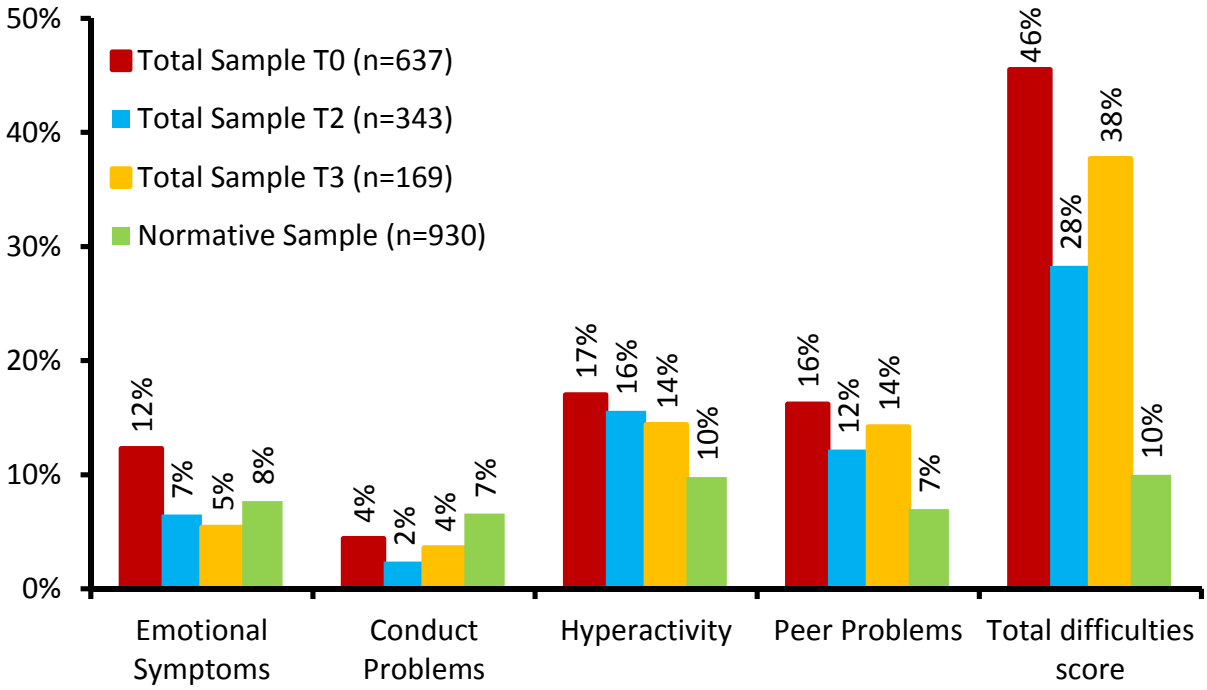


Figure 13: Percentage of patients scoring above the clinical cut-off for parent-rated SDQ scales at T0, T2 and T3 (compared to a normative sample), 2009-2012

Effects of obesity treatment on participant's behavioural and emotional problems

A subsample of 169 subjects was assessed before and two times after the intervention.

Each participant in the analysed subsample had three SDQ scores (T0, T2, T3) for each SDQ scale and the SDQ total score. As shown in Table 17 and Figure 14, we found significant reductions for the SDQ scales "Emotional problems", Conduct problems" and "Peer problems" and the "SDQ Total score" over time. All changes in the SDQ scores have Eta^2 values that indicate a medium to large effect size.

Table 17: Mean differences and statistical test results for each SDQ scale (N = 169, 2009-2012)

SDQ Scale	*Mean ± SD T0*	*Mean ± SD T2*	*Mean ± SD T3*	*Test scores* [a]	η^{2} [b]
Emotional Symptoms	3.59 ± 2.19	2.71± 2.14	2.32± 2.17	F = 22.35, p < .000	0.28
Conduct Problems	3.33 ± 1.69	2.93 ± 1.40	2.88± 1.46	F = 5.60, p < .01	0.09
Hyperactivity	4.83 ± 1.66	4.70 ± 1.67	4.57± 1.78	F = 1.59, n.s.	
Peer Problems	5.12 ± 1.87	4.45 ± 1.97	4.38± 1.92	F = 11.00, p < .000	0.16
Total score	16.88 ± 5.08	14.77 ± 4.55	14.25 ± 5.14	F = 19.90, p < .000	0.28

Note: [a] Results obtained by repeated measures ANOVAs. [b] Effect size (if result is significant): η^2 <.06 = small; .06 <= η^2 < .14 = medium, η^2 >= .14 = large effect.

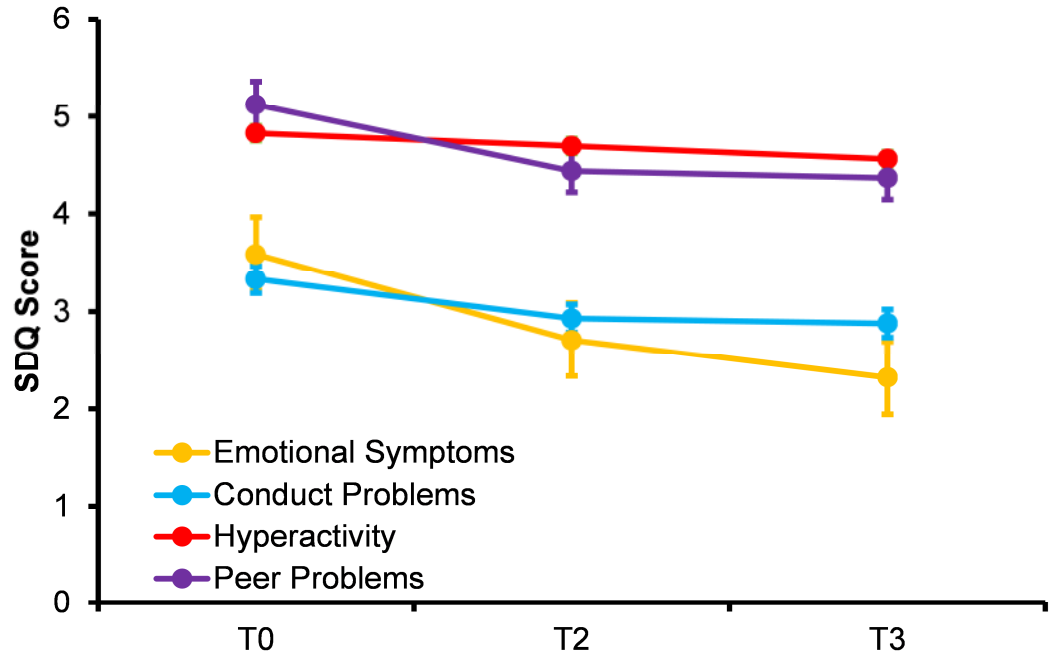


Figure 14: SDQ scores (means ± SEM) before and after obesity treatment (n=169, 2009-2012)

As shown in Figure 15, the number of children, who scored above the clinical cut-off score for the SDQ total and subscales was significantly reduced from T0 to T2. While 45.5 % of our patients had emotional or behavioural difficulties before treatment, only 30,7% had difficulties above the clinical cut-off after the obesity training ($\chi^2 = 51.27$, $p < .001$[10]).

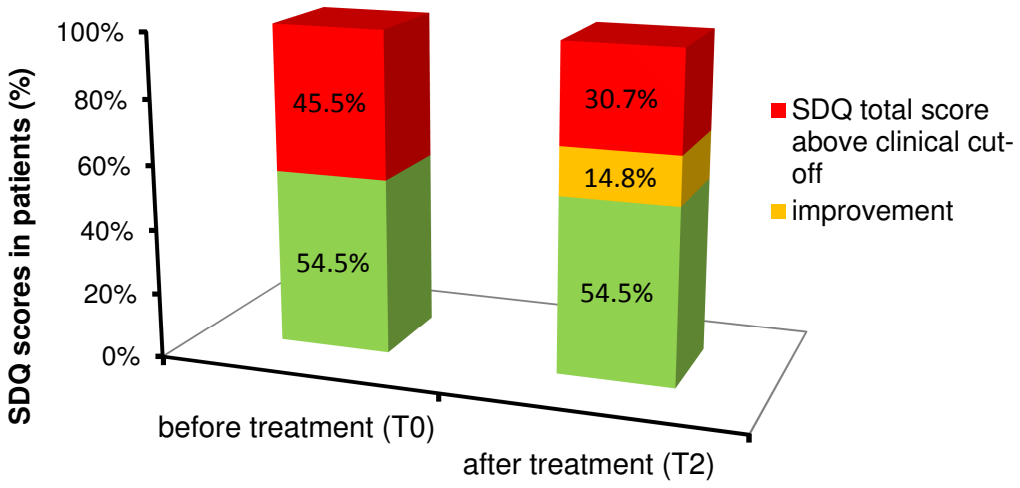


Figure 15: Percent of children scored above the clinical cut-off for the SDQ total difficulties score before and after obesity treatment, (n=189, 2009-2012)

[10] The exact test according to Fisher provided same p's.

Association between mental health problems and treatment outcome

We compared the treatment outcome (BMI-SDS) of patients with and without mental health problems (SDQ total difficulties score above the clinical cut-off). Results[11] indicated a significant decrease of BMI-SDS during the treatment (main effect of time: $F_{1;349} = 84.88$, $p < .001$, $\eta^2 = .20$), indicating that group therapy reduces the BMI-SDS significantly in our patients. We also found significant between subject effects for mental health on *BMI-SDS* ($F_{1;349} = 4.42$, $p < .05$, $\eta^2 = .012$). As shown in Figure 16 mental health status at T0 significantly predicted BMI-SDS change from T0 to T2.

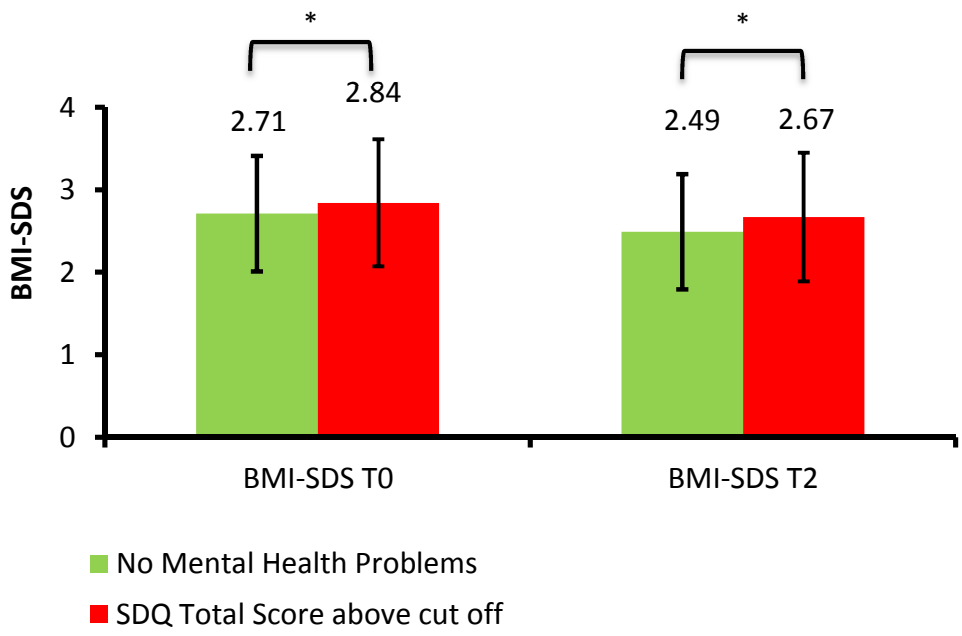


Figure 16: Association between mental health problems at T0 and BMI-SDS change (N =351, means ± SEM), 2009-2012.

[11] Results were obtained by a repeated measures ANOVA with time as within subject factor and SDQ Total score T0 as between subjects factor.

7.2.3 Health-related quality of life assessed by KIDSCREEN

Although obesity is associated with many medical consequences even at young age, the most common short-term consequences of obesity in children are psychosocial in nature, such as psychological problems, discrimination or teasing (Wille et al 2010). The concept of health-related quality of life (HRQoL) expands the view on health beyond somatic factors to include the patients' subjective perspective on the physical, psychological and social aspects of health.

Regarding sample characteristics at start of therapy (T0), study participants, as expected, showed significantly lower values on all scales of HRQoL than their Swiss peers (Bisegger & Cloetta 2005). They achieved particularly low values on the dimensions regarding physical well-being (44.4), self-perception (41.7) and social acceptance by peers (45.7) - values of 45 and less indicate a medium effect size regarding the difference to the norm (Table 18).

Study participants were, on average, physically more exhausted and less fit than their peers, had a more negative body awareness and lower self-esteem and they were more frequently bullied by their peers.

Effects of obesity treatment on participant's health-related quality of life

As seen in Figure 17, a steady increase in all subscales of HRQoL was observed one year and two years after the start of therapy. Test statistics are shown for the longitudinal subsample in Table 19. Repeated measure ANOVA showed significant results for all subscales and the overall index between T0 and T3 except for school environment. Most changes in the scores have Eta^2 values that indicate a medium to large effect size.

