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Original Article

A Structured, Manual-Based Low-Level Intervention vs. Treatment as Usual Evaluated in a Randomized Controlled Trial for Adolescents with Extreme Obesity – the STEREO Trial

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Keywords
Extreme obesity · Youth · Adolescents · Adherence · Quality of life · HRQoL

Abstract
Background: To compare efficacy and safety of a manual-based low-level psychological intervention with treatment as usual (weight loss treatment). ***Methods:*** A two-armed randomized controlled trial without blinding and computer-based stratified block randomization included adolescents and young adults (14.0–24.9 years) with a BMI ≥ 30 kg/m^2 at five German university hospitals. Primary outcomes were adherence (participation rate ≥ 5/6 sessions) and quality of life (DISABKIDS-37) 6 months after randomization. Secondary outcomes included

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depression, self-esteem, and perceived stress scores. ***Results:*** Of 397 screened adolescents, 119 (mean BMI 40.4 ± 7.0 kg/m^2, 49.6% female) were randomized to the manual-based low-level intervention (n = 59) or treatment as usual (n = 60). We observed no group difference for adherence (absolute risk reduction 0.4%, 95% CI –14.7% to 15.5%; p = 1.0) or health-related quality of life (score difference 8.1, 95% CI –2.1 to 18.3; p = 0.11). Among all secondary outcomes, we detected explorative evidence for an effect on the DISABKIDS-37 'social exclusion' subscale (score difference 15.5; 95% CI 1.6–29.4; p = 0.03). 18/19 adverse events occurred in 26 participants, none were classified as serious. ***Conclusion:*** Adherence to a coping-oriented intervention was comparable to weight loss treatment, although it was weak in both interventions. Psychological interventions may help to overcome social isolation; further confirmation is required.

Introduction

Worldwide, 5% of children and adolescents are affected by obesity [1]. Weight loss programs for children and adolescents lead to statistically significant effects on weight status, but the overall amount of weight reduction is modest [2, 3]. One major problem in evaluating the effects of such treatments is the high attrition rate of up to 42–50% [2, 3]. Determinants of the frequent 'drop out' are poorly understood.

Based on data from systematic reviews [2, 3] and clinical trials [4], adolescents with extreme obesity (BMI ≥ 99.5th percentile) cannot be expected to reach substantial weight loss through lifestyle interventions over the intermediate term. Extreme obesity entails a high risk of somatic [5] and psychiatric [6] co-morbidities. Extremely obese adolescents face stigmatization in peer groups [7] and work settings, entailing the risk of long-term unemployment [8, 9]. Accordingly, an increasing number of adolescents are treated with bariatric surgery [10]. Weight loss surgery appears to be the only effective treatment for extreme obesity regarding weight loss and improvement of co-morbidities [11, 12].

While conservative treatment may lead to feelings of failure regarding weight reduction, coping with obesity-related psychosocial impairments is not regularly part of the standard care. Effects of obesity treatment on psychosocial outcomes have infrequently been evaluated in previous trials. In our review [3], only one of the included randomized controlled trials (RCTs) defined self-efficacy as a primary outcome [13], even though the focus of the intervention was on weight loss. We are not aware of any RCT with a focus on adherence as the primary outcome in an intervention, in which weight loss was not a treatment goal.

Adherence has frequently been measured by the participation rate in an intervention [3, 14]. Additionally, the term adherence has been applied to behavioral targets (e.g. healthy diet/activity behaviors) [15, 16]. In light of the overall weak effects of weight loss treatment on weight status in extremely obese adolescents [2–4], we concentrated on the participation rate as the main and sole measure of adherence, which is our primary outcome. The participation rate in an intervention aimed at promoting coping strategies and acceptance of obesity represents an appropriate type of outcome for this extreme weight group. We assume that a successful participation may represent an important indicator of long-term adherence of patients who subsequently receive bariatric surgery. Long-term adherence may in turn help minimizing possible complications after bariatric surgery due to continuous monitoring. Provided that this assumption is correct, assessment of adherence may also help to identify individuals eligible for bariatric surgery.

Acknowledging the limited efficacy of weight loss treatment and potentially related feelings of failure and shame, we hypothesized that adolescents and young adults with

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extreme obesity may show a greater adherence in a treatment program with the aim of coping with obesity rather than weight loss. Thus, this RCT was designed to evaluate i) efficacy and ii) safety of a manual-based low-level intervention aimed at improving quality of life, mood, self-esteem, and perceived stress compared to treatment as usual. We hypothesized that i) adherence to the program and ii) covariate-adjusted changes in quality of life between baseline and the 6-month follow-up differ between the two treatment groups.

Material and Methods

Trial Design

The STEREO trial was designed as an open two-armed RCT conducted at five centers in Germany (Pediatric University Hospitals in Ulm, Datteln, Berlin and Leipzig, and Child and Adolescent Psychiatry in Essen) that randomized 13/32/38/0/36 participants. The STEREO trial was part of the Youth with Extreme Obesity Study (YES) [17].

Participants

Participants were recruited between September 2012 and June 2014. The 6-month follow-up assessments were conducted from March 2013 to December 2014. Recruitment pathways involved regional outpatient obesity care units and advertisement via internet, media, and job centers [17]. In Essen, recruitment was mainly based on a co-operation with the job center with a focus on unemployed young subjects aged between 15.0 and 24.9 years, and the diagnostic and therapeutic procedures were offered on the premises of this job center. An age range from 14.0 to 24.9 years (42/119 randomized participants were aged ≥ 18 years) and a BMI ≥ 30 kg/m^2 formed the inclusion criteria. In March 2013, the former inclusion criterion of an age range 14.0–20.9 years was modified by an amendment of the study protocol in order to also reach the high-risk group of young adults and to stimulate recruitment. Moreover, the traveling time spent between residence and center had to be below 90 min using either private or public transportation. Exclusion criteria were insufficient knowledge of German language, intellectual disability, and conditions precluding an outpatient treatment (i.e. immediate or imminent requirement of hospitalization due to severe somatic or psychiatric disorders).

The collected baseline characteristics included sex, age, native country, measured height and weight for calculation of BMI, and self- or participant-reported parental BMI, parental educational status, and parental nationality.

Interventions

The STEREO trial had two intervention arms [17]: an innovative manual-based low-level intervention focusing on coping with obesity and promoting quality of life and an interdisciplinary lifestyle intervention aimed at weight reduction (treatment as usual (TAU)). Both interventions were performed on the basis of a structured manual to ensure consistency between study centers. Each program consisted of six 90-min group sessions offered every 2 weeks. Thus, the intervention was classified as low-level. The same amount of sessions for each program allowed for comparison. Prior to the randomization, participants were informed that based on the current scientific evidence no superiority of one of the interventions concerning weight loss is assumed. Participants of both interventions who attended at least five sessions were offered participation in a subsequent information and preparation program on bariatric surgery ([17]; data not presented); this information was provided at baseline.

Manual-Based Low-Level Intervention

The overarching aim of this intervention was coping with obesity and its acceptance. Importantly, weight reduction was not a focus. The manual-based low-level intervention program included elements of cognitive behavior therapy and motivational interviewing. It was delivered by trained psychologists and

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involved the topics life satisfaction (e.g. family, friends, and school/work), self-esteem (e.g. concentrating on other strengths than physical appearance), social competency (e.g. initiating friendships), body image (e.g. acceptance of body shape), and coping with bullying and anger. The sessions comprised psychoeducative elements, role-playing, body image exposition or response prevention (avoidance of looking at or excessively checking one's own body shape), activation, problem solving, and therapeutic homework to consolidate the learned skills. During and after the intervention, the participants had access to a local expert network (e.g. psychotherapist, vocational counseling) depending on their own needs.

TAU

The overarching focus of TAU was weight reduction. The TAU program corresponded to the recommendations of the German evidence-based guidelines for the treatment of obesity in childhood and adolescence [18]. It was delivered by a multiprofessional team involving trained psychologists, physicians, dieticians, and physical activity therapists. The topics were medical information (causes, consequences, and treatment options of obesity), nutrition (healthy food choices and frequency of meals), eating behavior (e.g. distinguishing between hunger and appetite, learning action alternatives for emotional eating), self-esteem (focusing on personal strengths), and media consumption (reduction of sedentary behavior).