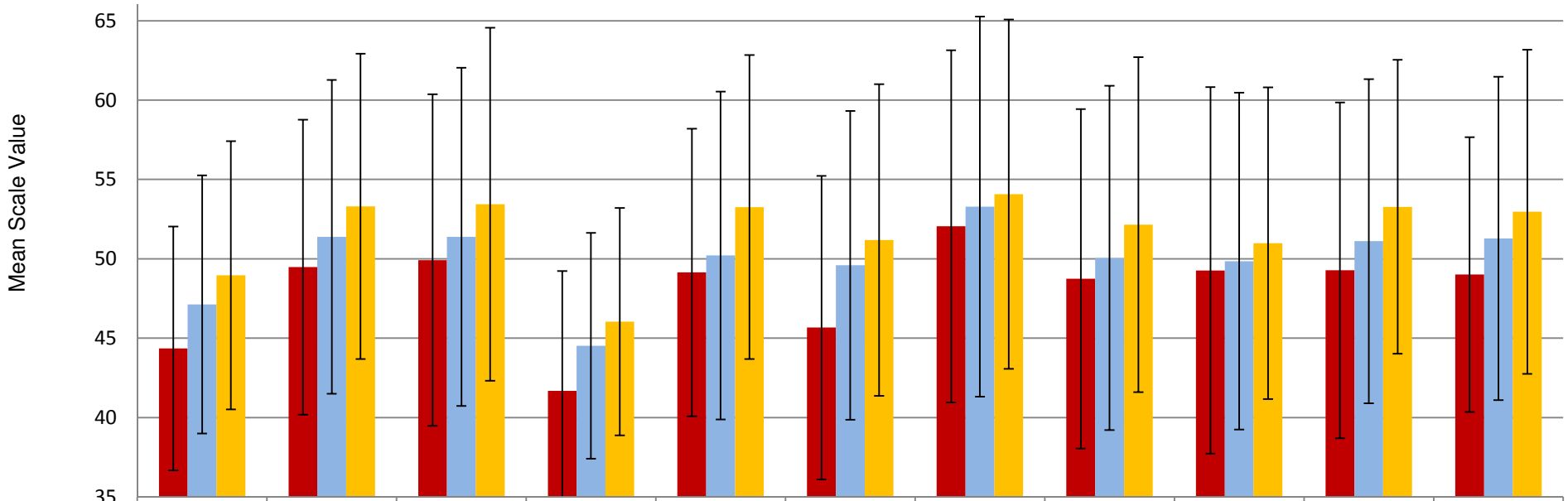
Remarkably, besides improvements in all relevant dimensions of HRQoL, those with lowest average values at start showed great increases, e.g. physical well-being, self-perception and self-esteem as well as social acceptance by peers.

Furthermore, study participants felt also significantly happier and more satisfied on average than before therapy, they had improved relationships to their family and peers, felt more independent and free in the decisions and had more financial resources.

Table 18: Means (T-standardized) and standard deviations for dimensions of KIDSCREEN-52 of study participants and Swiss German-speaking children and adolescents, 2009-2012

	Study participants (n=605-633)		**Swiss German peers** (n=1639-1688) [a]		
KIDSCREEN-52 Dimensions	Mean (T) at T0	SD	Mean (T)	SD	p[b]
Physical Well-being	44.36	7.68	52.66	9	0.000
Psychological Well-being	49.47	9.29	53.25	8.41	0.000
Moods and Emotions	49.92	10.44	51.56	9.72	0.000
Self-Perception	41.68	7.54	52.95	9.7	0.000
Autonomy	48.74	9.06	52.38	8.43	0.000
Parent Relations and Home Life	49.27	9.57	52.26	8.55	0.000
Social Support and Peers	49.14	11.09	51.12	9.07	0.000
School Environment	52.05	10.7	52.95	9.28	0.035
Social Acceptance (Bullying)	45.67	11.54	49.4	9.83	0.000
Financial Resources	49.28	10.58	53.71	8.31	0.000
Overall Score	49.01	8.66	52.8	9.23	0.000

Legend: [a] Bisegger et. al (Bisegger & Cloetta 2005) ; [b] analysed by one sample T-tests.



	Physical Well-being	Psychological Well-being	Moods & Emotions	Self-Perception	Social Support& Peers	Social Accep-tance /Bullying	School Environ-ment	Autonomy	Parental Relations	Financial Ressources	Overall Index
Baseline	44.4	49.5	49.9	41.7	49.1	45.7	52.0	48.7	49.3	49.3	49.0
1 yr post	47.1	51.4	51.4	44.5	50.2	49.6	53.3	50.1	49.9	51.1	51.3
2 yr post	49.0	53.3	53.4	46.0	53.3	51.2	54.1	52.2	51.0	53.3	53.0

Figure 17: Main KIDSCREEN-52 dimensions and overall score (T-Values, Mean±SD) for study participants at start of therapy (T0, N=633-605), one year (T2, n=355-337) and two years later (T3, n=169-160), 2009-2012[12].

[12] Sum scores were transformed according to the manual firstly into Rasch scaled values and secondly into standardized T-values (Bisegger & Cloetta 2005) ; the line corresponds to mean of normative references.

Table 19:Mean differences and statistical test results for each HRQoL scale, 2009-2012

HRQOL Scale	*Before Therapy, T0*	*1 year after start,T2*	*2 years after Start. T3*	*Test scores* [a]	η^{2} [b]
	Mean ± SD	*Mean ± SD*	*Mean ± SD*		
Physical Well-being (N=130)	44.20 ± 7.32	47.49± 7.58	49.38 ± 8.69	F = 21.63, p < .001	0.15
Psychological Well-being (N=136)	49.74 ± 8.75	52.65 ± 9.26	53.82± 9.80	F = 10.21, p < .001	0.07
Moods & Emotions (N=136)	49.66 ± 9.50	51.17 ± 10.08	53.13± 10.78	F = 5.90, p < .01	0.04
Self-Perception (N=132)	42.40 ± 6.24	45.15 ± 6.68	45.85± 6.61	F = 17.25, p < .001	0.12
Autonomy (N=134)	49.19 ± 8.67	50.75 ± 9.57	52.98± 9.41	F = 8.79, p < .001	0.06
Parent Relations & Home Life (N=130)	49.04 ± 8.63	49.80 ± 9.67	51.26± 9.98	F = 3.34, p < .05	0.03
Social Support and Peers (N=135)	49.13 ± 11.14	51.02 ± 12.15	54.36± 9.87	F = 11.28, p < .001	0.08
School Environment (N=129)	53.87 ± 9.77	54.23 ± 10.30	54.69± 10.59	F = 0.39, n.s.	--
Social Acceptance (Bullying) (N=126)	45.31 ± 11.98	49.58 ± 10.46	50.90± 10.05	F = 15.39, p < .001	0.11
Financal Ressources (N=119)	49.61 ± 10.20	50.57 ± 10.70	53.77± 9.30	F = 9.39, p < .001	0.08

Note: [a] Results obtained by repeated measures ANOVAs. [b] Effect size (if result is significant): η^2 <.06 = small; .06 <= η^2 < .14 = medium, η^2 >= .14 = large effect.

Association between health-related quality of life and changes of BMI-SDS

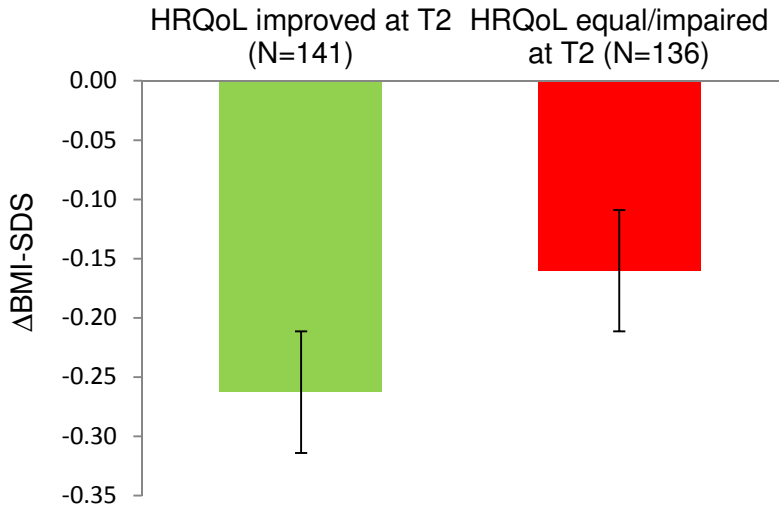


Figure 18: Means ± confidence intervalls for reduction in BMI-SDS for participants with improved vs. equal or lower HRQoL at T2 (N=277, 2009-2012).
Legend: Repeated measures ANOVA, interactive effect: F=3.20, p<0.05, η^2=.0.03.

Finally, we compared changes in BMI-SDS with changes in the overall score of health-related quality of life of study participants between T0 and T2 (see Figure 18). The cut-off point for improvements in quality of life (overall score) was set by more than 0.2 standard deviation, in accordance with (Boehler et al 2012).

Children with a gain in health-related quality of life during therapy showed a significantly greater decrease in BMI-SDS than the others (Figure 18).

7.2.4 Eating disorders and addiction assessed by AD-EVA

The multiprofessional group therapy approach focusses on acquisition of healthy lifestyle and strengthening of family resources. Long term reduction of fat mass will result from healthy lifestyle including non-disordered eating behaviour and adequate physical activity.

Effect of therapy on participants' life style, eating behaviour and (pre)clinical eating symptoms

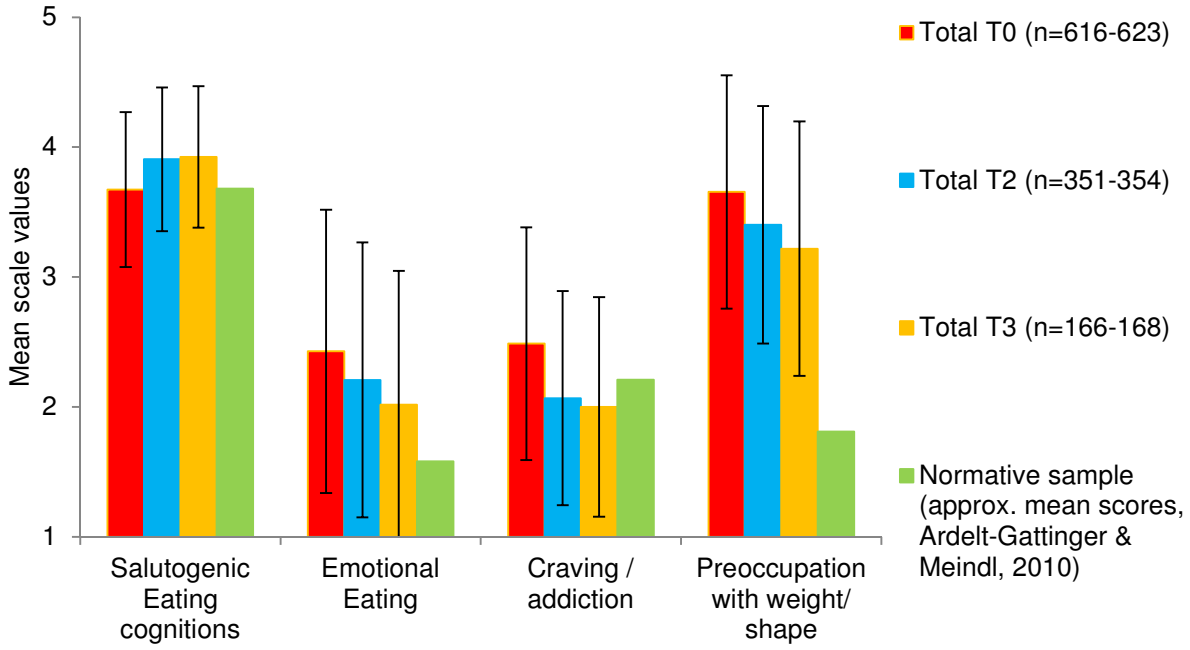


Figure 19: Means and standard deviations for the cross-sectional sample for T0, T2 and T3, compared to a normative sample, 2009-2012.

Cross-sectional results (Figure 19) show that in obese children, compared to normative samples:

- theoretical knowledge on healthy lifestyle (salutogenic eating cognitions) is present to a similar extent,
- symptoms of emotional eating, e.g. due to boredom, loneliness or sadness, are higher,
- craving / addiction to overeating scores at baseline are somewhat higher and
- preoccupation with weight and shape seem to be quite more abnormal in our study.

Interpreting the cross-sectional results at T2 (one year after therapy), salutogenic eating cognitions seem to be favourably heightened, whereas emotional eating, craving for and addiction to overeating, as well as the preoccupation with weight and shape seem to be less pathological. These trends are stable till two years after the therapy start (T3). These data stand for favourable prognosis to maintain a healthier lifestyle (Bulik et al 2000).

Longitudinal results confirm these changes in the desirable direction (see Table 20 and Figure 20):

Table 20: Descriptive statistics and tests scores for longitudinal sample (n = 134-136), 2009-2012.

Scale values for	Mean +/- SD T0	Mean +/- SD T2	Mean +/- SD T3	Test scores	η^2	T0-T2	T0-T3
Salutogenic eating cognitions (n=135)	3.65 +/- 0.61	3.97 +/- 0.52	3.94 +/- 0.56	F = 23.33, p < .001	0.15	***	***
Emotional eating (n=136)	2.28 +/- 1.03	2.12 +/- 1.05	1.98 +/- 1.00	F = 5.09, p < .01	--	n.s.	**
Craving / addiction (n=135)	2.50 +/- 0.83	2.09 +/- 0.81	2.00 +/- 0.86	F = 21.10, p < .001	0.14	***	***
Preoccupation with weight /shape (n=134)	3.65 +/- 0.90	3.41 +/- 0.87	3.26 +/- 0.94	F = 11.03, p < .001	0.08	*	***

Legend: [a] Results obtained by repeated measures ANOVAs. [b] Effect size (if result is significant): η^2 <.06 = small; .06 <= η^2 < .14 = medium, η^2 >= .14 = large effect. Scale from 1 = I don't agree not at all, to 5 = I totally agree.

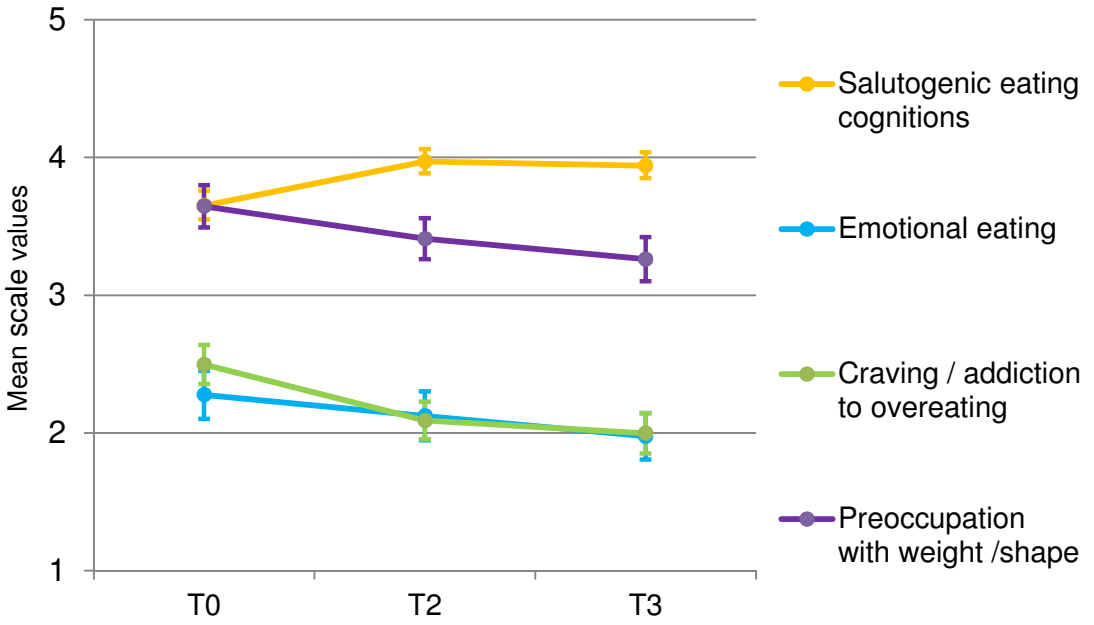


Figure 20: Means and their confidence intervals in the longitudinal sample (n=134-136), 2009-2012.
Legend: for significant changes over time, see Table 20.

Symptoms of preclinical and clinical disorders

To assess potential risks of the intervention, preclinical and clinical eating disorders were analysed separately for the monthly and more occurrence of symptoms as indicator, observing the following cross-sectional frequencies[13] (Table 21).

Table 21: Cross-sectional frequency of symptoms of (pre)clinical eating disorders, 2009-2012.

	Total cross-sectional		
	T0 (n = 603-613)	T2 (n = 314-345)	T3 (n = 145-164)
(pre)clinical vomiting	n=25 (4%)	n=10 (3%)	n=2 (1%)
(pre)clinical purging	n=11 (2%)	n=5 (1%)	n=2 (1%)
(pre)clinical binge eating	n=131 (21%)	n=40 (11%)	n=20 (12%)

During therapy the prevalence of binge eating decreased and only very few patients reported a higher frequency of symptoms at T2 (Table 22):

[13] Patient's answer was interpreted as (pre)clinical suspicious, if they reported a monthly or more frequency of symptom.

Table 22: Longitudinal changes and stabilities (T0-T2) in symptoms of (pre)clinical eating disorders, 2009-2012.

Group according to changes T0-T2	**(pre)clinical vomiting (n=330)**	**(pre)clinical purging (n=323)**	**(pre)clinical binge eating (n=331)**
stably normal	310 (94%)	313 (97%)	234 (71%)
normalizing	11 (3%)	6 (2%)	59 (18%)
deteriorating from normal to suspicious	6 (2%)	4 (1%)	25 (8%)
stably suspicious	3 (1%)	--	13 (4%)

These indicators

- show a similar number of symptoms of pre-clinical eating disorders, compared to common prevalence for youngsters less than 14 years (De Zwaan & Schüssler 2000) and
- were stable or mostly regressed during therapy, as demonstrated by longitudinal analysis.

Association between changes in eating behaviours and changes of BMI-SDS

Additional analyses show that changes in two of the four eating behaviour styles[14] were associated with changes in BMI-SDS:

- Patients with stable or increased consciousness of possibilities to influence weight by a healthy life style and by physical exercises (salutogenic eating cognitions, see blue and red continuous lines in Figure 21) showed a significant decrease of BMI-SDS (T0 to T2), stabilizing this lower BMI-SDS till T3; patients who reduced this awareness, for example due to less believe in effectiveness of a healthy life style,could not reduce their obesity (green dotted line in Figure 21).
- Patients with a decrease in scores for craving / addiction to overeating (green continuous line in Figure 22) also significantly decreased in BMI-SDS between T0 and T2 and stabilized their BMI-SDS till T3, whereas in patients with stable or increasing scores for craving BMI-SDS did not significantly decline (blue and red dotted lines in Figure 22).

[14] Groups for patients with changes in eating behaviour styles vs. no changes were formed including the standard deviation of the whole sample at T0: If a patient changed his/her individual score from T0 to T2 more than half of the standard deviation, we interpreted it as a remarkable change (increase or decrease). Stability of behaviour score was interpreted with changes of scores less than a half of the standard deviation of the T0 sample.

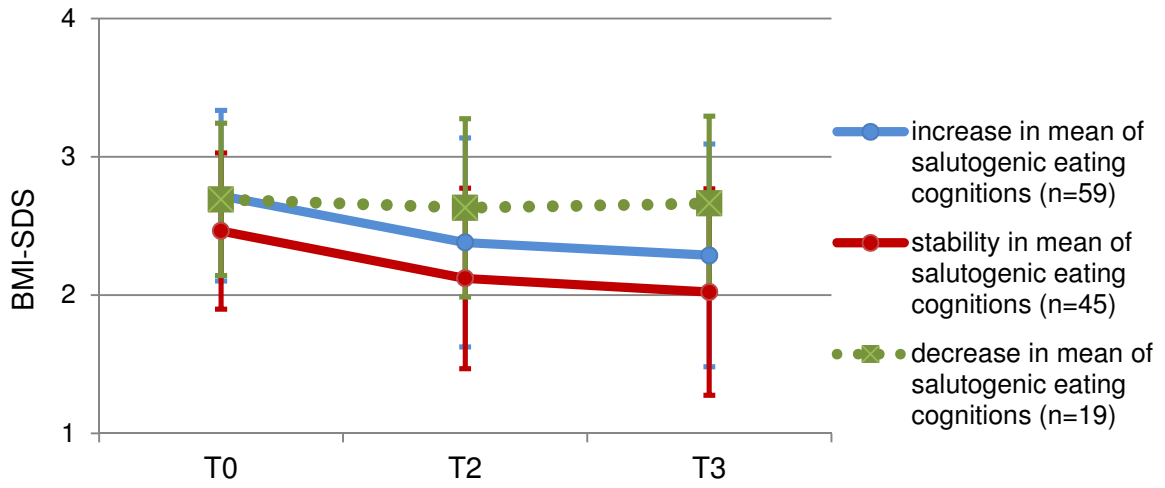


Figure 21: Longitudinal means of BMI-SDS for different groups of changes in salutogenic eating cognitions, 2009-2012[15]

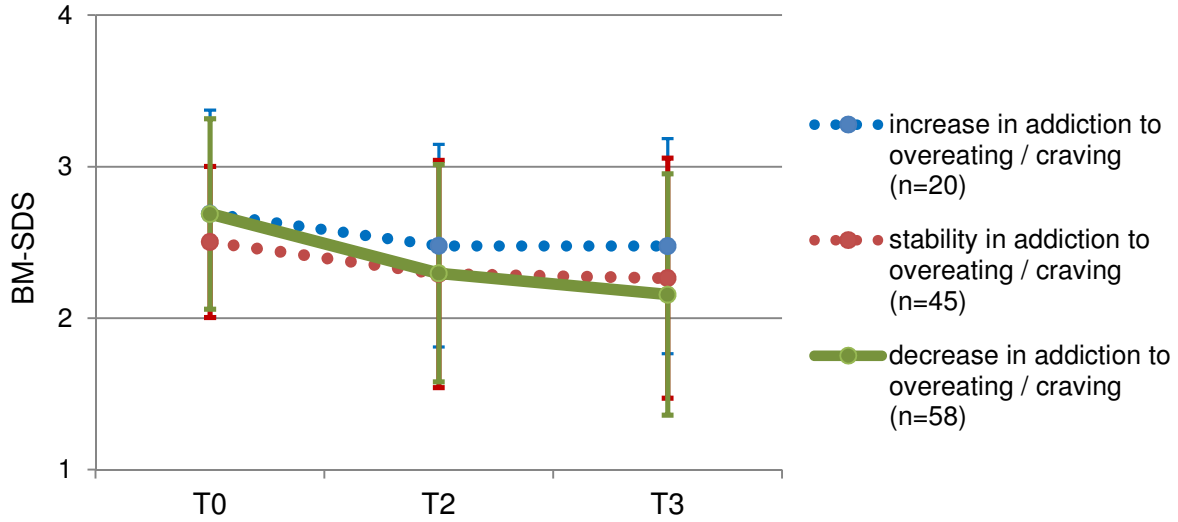


Figure 22: Longitudinal means of BMI-SDS for different groups of changes in addiction to overeating / craving, 2009-2012[16]

[15] Respective interaction effect was significant with $F = 3.24$, $p < .05$, $\eta^2 = .05$; for significant differences see text.
[16] Respective interaction effect was tends to be significant with $F = 2.17$, $p < .10$, $\eta^2 = .04$; for significant differences see text.

7.2.5 Physical capacity and activity

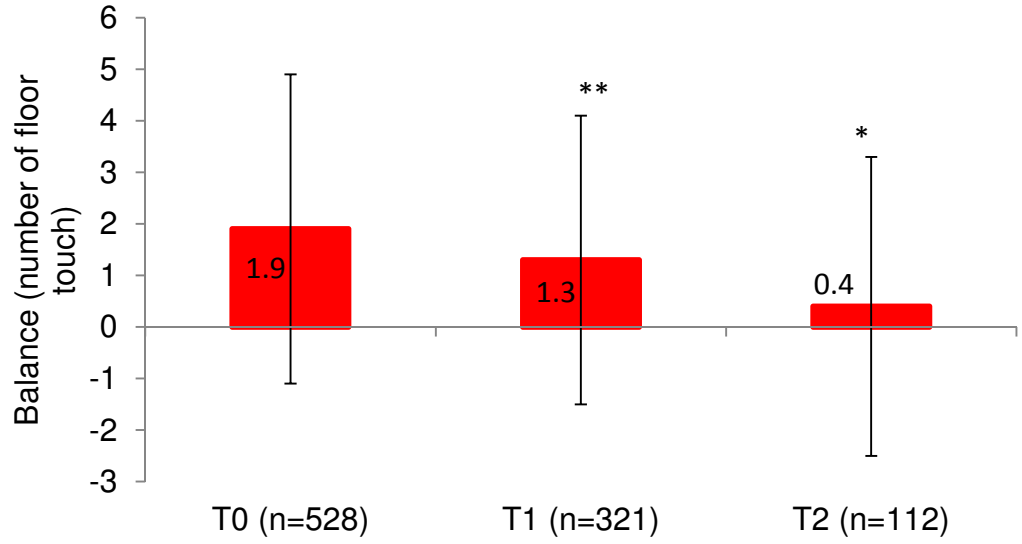
Six selected Eurofit tests were performed by the children at baseline, after the intensive phase and at 1 year[17]: the Single Leg Balance Test (balance), the Plate Tapping Test (coordination), the Long Jump Test (explosive strength of the legs), the Sit Up Test (abdominal strength and endurance), the Shuttle Run (10 x 5 meter, speed), and the Leger Fitness Test (20m-shuttle run, aerobic fitness).

As shown in the previous milestone reports, physical capacities and fitness were lower compared to normative Swiss and European references. Descriptive results at baseline and during the first year of therapy are shown in Figure 23 (a, b, c, d, e, f, g).

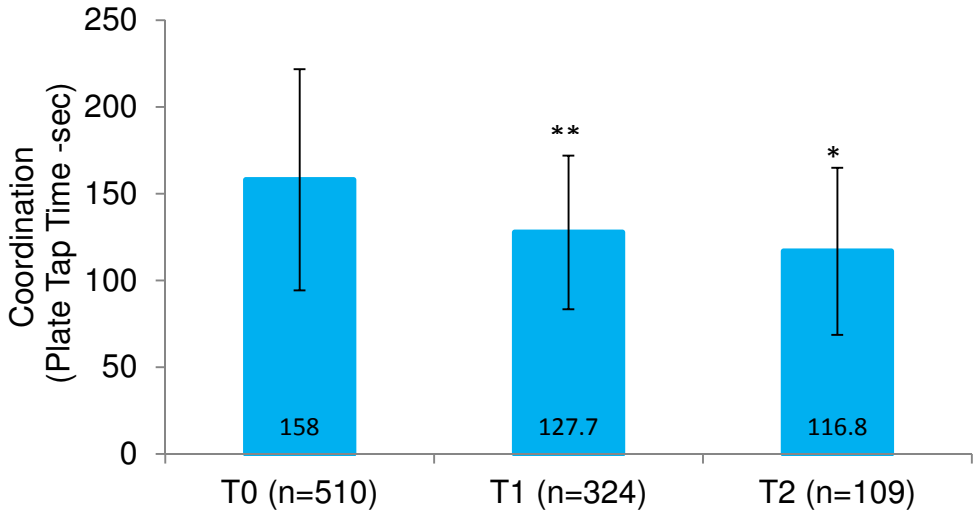
After the intensive phase of therapy (T1), significant improvements were observed in all components of physical fitness. At 1 year (T2), further increases in body balance, coordination, speed and aerobic fitness were registered.