Outcomes

Outcome measures for efficacy were assessed 6 months after randomization by trained physicians and/or psychologists. The primary outcome variables were i) adherence to the six sessions and ii) changes of global health-related quality of life (HRQoL) between randomization and the 6-month follow-up. Successful adherence was defined as participating in at least five distinct sessions within the 6 months after randomization. HRQoL was measured by the global score of the DISABKIDS-37 questionnaire (chronic generic module [19]). Secondary outcomes included changes from randomization to 6-month follow-up in different domains of HRQoL (on six subscales of the DISABKIDS questionnaire and the KIDSCREEN-52 questionnaire [20]), the depression score (Beck's Depression Inventory II (BDI-II) [21]), self-esteem (German version of the Rosenberg-Scale [22]), perceived stress (German version of the Perceived Stress Questionnaire (PSQ) with 20 items [23]), self-reported occupation (including school/university attendance, vocational training or work as a proxy for time spent outside the home), and self-reported physician/psychotherapist contacts.

Safety was measured by (serious) adverse events during the intervention. Participants were queried about adverse events at the end of each session and were offered to report them to the therapist individually. All events were documented and classified according to the Medical Dictionary for Regulatory Activities.

Ethics

The study protocol was approved by the human research ethics committees at the Universities of Ulm, Essen, Datteln, Berlin, and Leipzig. An independent Data Safety and Monitoring Board, consisting of experts in the fields of psychiatry, adolescent medicine and biometry/statistics, steadily supervised the process of recruitment and safety parameters according to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (Good Clinical Practice). Participants aged 18 and above gave written informed consent. In the case of minors, written informed consent was obtained independently from the adolescent and at least one caregiver.

Sample Size

Originally our study was designed to detect mean differences of 0.33 units of standardized effect sizes (Cohen's d) [17]. This resulted in 2 × 175 = 350 participants to be randomized to meet a power of 80%, while allowing for a drop-out rate of ~15%. Due to substantially lower adherence rates, the trial was stopped early, including 119 participants only. Thus, the study was underpowered to detect the effect sizes of the original

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plan. In fact, a study with 59 + 60 = 119 participants has a power of 80% to detect mean differences ≥ 0.5 units of standardized effect sizes for the HRQoL-related research question. Projected to the first of the two primary research questions (adherence rate), the power is 80% to detect differences between e.g. 10% and 33%. The trial had no planned interim analyses.

Randomization and Blinding

Concealed allocation was performed by the independent Center for Clinical Trials Essen after participant registration; the validated software TENALEA (*https://nl.tenalea.net/amc/ALEA/Login.aspx*) was used for computer-based stratified (strata: center, gender, age (<18 years, ≥18 years), BMI class (30–35 kg/m^2, ≥35 kg/m^2)) blocked randomization with randomly varying the block size. The study had a design without blinding.

Statistical Methods

The confirmatory test of the two hypotheses related to the primary outcomes followed a priori hierarchically ordered testing [24] to control the family-wise error rate in a strong sense at a significance level α (two-sided) of 5%. As confirmatory test, we used Fishers' exact test for the first primary dichotomized outcome in successful (≥five out of six sessions) and unsuccessful (<five sessions) adherence. For the second primary outcome, changes in the DISABKIDS global score between baseline and follow-up were analyzed. For all secondary outcomes we had to use methodologically simpler analyses (Welch's t tests and non-parametric Wilcoxon-Mann-Whitney test tests as sensitivity analysis (data not shown due to results highly similar to those obtained with Welch's t tests)) as compared to our initial plan [17] to address the limited number of observations. For the same reasons, we decided not to work with the change scores, but instead referred to the cross-sectional results at 6 months after randomization. The confirmatory tests were run in the intention-to-treat population. As sensitivity exploratory analyses, we re-ran the analyses in the per-protocol population (data not shown as results were identical due to only one protocol violation) and decided against stratified analyses due to the small sample size of participants with 6-month follow-up data. We report estimated effects, corresponding 95% confidence intervals and two-sided p values. We applied no multiplicity adjustment for the exploratory sensitivity and secondary outcome analyses. All analyses were performed in R 3.1.1 or SAS 9.3.