Figure 23: Evolution of physical capacities and fitness during therapy, 2009-2012.
Legend: * p<.05, ** p<.01

a) Body balance

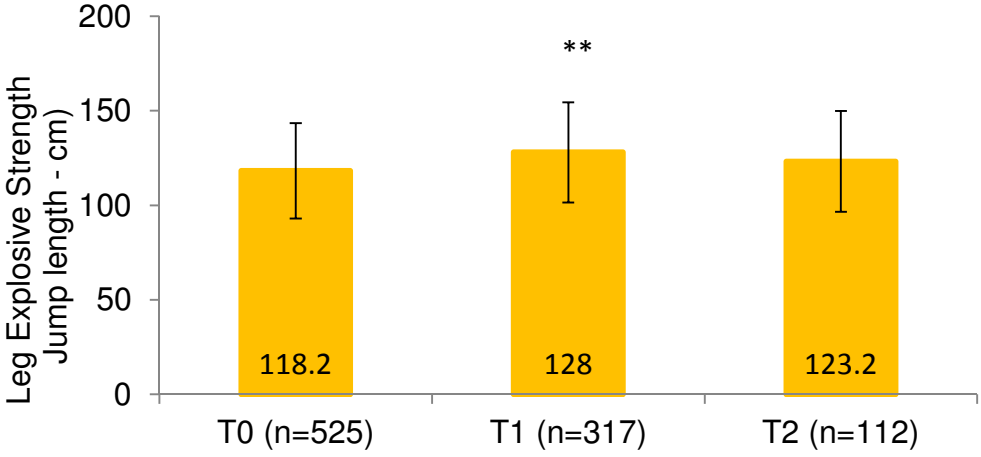


b) Coordination

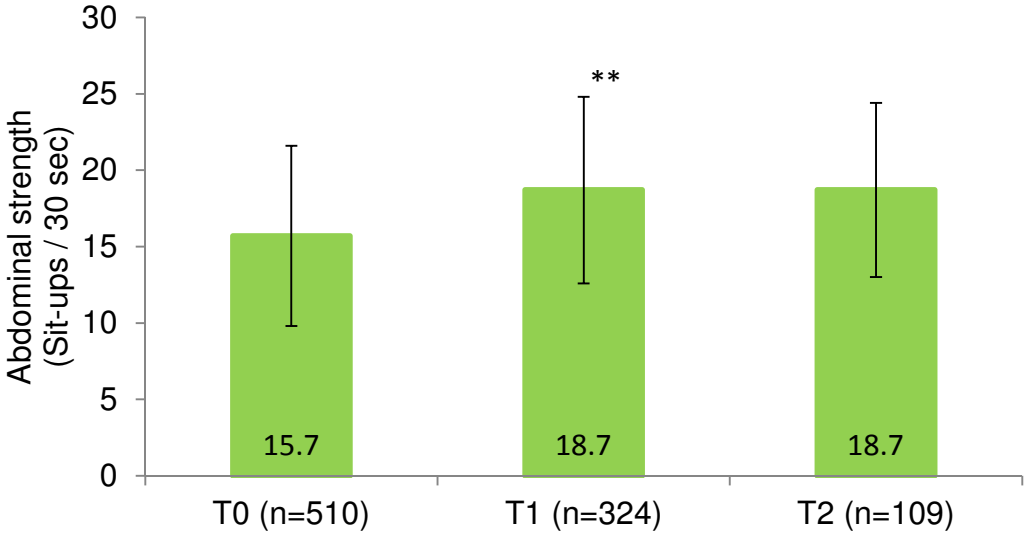


[17] Data two years after therapy start (T3) are not shown because Eurofit was not compulsory at T3; thus data are not complete for this longitudinal analysis.

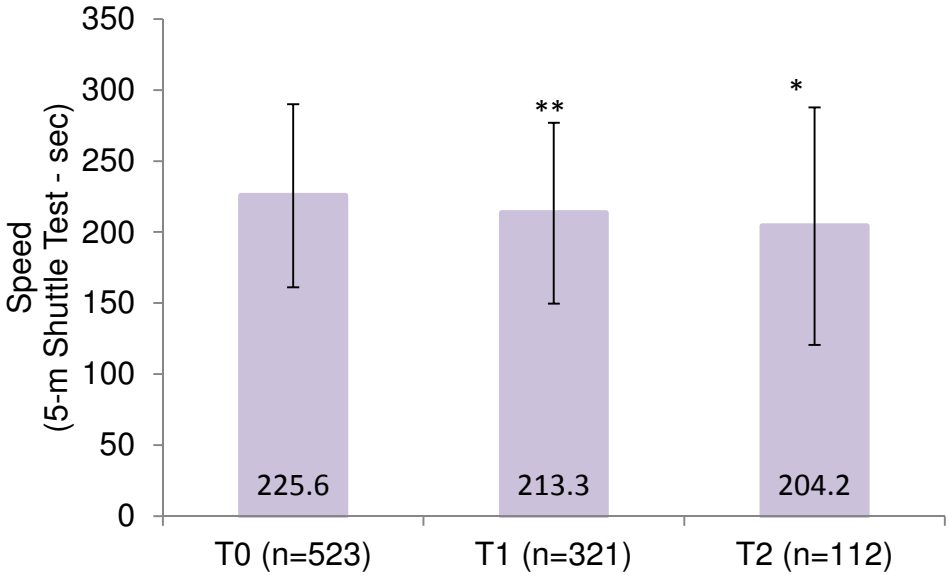
c) Leg explosive strength



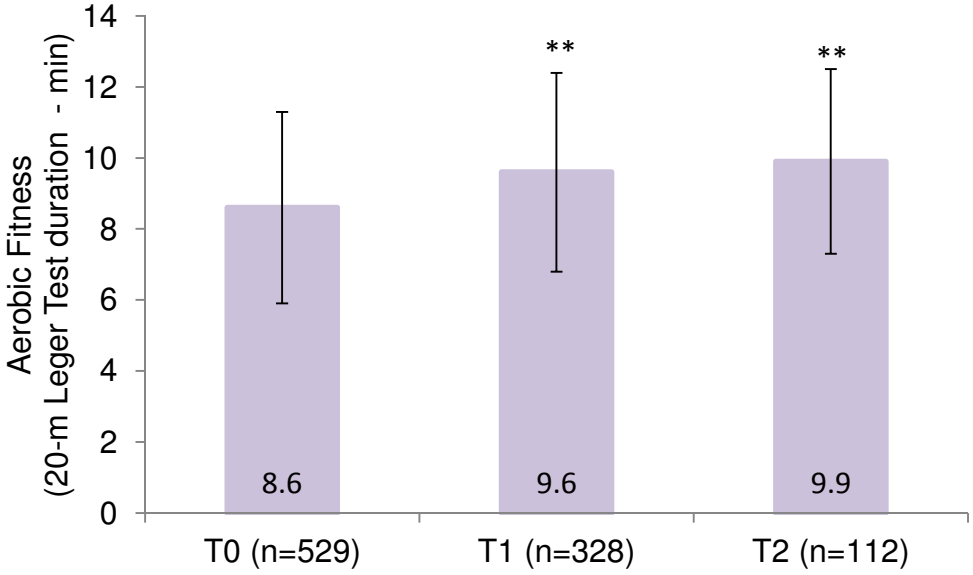
d) Abdominal strength



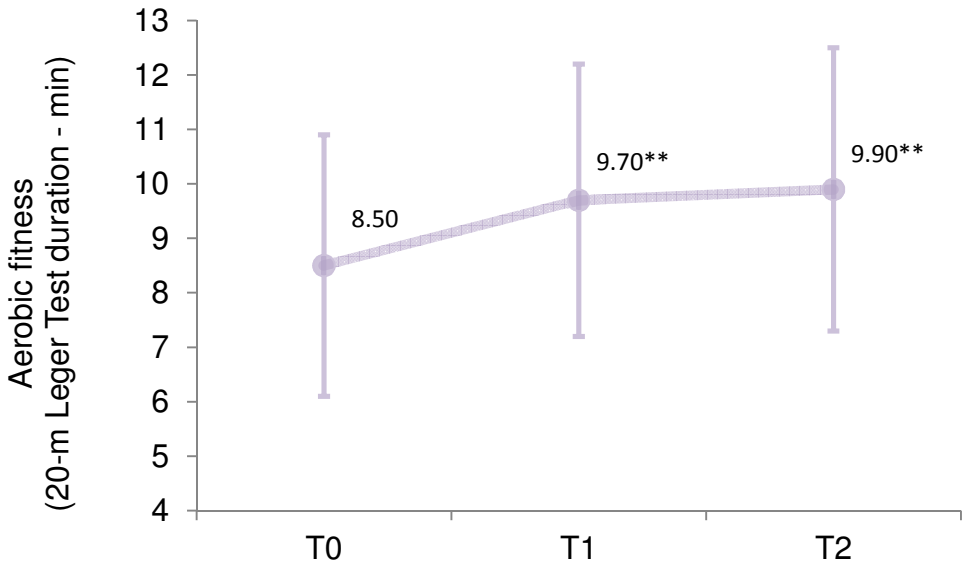
e) Speed



f) Aerobic fitness



g) Aerobic fitness in the 85 children who performed 2 tests (T1 and T2) during the 1st year of therapy



Legend: ** = p<.0001, significant improvement between T0 and T1, and T1 and T2.

The changes in physical capacity according to age and BMI class (overweight-obese and severely obese) were studied. A significant improvement of aerobic fitness was observed at T1 and T2, independently of age or degree of obesity (see Figure 24). Similar significant results were found at any time for all other components of physical fitness, except for the shuttle run test at 1 year test in adolescents above 12 years.

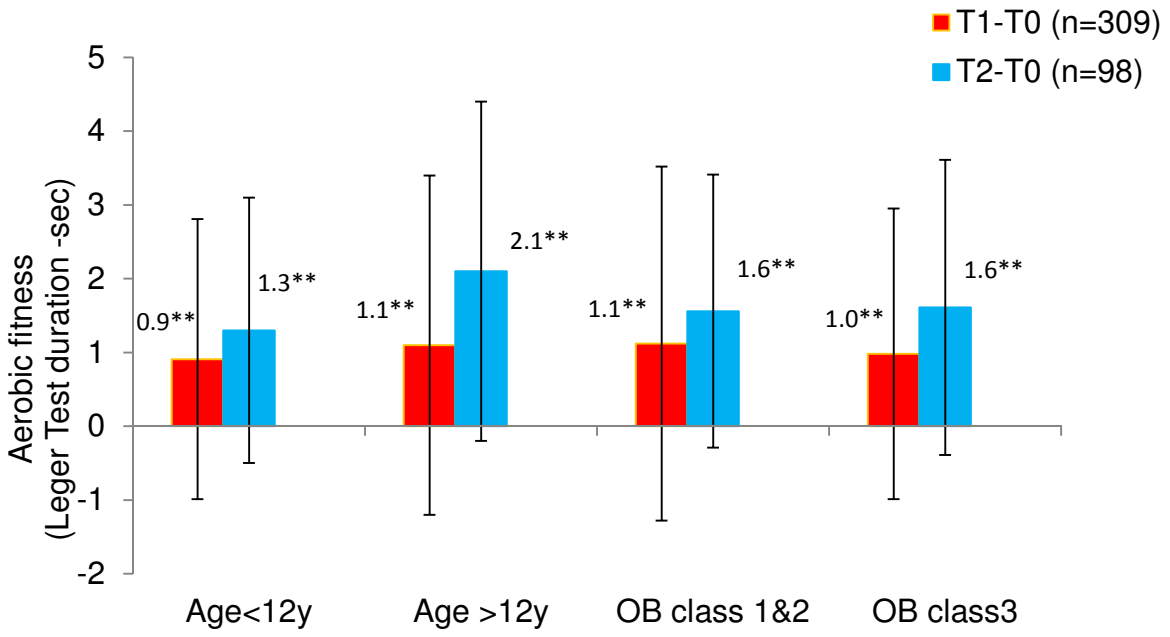


Figure 24: Changes in fitness according to age and degree of obesity, 2009-2012.
Legend: OB, obesity. ** = p<.0001, significant improvement between T0 and T1, and T0 and T2.

7.2.6 Family eating and activity habits questionnaire (FEAH)

Children's eating habits and food choices are largely influenced by their environment (Crockett & Sims 1995) and the family plays an important role in both the development and prevention of overweight in children (Epstein 1996; Epstein et al 1994a). Parents should control the quality and pattern of the home food environment and ensure appropriate eating habits and activity patterns. Parents may also influence eating behavior through modeling. Children's health behaviors can be modified by changing specific environmental determinants; for example, by exposing them to healthier foods, influencing parental food selection and providing opportunities for physical activity. Directing attention to the family, inducing change in the house and placing the responsibility for the recommended changes on the parents rather than on the child himself can improve the outcome of the therapy (Golan et al 2006)).

The FEAHQ (validated by Golan M. et al., 1998 (Golan & Weizman 1998)) assesses family eating and physical activity habits. It has four separate scales based on the factors most likely to be associated with weight change including:

1) activity level: frequency with which the parent, spouse and obese child engage in physical and sedentary activity;

2) stimulus exposure: presence and visibility of snacks, sweets, cakes and ice-cream in the home;

3) eating related to hunger: person in family who initiates eating; eating and hunger;

4) eating style: eating while standing at the open refrigerator or from the pot, while watching TV or doing homework or reading, following stress (anger, frustration, boredom), and between meals.

Each item is individually scored. **Higher numerical scores reflect less-appropriate lifestyle.** The total score is considered an index of overall inappropriateness of eating patterns and physical activity in the whole family. A decrease in score over time is considered as a beneficial change of family habits.

Figure 25 presents results of the FEAHQ at baseline in 650 overweight/obese children compared to published references. We can observe a much higher activity score in overweight children, suggesting a lower reported physical activity level. Furthermore, stimulus exposure, as well eating related to hunger, appear slightly higher in the overweight group compared to normal lean children.

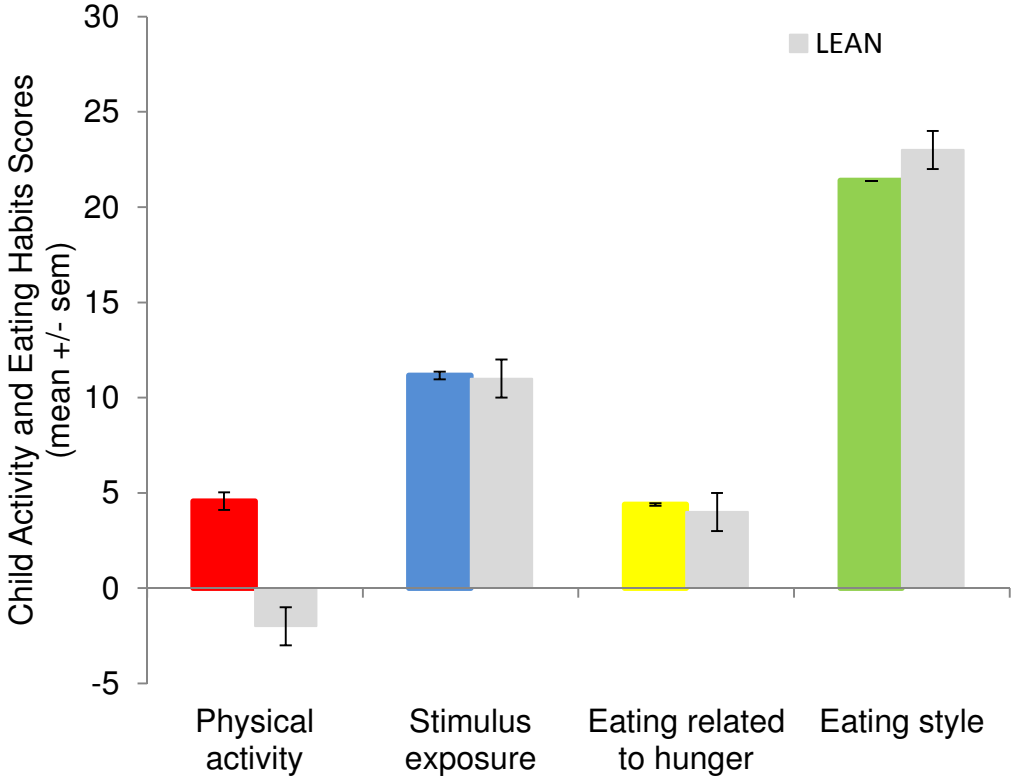


Figure 25: Physical activity and eating habits in 650 overweight children compared to normative references at baseline, 2009-2012.

Legend: Children activity and eating habits scores compared to normative published data (Golan & Weizman 1998). Data are presented as means and standard error of the mean. Higher numerical scores reflect less-appropriate lifestyle.

At 1 year, 216 of 536 families filled completely the questionnaire for parents and incomplete questionnaires could not be included into evaluation, because the evaluation is done by a sum score; refer to discussion for explanation of this low response rate (8.3.5). All components of family habits improved significantly, except "eating to hunger" in both parents (Figure 26).

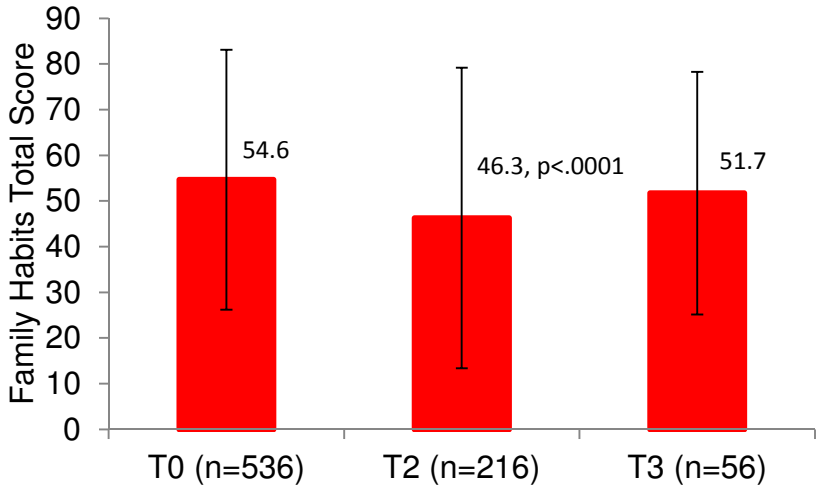


Figure 26: Descriptive results of family activity and eating habits at 1 and 2 years, 2009-2012.

Only 176 parents filled the FEAHQ both at 1 and 2 years ; refer to chapter 8.3.5. to explain this low response rate of parents and an analysis of families retiring from therapy after start is presented in chapter 7.4. The evolution over time is demonstrated in Figure 27. In this sub-group, results showed significant changes in some components of family habits. Children and fathers reported a significant decrease in stimulus exposure. Children also enhanced eating related to hunger (reflecting improved control of food intake), while both mothers and fathers improved their eating style.

Between 1 and 2 years (follow-up period), we observed further improvement in eating related to hunger in parents. However, a loss of benefits in regards to stimulus exposure was reported by both parents and children, and an alteration of children's eating style.

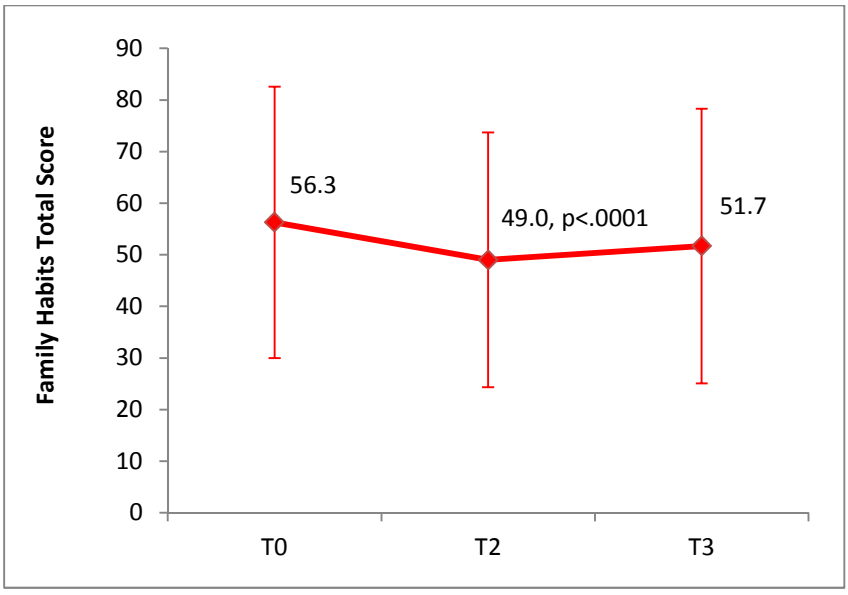


Figure 27: Evolution of family activity and eating habits at 1 and 2 years (n=176, per-protocol analysis, 2009-2012)

We then evaluated the effects of therapy on family habits total scores according to age group and BMI-SDS class (overweight-obese and severely obese). Beneficial changes (reduction

of scores) were significant in both age groups, as well as in the severe obesity category (Figure 28).

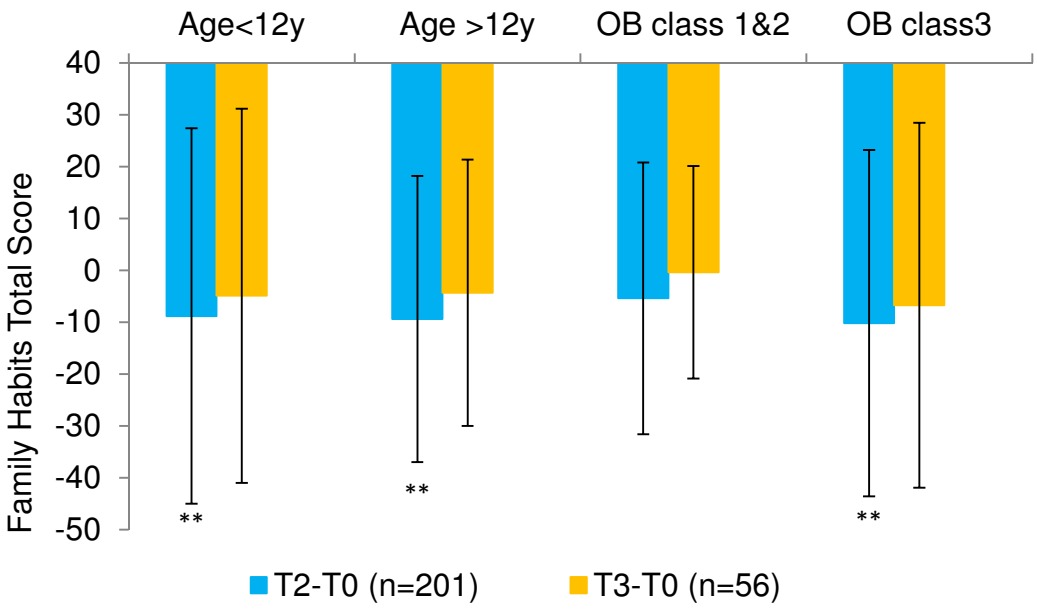


Figure 28: Beneficial changes in family activity and habits total score according to age or degree of obesity, 2009-2012

Legend: OB, obesity. ** = p<.0001, significant improvement between T0 and T2.

7.2.7 School physical education and organized sport

By law, all Swiss children should benefit of at least 2.25 hours per week of school physical education (3 * 45 min./ week). In this study, only 65% of the overweight children reached this guideline. It was beyond the scope of the present study to collect data to explain this finding. But at 1 year, the proportion augmented to 77% and at 2 years, 72% of the overweight children maintained a sufficient level of physical education.

At baseline, only 36% of overweight children participated to a club/association sports activity, whereas 68% of them reported an activity at 1 year. However, the proportion of active children dropped at 42% at 2 years, after the cessation of therapy.

The Figure 29 shows the time spent in physical education and organized sports over time (descriptive analysis). At 1 year, children augmented significantly the number of hours per week of organized physical activity in clubs.

Finally, 158 children filled the physical activity questionnaire at 2 years (Figure 29). There was a significant increase in sports participation during the first year of therapy, and interestingly the number of hours per week remained almost stable thereafter.

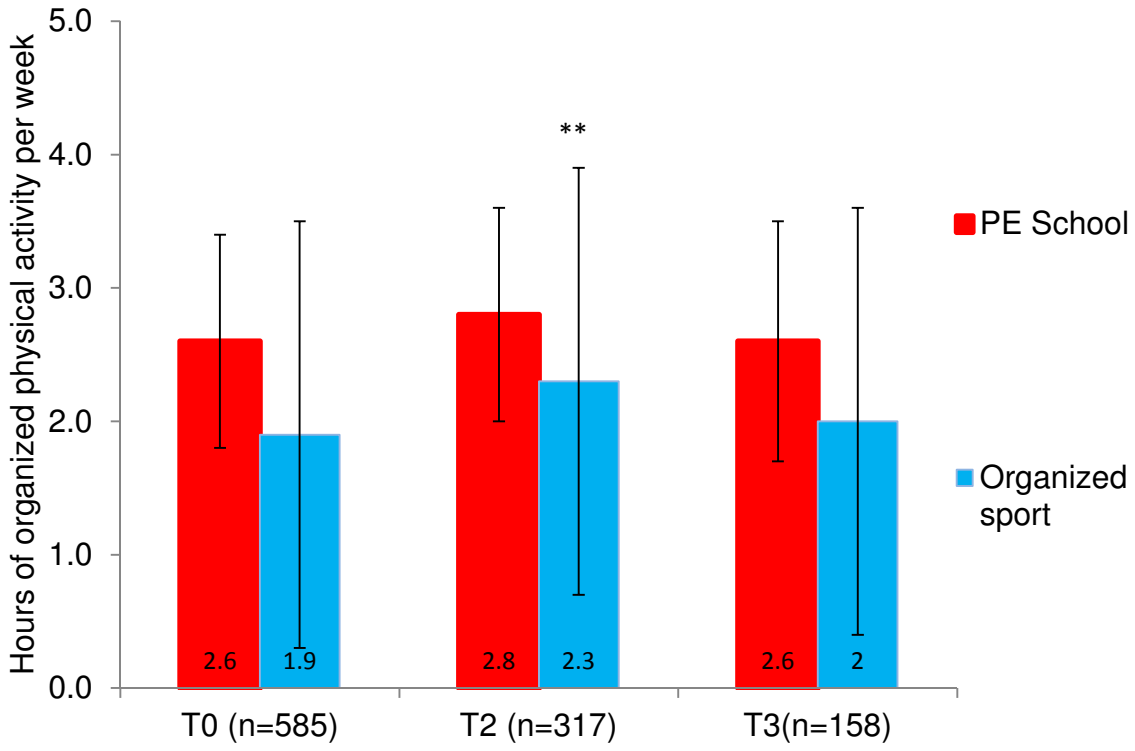


Figure 29: Time spent per week in school physical education and organized sports at baseline, 1 and 2 years, 2009-2012.