Results

Sample Characteristics

Trial flow and baseline sample descriptions are shown in figure 1 and table 1. 30.0% of the screened individuals fulfilled the inclusion criteria and were willing to participate in the RCT. Of 119 randomized participants (mean age 17.6 ± 3.1 years, 49.6% female), between 19 and 31 (19–26% depending on the outcome) case report forms were available for the 6-month follow-up assessment. Mean baseline BMI of the whole study group was 40.4 ± 7.0 kg/m^2.

Efficacy

Table 2 presents the results of the group comparisons for the primary and secondary outcomes. Depending on the scale of the outcome, either absolute risk reductions or mean differences are reported as estimated effect such that higher values of the differences indicate better performance of the manual-based low-level intervention.

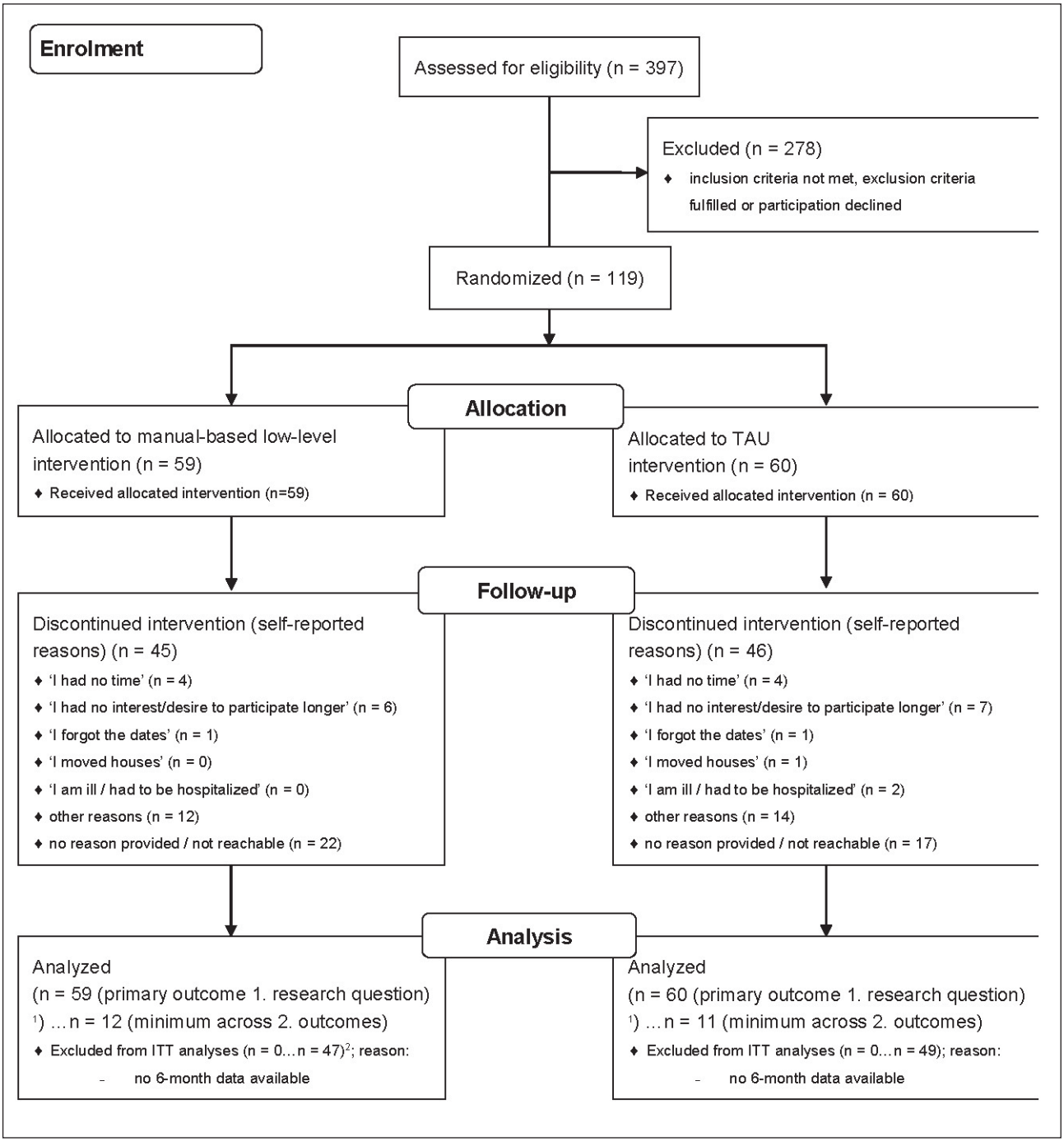

Fig. 1. CONSORT 2010 Flow Diagram [28] for the STEREO trial.[1]Note that adherence as part of the primary outcome will be available for all allocated participants. [2]One participant had to be excluded from the per protocol analyses due to violations of inclusion/exclusion criteria that were noted after the randomization.

Primary Outcomes

In each treatment group, only 14 participants (manual-based low-level intervention: 23.7% vs. TAU: 23.3%) attended at least five of the six sessions. Thus, adherence did not differ between the treatment conditions in the confirmatory analysis (absolute risk 0.4%; 95% CI

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Table 1. Baseline sample descriptions in the two intervention groups; either means ± standard deviation or n (%) are displayed