Legend: PE, physical education. ** = p<.01, at T2 more organized sports than at T0

7.3 Obesity of parents before and after therapy of their children

Table 23: Percentage of obesity in parents before, during and after therapy of their children, 2009-2012.

a) Mothers

		TO	T1	T2	T3
	n	638	123	202	71
Mother Normal	%	31.0	37.4	36.1	47.9
Mother Overweight	%	32.3	26.0	28.7	29.6
Mother OB 1°	%	23.4	20.3	21.8	14.1
Mother OB 2°	%	7.1	11.4	8.9	4.2
Mother morbid OB 3°	%	6.1	4.9	4.5	4.2

b) Fathers

		TO	T1	T2	T3
	n	591	87	160	61
Father Normal	%	23.2	18.9	19.5	16.4
Father Overweight	%	44.0	47.2	44.1	47.5
Father OB 1°	%	23.4	24.5	25.4	29.5
Father OB 2°	%	6.9	5.7	6.8	6.6
Father morbid OB 3°	%	2.5	3.8	4.2	0.0

OB 1°= BMI 25-30, OB 2° = BMI 30-40. OB 3° =BMI >40 kg/m^2

The degree of the child's overweight was shown to be tightly correlated with the BMI of the mother before and during obesity intervention; therefore, weight of both parents was measured. Unfortunately, measuring and reporting of parental weight is very incomplete during therapy: far less than 50% of parents are examined (at T2 36 % of mothers and 28% of fathers). Parents of obese children are also mostly overweight or obese, namely 2/3 of mothers and 3/4 of fathers, and mean BMI is 28.6 kg/m2 both in mothers and in fathers at start of the programs (Table 23).

During and after therapy of their children, the increase in BMI of fathers is significant for the whole period of treatment until T2 (T-Test at T2 and ANOVA in subsample, see Table 24). The weight of mothers is stable during therapy and does not decrease in the longitudinal subsample until 2 years after therapy. The number of parents, especially of fathers, was incomplete and there was no untreated control group allowed for by the FOPH. Therefore, the causes of parental weight changes are unknown and may correspond to the well-known steady increase of weight of obese individuals!

Table 24: Descriptive statistics on BMI of parents before and during therapy of their children and analysis of a longitudinal subsample (T0-T2-T3, 2009-2012).

a) Mothers BMI

	T0	T1	T2	T3
n	638	123	202	71
Median	**27.55**	**27.44**	**27.26**	**25.31**
Mean	28.59	28.22	28.33	26.57
SD	6.41	7.25	6.51	6.03
Minimum	15.85	18.13	15.63	12.01
Maximum	59.52	63.21	50.15	47.75
P versus T0		ns	ns	ns
Longitudinal subsample	n = 41			

b) Fathers BMI

	T0	**T1**	**T2**	**T3**
n	591	87	160	61
Median	**27.82**	**29.28**	**28.64**	**28.37**
Mean	28.62	30.35	28.95	28.75
SD	4.92	7.05	4.91	3.92
Minimum	14.53	21.32	20.06	21.36
Maximum	52.24	75.00	50.61	39.92
P versus T0		ns	(*)	ns
Longitudinal subsample	n=35	F=5.2, p=0.028	F=5.2, p=0.028	

7.4 Dropout analyses

For most parameter measured, the sample was considerably smaller after one and 2 years than before therapy. In order to search for any differences, sample was divided into 2 groups:

- Longitudinal subsample with data available at least from T0 until end of intensive phase of therapy (>T1) versus
- Drop-out sample with data available only at T0.

Then, at baseline, comparisons were made for all relevant parameter between longitudinal and drop-out sample.

7.4.1 Obesity and somatic co- morbidities

Table 25: Drop-out and obesity or somatic co-morbidities, 2009-2012.

	Longitudinal sample			**Dropout sample**				
	n	M	SD	n	M	SD	Test scores	η^2
BMI-SDS	673	2.84	0.74	137	3.08	0.94	F=10.24 p<.001	0.01
Waist to Height-Ratio	528	0.59	0.06	118	0.60	0.07	F=7.07 p<.01	0.01
Waist SDS	528	2.68	0.53	118	2.74	0.59	n.s.	--
Waist to Hip-ratio SDS	489	1.47	1.15	111	1.40	1.17	n.s.	--
Systolic BP SDS	538	0.73	1.04	123	0.85	1.07	n.s.	--
Diastolic BP SDS	538	0.43	0.89	123	0.37	1.01	n.s.	--
BMI mother	460	28.66	6.37	107	28.38	6.07	n.s.	--
BMI father	426	28.54	4.85	97	28.75	5.44	n.s.	--

Note: [a] Results obtained by repeated measures ANOVAs. [b] Effect size (if result is significant): η^2 <.06 = small; .06 <= η^2 < .14 = medium, η^2 >= .14 = large effect.

Children withdrawing from therapy before T1 were significantly more obese and had a significantly higher waist circumference, though effect size was rather small (Table 25).

7.4.2 Drop-out and socioeconomic status

There were a significantly higher proportion of foreign parents in the drop-out sample than in the Swiss sample, meaning that patients with foreign parents dropped out more often than patients with Swiss parents (Table 26).

Educational degrees and workload of parents, however, were not significantly different between drop-out and longitudinal sample.

Table 26: Origin of parents for longitudinal and drop-out subsample, 2009-2012.

	longitudinal subsample (total mother: n=560; total father: n=548)		dropout subsample (total mother: n = 105; total father: n = 97)		
	n	% of subsample	n	% of subsample	Test scores
foreign origin of mother (n=302)	242	43%	60	57%	χ^2=6.92, p<.01
foreign origin of father (n=319)	262	48%	57	59%	χ^2=3.96, p<.05

7.4.3 Drop-out in dependence of psychological parameter

7.4.3.1 Motivation and psychological strain due to obesity

We assessed treatment motivation of our sample using a questionnaire at T0 [18](l'Allemand et al 2009). We were interessted, if families did less often withdraw from treatment, when they were more motivated and had higher psychological strain due to the child's obesity.

Patients in the group dropping out from therapy reported before start a significantly lower motivation to participate in the program and were suffering less from psychological strain due to overweight (T-Tests for independent measures; $T_{patients}$ = -2.86, p< .05 and $T_{patients}$ = -2.26 , p< .05, respectively) than those children remaining in therapy for at least 1 year. The same findings with regard to their child's obesity were present in the parents ($T_{parents}$ = -2.73, p< .05 and T = -2.58 , p< .05) dropping out from therapy (Figure 30).

[18] Refer to the final report of the 1st part, contract # 08.004938/ 204.0001 /-523,"Konzept zur Evaluation der Behandlung von adipösen und übergewichtigen Kindern und Jugendlichen in multiprofessionellen Gruppenprogrammen in der Schweiz - Teil 1, Entwicklung von Programmen und Untersuchungsinstrumenten. l'Allemand, D, Sempach, R & Farpour-Lambert, N, January 20th, 2009.

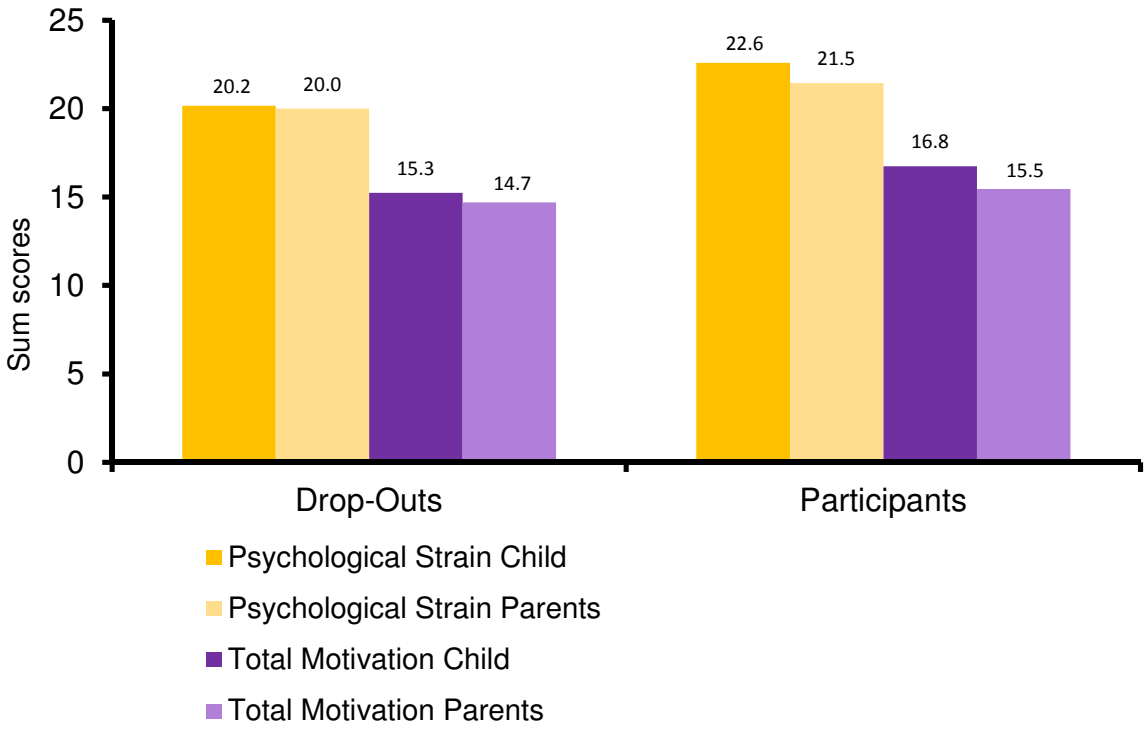


Figure 30: Psychological strain due to the child's obesity and total motivation in drop-outs and patients (sum scores from motivational interviews, 2009-2012)

7.4.3.2 Drop-out analysis of psychological parameter assessed by standardized questionnaires

No significant differences between drop-out and longitudinal sample were found with respect to

- (pre)clinical symptoms of eating disorders or craving (AD-EVA)
- mental health as assessed by SDQ and
- quality of life assessed by KIDSCREEN-21 overall score.

Indicators of adhesion to therapy are Swiss origin, less severe obesity, high motivation and lhigh psychological strain due to overweight.

In conclusion, families withdrawing prematurely from obesity therapy in group programs

- more often are of non-Swiss origin,
- have more obese children,
- are less motivated and
- declared lower psychological strain due to overweight.

8 Discussion

8.1 Frame of the KIDSSTEP Study and paediatric obesity care in Switzerland

The multiprofessional group approach, as described in this study, is effective in improving both physical and psychological health of obese children. Interdisciplinary comprehensive therapy is a prerequisite to achieve sustained changes, as shown in this cohort of Swiss children 2 and 3 years after therapy. Indeed, current research suggests that behavioral interventions can be effective in managing weight in obese children and adolescents (Oude Luttikhuis, Baur, Jansen, Shrewsbury, O'Malley, Stolk, & Summerbell 2009; Reinehr et al 2009; Whitlock et al 2010).

The establishment of an active nationwide network to treat overweight and obese children is unique in Switzerland. Results of this project have shown that the risk of chronic non-transmissible diseases can be decreased significantly, and the quality of life can be improved. In the context of this project, new certified multiprofessional group therapy programs for paediatric obesity were developed and a procedure for certification and quality control established.

This 5-year nationwide evaluation of health outcomes was performed using a multicentre longitudinal design including 1251 obese children and adolescents aged 8 to 18 years, out of 119'140 needing therapy. This is due to the fact that, before 2014, only MGP was reimbursed by health insurances and thus, the access to care could not be warranted for all regions. Fortunately, the rate of patients who were treated in individual setting in large hospitals, mainly due to the presence of co-morbidities, did increase to roughly 30% of all referrals until the end of 2013.

8.2 Findings before therapy

In the present cohort of Swiss overweight children, the start of MGP at the mean age of 12 years is late, because the first signs of obesity were already present at the age of 6.1 years. The average age of the 1031 patients is 12.2 years, including 54.3 % of girls, and children are just at onset of puberty. Hence, this is a critical stage of development characterized by more difficulties to adhere to rules, than in younger children. In addition, theoretical knowledge on healthy lifestyle is already present in 12 years old children despite their obesity.

The recruitment of patients for group therapy is difficult and only about 36% of referrals for treatment can start group therapy. This is due to the presence of contraindications, e.g. invalidity, psychiatric disease, or to the occupation of parents, or a lack of family motivation. The group setting is time consuming (116 hours) and exceeds by far the resources and availability of most families with obese children. This had been predicted before the start of the present study and was also described in other populations (Reinehr, Hoffmeister, Mann, Goldapp, Westenhofer, Egmond-Froehlich, Bullinger, Ravens-Sieberer, & Holl 2009;Wiegand, Dannemann, Vahabzadeh, Ernst, Krude, & Gruters 2005).

A worrying finding is the high attrition rate even before start of therapy, reaching about 10 to 20 % of obese patients needing therapy. Even higher attrition rates have been described also in other studies and in other forms of therapy (Eliakim et al 2004; Wiegand, Dannemann, Vahabzadeh, Ernst, Krude, & Gruters 2005). Therefore, a detailed evaluation of patients withdrawing before or at early stage of therapy is considered important to improve the recognition of the causes.

Patients refraining from therapy before start of the program were slightly younger and less obese than those participating in the therapy. In contrast, during therapy, the drop-out

sample was characterized by the following characteristics, compared with the longitudinal sample, matching results of other studies (Boehler, Bengel, Goldapp, & Mann 2012):

- patients with foreign parents dropped out more often than patients with Swiss relatives.
- Total obesity and abdominal obesity (BMI-SDS, and waist –to-height ratio) were significantly increased.
- Motivation for therapy and suffering from being obese were lower.

Interestingly, patients suffering from mental disorders, craving / addiction to overeating or preclinical eating disorders, or decreased quality of life, did adhere to the program and continued similarly to healthier pairs.

The proportion of families with migration background, of lower educational level and from single-parent households was above the Swiss average. All this was also shown in overweight and obese children by a study of Swiss Health Promotion (Stamm 2010). Namely the proportion of children from families with migration background was elevated in overweight and obese children. Probably this part of the population isn't reached by public health (primary prevention and health promotion) as wanted. This is in line with other European studies (Müller, M 2001, 2010). But our study shows that MGPs can include vulnerable groups and they profited similarly to group therapy (refer also to milestone 6 report, 2011). Barriers of language partly hinder parents to complete all questionnaires and participate in the whole program. Nevertheless, the families staying in program profit the same from treatment as families with Swiss origin. The declared drop-out rate is very low, in the present setting of group programs, which might be due to the strict selection criteria and the fact that the complete participation is a pre-requisite for reimbursement by health insurances. Further support of families with migration background is warranted but totally impossible within the insufficient financing of group therapy by health insurances. Another issue may be related to a lower socioeconomic status, meaning that time and income of the parents to cooperate in such a group program are insufficient; therefore, locally offered multiprofessional services based on small groups or individual treatment could be more adequate for these families.