	Manual-based low-level intervention (n = 59)	TAU intervention (n = 60)	Total (n = 119)
Age	17.7 ± 3.2	17.5 ± 3.0	17.6 ± 3.1
Sex, n (%)			
Female	28 (47.5)	31 (51.7)	59 (49.6)
Male	31 (52.5)	29 (48.3)	60 (50.4)
BMI, kg/m^2	40.7 ± 7.8	40.2 ± 6.2	40.4 ± 7.0
BMI percentile[1]	99.8 ± 0.3	99.9 ± 0.2	99.8 ± 0.2
Native country, n (%) (n = 113)			
Germany	52 (94.5)	55 (94.8)	107 (94.7)
Other	3 (5.5)	3 (5.2)	6 (5.3)
Parental education[2], n (%) (n = 101)			
Basic school graduation[3]	13 (27.1)	13 (24.5)	26 (25.7)
Medium school graduation[4]	23 (47.9)	19 (35.8)	42 (41.6)
High school graduation[5]	7 (14.6)	13 (24.5)	20 (19.8)
Other	1 (2.1)	3 (5.7)	4 (4.0)
Without school graduation	4 (8.3)	5 (9.4)	9 (8.9)
Mother BMI[6], kg/m^2	30.8 ± 6.4 (n = 49)	30.0 ± 7.5 (n = 48)	30.4 ± 7.0 (n = 97)
Nationality mother, n (%) (n = 109)			
German	44 (83.0)	48 (85.7)	92 (84.4)
Other only	9 (17.0)	8 (14.3)	17 (15.6)
Father BMI[6], kg/m^2	29.1 ± 4.6 (n = 42)	29.4 ± 8.0 (n = 43)	29.3 ± 6.5 (n = 85)
Nationality father, n (%) (n = 105)			
German	39 (76.5)	46 (85.2)	85 (81.0)
Other only	12 (23.5)	8 (14.8)	20 (19.0)

[1]Based on extrapolated values from a German reference population [29, 30].
[2]Higher combined educational status across both parents.
[3]German 'Hauptschulabschluss/Volksschulabschluss'.
[4]German 'Mittlere Reife, POS'.
[5]German 'Abitur, Fachhochschulreife';
[6]Based on self- or participant-reported parental weight and height.

–14.7% to 15.5%; p = 1.0). Self-reported reasons for low adherence are listed in figure 1. Similarly, we observed no evidence for a group difference in the global score of the DISABKIDS questionnaire as the second primary outcome measure (between group score difference at follow-up 8.1; 95% CI –2.1 to 18.3; p = 0.11).