8.3 Outcome of therapy

8.3.1 Changes in adiposity

The decrease of weight is not a necessary aim of effective therapy in obese children, and BMI also is a moving parameter during growth. Therefore, other measures, such as BMI-SDS and waist-to-height-ratio, are presented in chapter 6.1.1.

The cohort examined was extremely obese, mainly corresponding to morbidly obese adults: the median BMI of these 12-years old patients was 28.4 (range from 19.6 to 55.9 kg/m^2). Almost 80 % of patients had an extreme obesity, corresponding to a BMI >40kg/m^2 in adults. During therapy, this rate decreased to 62% after 2 years.

After a therapeutic period of 9-12 months, the degree of obesity was significantly reduced in 70.5 % of all children:

- 47.5% decreased significantly their BMI by more than -0.2 SD,

- 23.0% showed a smaller decrease between -0.01 and -0.2 SD and

- 18.9% decreased their BMI significantly by more than - 0.5 SD .

A clinically relevant decrease of BMI-SDS above 0.5 is considered as a significant predictor of changes in metabolic parameters, such as a decrease of insulin resistance (Reinehr & Andler 2004) and cost-effective.

In other European studies, a similar, but slightly lower decrease of BMI-SDS was found: In United Kingdom, median effect of interventions versus control from 10 RCTs, was a difference in BMI-SDS of -0.13 at 12 months. But the range of effects among interventions was broad (0.04 to -0.60) (Hollingworth et al 2012). In a German cohort study, the mean decrease in BMI-SDS was -0,27 ± 0,28 after therapy, -0,23 ± 0,47 SD one year after end of therapy and -0,19 ± 0,63 two years after therapy(Boehler, Bengel, Goldapp, & Mann 2012).

The International Diabetes Federation (IDF) has recommended to include a screening marker of abdominal obesity in children and has defined WC as one of the risk criteria for metabolic syndrome in youth > 10 years (Katzmarzyk et al 2006) and even also in those aged above 5 years (Plachta-Danielzik et al 2008). Waist circumference, waist-to-hip ratio (WHR), and waist-to-height ratio (WtHR) seem to be better predictors of cardiovascular risk factors in obese children than BMI alone (Janssen et al 2005; Lee et al 2009), and WC may predict risk for obesity-related co-morbidities, such as dyslipidemia, diabetes or non-alcoholic fatty liver Disease (NAFLD) (Meng et al 2011) beyond that predicted by BMI.

Therefore, we conclude that Swiss health insurances should also accept waist circumference or fat mass in addition to BMI to define obesity, as indicated in the national pediatric guidelines (l'Allemand , Farpour-Lambert, & Laimbacher 2006).

In a public health perspective, waist-to height–ratio (WtHR) above 0.5 is considered as a convenient index to identify a high metabolic risk in overweight children, at least as useful to describe morbidity as BMI, but without need for age- related adjustments (Maffeis, Banzato, & Talamini 2008).

8.3.2 Changes in co-morbidities

8.3.2.1 Somatic findings

Co-morbidities and metabolic parameters are known to be both related to BMI and waist circumference (WC). In this study, systematic examination was performed only for blood pressure, but not for metabolic parameter assessed by more invasive techniques.

The most prevalent co-morbidity was related to orthopaedic problems (68% of patients, e.g. pathologies of knees, feet and back). This co-morbidity is under-estimated in most reports, but may contribute to impaired ability to work and increased healthcare costs in adulthood (Sabharwal & Root 2012). The group therapy, by improving physical activity and capacity, is also resulting in a decreased prevalence of problems of feet and knees.

Arterial hypertension was detected in less than 15% and showed a significant decrease in systolic values after therapy.

Same rates have been observed for other co-morbidities, mostly related to insulin resistance syndrome, as liver steato-hepatitis, hypertriglyciderinamia and sleep apnea, reported in Swiss children (l'Allemand et al 2011; l'Allemand-Jander 2010) as well as in central European children (l'Allemand et al 2008). Hypercholesterolemia (in about 8%) and type 2 diabetes mellitus (0.5%) are even rarer in this population.

In fact, the improvement of blood lipids (Reinehr et al 2006), liver enzymes (Nadeau et al 2009) and carbohydrate metabolism (Savoye et al 2007) in association with decreased of BMI or loss of fat tissue was shown extensively, not only in international studies, but also in Swiss children (Farpour-Lambert et al 2009).

8.3.2.2 Mental health and eating disorders

The second most prevalent co-morbidities were mental disorders (46%). Scores highlighted difficulties in the field of hyperactivity and attention disorders, psychological co-morbidities of obesity are indeed well recognized (White, Nicholls, Christie, Cole, & Viner 2012).

In the present study, we found that:

- a significant number (46%) of obese children were severely impaired by behavioural and emotional problems.
- a significant number of patients who adhere to the treatment, improved significantly their scores related to psychological disorders.

A higher prevalence of overweight or obesity has also been reported in clinical samples of patients with Attention-Deficit/Hyperactivity Disorder (ADHD (Erhart et al 2012; van Egmond-Froehlich et al 2012). Children with ADHD more frequently reported eating problems as compared to their non-clinical counterparts. In a population-based study by Erhart et al. (Erhart, Herpertz-Dahlmann, Wille, Sawitzky-Rose, Holling, & Ravens-Sieberer 2012) overweight/obese children with ADHD displayed the highest level of health services utilization.

In this present study, symptoms of eating disorders were not more prevalent in obese youth than in normative sample (De Zwaan & Schüssler 2000), and they remained stable or even regressed during therapy, especially binge eating.

At baseline, the prevalence of unfavorable eating behaviors was increased, such as craving and addiction to overeating, emotional eating due to boredom, loneliness or sadness, and preoccupation with weight and shape. The knowledge on healthy lifestyle was in the normal range.

After therapy (T2), most aspects of eating behaviours evolved favourably. There were significantly less patients with overeating trends. The awareness of possibilities to influence their own health and weight by a healthy life style (eating and physical activity) did increase.

8.3.3 Changes in physical fitness and capacity

As previously published, physical capacities, such as balance, coordination, strength and speed, as well as cardiorespiratory fitness, were low at baseline compared to normative references.

After the intensive phase of therapy, significant improvement in all components of physical capacity were observed independently of age and BMI. Indeed, increased aerobic fitness in obese children is an important determinant of cardiovascular diseases (CVD). There is strong evidence that an improvement of cardiorespiratory fitness in obese children is accompanied by a reduction of CVD risk factors, and early signs of atherosclerosis. (Farpour-Lambert, Aggoun, Marchand, Martin, Herrmann, & Beghetti 2009; Meyer et al 2006). These changes may also appear without changes in BMI-SDS.

Findings of this present study highlight the fact that promoting regular physical activity in obese children may result not only in a reduction of the degree of obesity, but also in a decrease of cardio-metabolic risks or in functional incapacity. Therefore, physical activity should be systematically proposed in therapeutic programs, independently of BMI changes. As shown in non-obese children, physical activity may also reduce social isolation and increase self-esteem.

Unfortunately, overweigh children do not meet the recommendations on school sport's activity and only one third is active in sports clubs. Often obese children refrain from regular activities because of mobbing or due to inappropriate exercising or due to injuries of joints. Though motivation for the participation in sports' clubs, during the KIDSSTEP training, the number of active children has not significantly increased because it is difficult to find organisations providing adapted sports for overweight youth. According to the feedback of obesity therapists and patients, obese children are not only teased by peers due to their difficulties in sport's, but also by adults and by teachers or trainers (personal communication of program providers).

8.3.4 Changes in health-related quality of life

The concept of HRQoL expands the view on health beyond somatic factors to include the patients' subjective perspective on the physical, psychological and social aspects of health. In order to promote sustained lifestyle changes for the prevention of chronic diseases, it is fundamental to take into account the patient's health concept.

Although obesity is associated with many medical consequences even at young age, the most common short-term consequences of obesity in children are psychosocial in nature, such as psychological problems, discrimination or teasing (Wille, Bullinger, Holl, Hoffmeister, Mann, Goldapp, Reinehr, Westenhofer, Egmond-Froehlich, & Ravens-Sieberer 2010). Thus, many studies have shown a low self-esteem of obese children and adolescents compared to peers, as well as a lower health-related quality of life (HRQoL) (Bullinger et al 2007; French et al 1995).

As expected, results show a significantly impaired health-related quality of life of study participants at start of therapy. During therapy, a significant number of patients were able to improve their well-being and their functioning in various areas in the short and long term. Remarkably, dimensions with lowest average at start, showed great increases, e.g. physical well-being, self-esteem and social acceptance by peers. Also in other weight loss programs the increase in self-esteem during therapy had been shown in as an important outcome (Bullinger, Schmidt, Petersen, Erhart, & Ravens-Sieberer 2007; French, Story, & Perry 1995) (Wille, Bullinger, Holl, Hoffmeister, Mann, Goldapp, Reinehr, Westenhofer, Egmond-Froehlich, & Ravens-Sieberer 2010). As this may be relevant for long term outcome of other indicators of health, as suggested by the results of KIDSSTEP, it is crucial to examine health-related quality of life and its changes throughout therapy.

8.3.5 Changes in parents and family habits

It has been shown that parents are main agents of change in childhood obesity (Golan 2006;Golan, Kaufman, & Shahar 2006) and maternal BMI predicts the degree of overweight of the child (Shala-Haskaj 2013). Thus parents have an important role to play in setting a good example of lifestyle (Epstein & Goldfield 1999; Graf et al 2003). In MGPs, at least one parent is urged to participate in the group programs, including weight measurements. In the present longitudinal dataset, however, the programs examined do not target overweight parents on their own. Therefore, perhaps, parents do not reduce their own BMI, and fathers even seem to gain weight. Putative weight gain in fathers should be measured in a larger group and compared to fathers of untreated controls. Weight gain may represent the steady increase of adiposity in individuals already obese. It can be assumed that women/mothers are more occupied by issues of health and education than men, and so mothers tried more to realise the goals of the program. Thus further consideration and interventions should be conducted to target the overweight of parents, especially the overweight of fathers. This target is important especially with parents of younger children.

From the beginning on, we were well aware of the fact that the cohort studied is characterized by low educational level and low concentration span, both in children and in parents. Nevertheless, one of the aims of this explorative study was to identify indicators of lifestyle predicting health outcomes. Therefore we submitted several questionnaires to the parents with the risk that they are not carefully answered. Thus, only less than half of FEAH questionnaires could be analysed, because the scoring of this questionnaire is especially sensitive to incomplete answering, rendering invalid the total set of questions. Findings after 1 year of treatment showed that multiprofessional group therapy resulted in beneficial changes in the family activity and eating behaviors. The effects were independent of age, but even greater in children with severe obesity. However, the maintenance of these changes at long-term is difficult, suggesting that an individual follow-up of the child and his parents is needed.

9 Conclusions and recommendations

9.1 Established Facts

9.1.1 Specific obesity care is not available for the majority of obese children in Switzerland

In Switzerland, he number of children with obesity or overweight with co-morbidity is estimated to 119'140. During 4 years, only 1027 out of 119'140 obese children could be treated and the degree of obesity significantly improved after therapy in about 70% of cases. Thus, at this rate, it would take 200 to 300 years to treat all Swiss obese children, if no other forms of specialized care are provided.

The reasons why therapeutic services have been insufficient to date are described in chapters 5 to 6.3. There is:

- A small number of multiprofessionals group providers (MGP) and a lack of coverage in many Swiss regions. This is mainly due to the fact that the costs of therapy are not covered if there is less than 12 patients per group. The recruitment is particularly difficult in remote regions, such as mountains.
- Patient's inability to participate in the group setting of MGPs due to the severity of somatic and psychological co-morbidities, to parental occupation or other constraints.
- A lack of multiprofessional individual therapy programs for obese children to complement MGP.

The main problem of obesity therapy in MGPs, as well of in weight management programs in other countries, is the high risk of drop out or relapse of obesity after therapy. This may be related to difficulty to match the needs of specific target groups, such as ethnic minorities or young children and their parents, as recently reviewed (Boehler, Bengel, Goldapp, & Mann 2012).

Primary care interventions in individual setting are rarely evaluated and may be beneficial only if caregivers are trained in the field of childhood obesity (Sargent et al 2011), as highlighted in chapters 6.1.6., 9.2.1. Primary care screening followed by brief counseling by general practitioner 3 monthly did not improve BMI, physical activity, or nutrition in overweight or mildly obese 5-10 years old children. It would be very costly if universally implemented (Wake et al 2009).

Measures of primary prevention and health promotion usually fail to target obese children because these are too sick (Graf et al 2006; Müller et al 2001). Ethical concern related to inequity and insufficient health services for obese children in Switzerland has been addressed to FOPH in 2009 by the Swiss Society of Paediatrics, Dr. Michael Hofer.

9.1.2 Cooperation of healthcare providers and transparency of services offered to the patients are insufficient

First, the management of obese children and their families is highly demanding for health professionals because of the complexity of the pathology, as shown in the KIDSSTEP study. Second, there is often a lack of coherent information on the regional availability of certified therapeutic programs as well as of the multitude of other cantonal or non-governmental interventions.

In face of this complex disease and its associated co-morbidities, the primary care physician often gives up treating overweight children and their families. Individuals or non-governmental organizations, such as akj, have little chance by themselves to counteract the childhood obesity epidemic still present in Switzerland (Murer et al 2012). More health personal should be educated to face this chronic condition.

9.2 Novel insights

9.2.1 Good quality of nationwide data collection is possible in paediatric obesity care

The KIDSSTEP evaluation was performed using a longitudinal observational study of a new medical service under real-life conditions and funded by governmental institutions. This project shows that a centralized system of training, certification and data registry can be established in many Swiss regions, in collaboration with regional providers. The data quality was good with return rates of 87% before and after one year of therapy, as the supply of data was a condition for the reimbursement by health insurances. However, the completeness of data collection is extremely time consuming and results in a return rate of only 51% after 2 years (T3). So the dataset is of good quality during the first year, as well as for relevant observations also in the second year.

A major problem is the incomplete assessment of weight-related clinical parameter by physicians. It was extremely difficult to obtain complete forms of medical examinations. In an earlier evaluation, we observed that even abnormal findings and pathological blood parameter, e.g. increased fasting glucose levels, were not reported. As stated elsewhere, the screening of co-morbidities was seldomly performed as recommended, and quality criteria for institutions have to be implemented to improve the medical care of overweight children.

9.2.2 Multiprofessional group therapy is effective to improve overweight, co-morbidities and physical capacity, quality of life and mental health being prerequisites

The following predictors of outcomes were determined:

- Children with a gain in health-related quality of life during therapy showed significantly greater decrease in BMI-SDS than the others.
- Mental health disorders have an impact on treatment outcome and extremely obese children have more difficulties to improve their degree of adiposity, than overweight and less obese children.
- Patients with stable or increased consciousness of possibilities to influence weight by a healthy life style and by physical exercises (salutogenic eating cognitions) showed a more significant decrease of BMI-SDS than the others.
- Patients with a decrease in scores for craving / addiction to overeating also significantly decreased in BMI-SDS between T0 and T2 and stabilized their BMI-SDS till T3, in contrast to the others.

9.2.3 Follow-up until 2 years shows sustained effects and longer term care is warranted

Most physical changes occurred during the intensive phase of therapy and were sustained thereafter for 2 years. The design of the study allowed the follow-up of only a small number of patients, however with a continuous specialized care, a relapse of severe obesity is prevented. As in every chronic disease, a follow up by a physician is warranted at least every 6 months, as long as overweight has not yet been normalized and co-morbidities resolved. Usually, a 2 to 5 years follow up is recommended.

9.2.4 Health condition is more rapidly improved in younger children

One of the most important predictors of rapid weight loss is young age. The extent of weight loss is significantly higher during the first year of therapy in younger children than in children older than 12 years, but similar for extremely obese as for less obese patients. A better effect of therapy has also been described in other studies, the younger or the less obese a child is, the shorter the obesity persists (Hofmeister U et al 2008). Furthermore, it appears that overweight precedes mental health problems in children, particularly peer problems and, on a lower level, emotional problems, rather than the reverse (Jansen et al 2013), and that

obese children aged 4-5 years have less psychosocial problems than those aged 10-11 years.

9.2.5 Multiprofessional therapy does not induce side effects or eating disorders

In other studies, dieting (OR 2.30, 95% CI 1.36 to 3.89) was associated with resolved childhood overweight or obesity (Wake et al 2010). The main concern, that eating disorders may be provoked by "weight –loss programs" due to preoccupation with weight and shape, was clearly refuted in KIDSSTEP study. Symptoms of disordered eating even decreased and eating behaviour changed into a healthier direction. Behaviours of vomiting or purging were mostly unknown to children of this study, but did not change during therapy, if present. Eating disorders are to be addressed separately in addition to MGPs.

9.3 Recommendations

9.3.1 Group therapy and additional forms of multiprofessional care are to be delivered to all obese children and their access in all regions must be guaranteed to decrease inequity of opportunities.

a) **Cultural and language** background of families is to be considered, e.g. by professionals with other language background, in order to minimize the dropout rate in foreign families; due to the high proportion therapists of non-Swiss origin, such a qualification can be found at reasonable expense.
b) A **smaller group size** is to be proposed because this would allow to provide therapy
   - In remote regions apart from large centres
   - To adapt groups for migration background or age
   - To multiply the number of therapy groups.

   To guarantee cost-effectiveness, reimbursement for group therapy has to be increased to 9000,- CHF instead of 4200.- CHF for the same therapy structure (about 116h per 1 to 2 years) as fixed in the 2009 tariff convention. The calculation of costs was presented separately[19] and approved by the FOPH/ Commission of medical services.
c) Group programs for young children aged 4 to 8 years should be developed, including for example less than half of the therapy sessions for children and roughly the same quantity for parents, at 50% of the costs calculated for older groups.
   So far, group programs for young children did work successfully but could no longer be offered, because through providing scientifically approved therapy, they did not comply with the fixed quantitative structure of MGPs. They could therefore not be certified.

As mentioned above, the availability of multiprofessional therapy is necessary to care for those too obese or too ill to recover within 1 year of MGP therapy. This will be proposed in a separate application for multiprofessional structured individual therapy for overweight and obese children (MSIT) [20].

In addition, a multiprofessional therapy in an **individual setting** must be established in clinical practice, according to the recent ordinance of December 6th, 2013, to prevent the maintenance of obesity into adulthood, especially for the following patients;

- disabled by orthopaedic or other somatic problems and / or
- with impaired mental health or very poor quality of life,
- with preclinical or manifest eating disorders,

[19] Antrag auf dauerhafte Übernahme der MGPs in die KLV, 8.5.2013, Laimbacher J et al.
[20] MSIT-Antrag an die ELGK, 13.5.2013

- in families with psychosocial strains and
- in those still severely obese after MGPs.

9.3.2 Multiprofessional group therapy and long term relapse prevention are to be imbedded into a system of tertiary prevention of non-transmissible chronic disease

Multiple effects on different aspects which influence health and a healthy way of living could be demonstrated and justify the permanent implementation of MGPs in Swiss healthcare system. Though this demanding therapy form is suitable only for a part of obese children, it remains the cornerstone of multiprofessional therapy. It was planned to embed this therapy into a system of obesity care. Unfortunately, relapse prevention or similar measures do not yet exist and classical sports' clubs are not suitable for these children still at overweight. A combination of prevention interventions with follow up care after MGPs is suggested.

Our results suggest that practitioners must pay special attention to patients with exceptionally low HRQoL scores and appropriate treatment should be provided to them, e.g. working on personal skills and improved self-perception. Finally, since HRQoL scores can be indicators of social problems of patients (school, peers, family etc.), practitioners should consider mutual interventions with professionals of these fields, f. ex. school social workers, to improve therapy outcomes. However, up to now, no funds are provided by the OKP (Krankenpflegeversicherung) for such interventions.

9.3.3 Screening for and therapy of early onset of obesity as a precursor of other non-transmissible diseases in young children is necessary to reduce cases and costs of subsequent co-morbidities

Screening for and therapy of obesity in young children demand special formation of health professionals to guarantee favourable long-term outcomes, as argued above. As different problems of mental health, musculoskeletal system and social functioning are concerned, a multiprofessional approach is warranted also in the primary care setting, including nurses, physical education teachers or other physical activity professionals and psychologists, as well as others. Health professionals are to be trained on causes and realistic outcomes of childhood obesity. Especially weight loss should not be the first goal of this therapy. If co-morbidities are reduced, well-being improved and physical activity performed regularly, direct and indirect medical costs will be reduced.

9.3.4 The quality of care is to be guaranteed in future

9.3.4.1 Benchmarking system using simple indicators

Recommendations for quality control of group programs:

Central registration of main outcome measures :

1. In structured multiprofessional therapy programs, health status should be assessed completely by the questionnaire #x05, every 12 months (available on the akj website) and the questionnaire on medical history, handed out to parents before the 1st examination, and completed by the physician.

The documentation of a minimum of 9 parameters before, after 1 and 2 years will be compulsory *to obtain certification:*

2. Centre of treatment

3. Date of examination,
4. Date of birth,
5. Gender,
6. Height,
7. Weight, to calculate BMI and BMI-SDS
8. Waist circumference,
9. Blood pressure,
10. Presence/ absence of children during therapy sessions

- additional 5 indicators related to therapy outcome, based on the KIDSSTEP study, will be assessed:

11. Measured actual weight of mother (Wrotniak et al 2004) and father,
12. Language spoken at home with parents (to be compared with country of birth of parents of the Swiss Federal Population Census- to assess migration background.)
13. Quality of life by question "Hast du dich fit und wohl gefühlt in der letzten Woche?" (Kidscreen-52),
14. "Do you have any problems at school?" (screens well-being, social integration and intellectual or severe mental health problems)
15. Hours of organized physical activity (after school) per week.

And at T0 and T2 (before and start of therapy):

16. SDQ score above clinical cut-off,
17. Chester step test to measure physical capacity /fitness
18. Kidscreen-10 for Health-related quality of life

Parameters # 7 to 9 and 13 to 18 are considered to be relevant indicators of health changes during therapy.

A central registry, supported by governmental or research funding, e.g. as in Germany, will document outcomes of complex therapies in paediatric obesity, and selected outcomes will be entered in the database directly by the therapy providers or the patients. This works in other fields of medical services, if the provision of data is a pre-requisite for certification by the professional association and for re-imbursement by health insurances. The existing independent KIDSSTEP Access database will be transformed into a protected nested network, e.g. with the support of the Service of Science Information of the University Hospital of Geneva (Prof. C. Lovis) or other research groups. This system will be tested under real life conditions in a follow-up project of the present pilot study.

9.3.4.2 A coordination and information platform is needed

As mentioned in the Federal Council's health-policy priorities "Health 2020" and within the scope "to improve the prevention of and screening for non-transmissible diseases, measures need to be taken". In the field of pediatric overweight management, such measures may include coordination and information platform, funded by governmental means

=> to improve accessibility and efficiency of services for obese children and

=> to organize formation of professionals as described in chapter 6.1.6.

10 Abbreviations

AAP	American Academy of Pediatrics
AD-EVA	Interdisziplinäres Testsystem zur Diagnostik und Evaluation bei Adipositas und anderen durch Ess- und Bewegungsverhalten beeinflussbaren Krankheiten (Ardelt-Gattinger & Meindl 2010)
akj	Fachverband Adipositas im Kindes- und Jugendalter
ANOVA	Analysis of variance
BAG/ OFSP/ FOPH	Bundesamt für Gesundheit / Office fédéral de la santé publique / Federal Office of Public Health
BP	Blood pressure
BMI	Body mass index, weight in kilograms divided by the square of height in meters.
BMI-SDS	Body mass index, standard deviation score
CI	Confidential interval
EDI	Eidgenössisches Departement des Inneren
Eurofit	Test for aerobic fitness, muscle strength, balance and coordination (Narring et al 1999), validated for many European countries
FEAH	Family Eating and Activity Habits Questionnaire – Revised (Golan & Weizman 1998)
FFQ	Food Frequency Questionnaire (Cavadini et al 1999)
FOPH	Federal Office of Public Health
GLM	General linear model
HRQoL	Health-related quality of life
IOTF	International Obesity Task Force
KIDSCREEN-52	Health-related quality of life questionnaires for children and adolescents (Ravens-Sieberer & The KIDSCREEN Group 2006), Version with 52 items
KIDSSTEP	Kinder-Adipositas in der Schweiz- Studie zur Therapie-Evaluation von Programmen in Gruppen
MGP	Multiprofessionelle Gruppentherapieprograme für übergewichtige und adipöse Kinder und Jugendliche
MSIT	Multiprofessionelle strukturierte Individual-Therapie für übergewichtige und adipöse Kinder und Jugendliche
OB	Obesity
SD	Standard deviation
SDS	Standard deviation score
SDQ	Strength and Difficulties Questionnaire (Goodman 1999)
T0, T1	visit at start and after intensive therapy
T2, T3, T4	visit 1, 2 and 3 years after start of therapy, respectively
SEM	standard error of the mean

SGP / SSP	Schweizerische Gesellschaft für Pädiatrie / Swiss Society of Paediatrics
WtHR	Waist-to-height ratio
WC	Waist circumference
WHO	World Health Organisation
ZKE	Zürcher Kurzfragebogen zum Erziehungsverhalten (Reitzle et al 2001)

11 Publications

Master theses:

Zivkovski O, Bolten M, and Flückinger C. Vorhersage des Therapieerfolgs bei der pädiatrischen Adipositastherapie durch die Therapiemotivation:1-91. 22-8-2011. Institut für Psychologie; Abteilung Klinische Psychologie und Psychotherapie; Universität Bern, Philosophisch-humanwissenschaftliche Fakultät.

Shala-Haskaj, Pranvera: Schlafverhalten sowie familiäre und gesundheitliche Risiken von Kindern und Jugendlichen mit Adipositas. Masterarbeit, Medizinische Fakultät, Universität Zürich: 1-68. 14.3.2013.

Diverse abstracts at national and international meetings:

1. Dagmar l'Allemand, Nathalie J. Farpour-Lambert, Robert Sempach, Esther Kirchhoff, Josef Laimbacher. Childhood obesity therapy in Switzerland – where are we? Swiss Medical Weekly 2010, 140(21-22)Suppl.180:36S, (Vortrag SGP, Crans-Montana, 18.6.2010)

2. L'Allemand D., Kirchhoff E., Bolten M., Zumbrunn A.; Sempach R., Laimbacher J., Farpour-Lambert N. Group therapy of overweight children in Switzerland – medical results after one year (FOPH #09.004211/204.0001/-629) Swiss med. Wkly 2011;141(Suppl 187); S. 4

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12 Attachments

1. List of certification for MGPs, March, 2013
2. Tariff contract with Santésuisse of October 29th, 2008
3. Questionnaire of history "Anamnese", #i04
4. Questionnaire of medical status, #i05
5. Pubertal stages as enclosure of #i05
6. A complete set of questionnaires in German, French and Italian versions was delivered with the final Report of the 1st part, on January 20th, 2009 (l'Allemand, Sempach, & Farpour-Lambert 2009), an actualized form will be sent with the paper version of this report.

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