Secondary Outcomes

We observed exploratory evidence for a group difference for the DISABKIDS subscale 'social exclusion', indicating a better performance of the manual-based low-level intervention group (score difference 15.5; 95% CI 1.6–29.4;, p = 0.03). For all other secondary outcomes, we found no evidence for group differences (all p > 0.05) even though eight of the nine analyzed secondary outcomes ($p_{\text{binomial sign test}}$ = 0.004) indicated a descriptively better outcome in favor of the manual-based low-level intervention (table 2).

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Table 2. Results of the primary and secondary outcomes by intervention group determined 6 months after randomization; either means ± standard deviation or n (%) are displayed

	Manual-based low-level intervention (n = 59)	TAU intervention (n = 60)	Estimated effect[1] (95% CI)	p value (two-sided)
Primary outcome(s)				
Adherence				
Successful	14 (23.7)	14 (23.3)	0.4% (–14.7%; 15.5%)	1.00
Unsuccessful	45 (76.3)	46 (76.7)		
HRQoL: DISABKIDS score (DCGM-37)[2]	67.6 ± 10.2 (n = 12)	59.5 ± 13.6 (n = 12)	8.1 (–2.1; 18.3)	0.11
Secondary outcome(s)				
HRQoL				
DISABKIDS score ('independence')[2]	67.6 ± 19.7 (n = 13)	62.2 ± 14.3 (n = 13)	5.4 (–8.6; 19.4)	0.43
DISABKIDS score ('physical limitation')[2]	69.6 ± 17.0 (n = 13)	61.5 ± 9.5 (n = 13)	8.0 (–3.3; 19.4)	0.16
DISABKIDS score ('emotion')[2]	63.1 ± 17.6 (n = 13)	49.2 ± 21.8 (n = 13)	13.9 (–2.2; 30.0)	0.08
DISABKIDS score ('social exclusion')[2]	79.3 ± 12.7 (n = 12)	63.8 ± 19.1 (n = 12)	15.5 (1.6; 29.4)	0.03
DISABKIDS score ('social inclusion')[2]	63.2 ± 12.1 (n = 13)	57.7 ± 18.9 (n = 13)	5.5 (–7.4; 18.4)	0.39
KIDSCREEN-52 score[3]	67.8 ± 13.2 (n = 12)	61.3 ± 16.4 (n = 11)	6.5 (–6.6; 19.6)	0.31
Depression				
BDI-II	7.3 ± 5.4 (n = 13)	7.6 ± 9.1 (n = 13)	0.3 (–5.8; 6.5)	0.92
Self-esteem				
Rosenberg[2]	67.8 ± 16.1 (n = 12)	67.9 ± 16.7 (n = 14)	-0.1 (–13.4; 13.2)	1.00
Perceived stress				
PSQ overall score[4]	37.8 ± 14.8 (n = 12)	40.7 ± 17.2 (n = 14)	2.9 (–10.0; 15.9)	0.64
Self-reported occupation[5] (n = 16+14)				ND
School attendance	8 (50.0)	8 (57.1)		
Vocational training/studies	2 (12.5)	2 (14.3)		
Gap year to do voluntary work in the social sector	1 (6.3)	0 (0.0)		
Employed	0 (0.0)	1 (7.1)		
Unemployed	5 (31.3)	3 (21.4)		
Self-reported physician / psychotherapist contacts[6]				ND
Physician[7] (n = 16+12)	16 (100.0)	11 (91.7)		
Psychotherapist[8] (n = 17+14)	2 (11.7)	1 (7.1)		
Hospital[9] (n = 16+14)	2 (12.5)	1 (7.1)		

[1]Depending on the scale of the outcome either absolute risk reductions or mean differences are reported such that higher values of the differences indicate better performance of the experimental intervention.

[2]Transformed to a 0; 100 scale (larger values indicate better outcomes).

[3]We created a global score which we transformed to a 0; 100 scale (larger values indicate better outcomes).

[4]Transformed to a 0; 100 scale (larger values indicate more perceived stress – i.e. a worse outcome).

[5]Current occupation 6 months after randomization.

[6]Multiple (yes/no) answers per participant were allowed.

[7]'Did you contact a physician during the past 6 months?'

[8]'Did you contact a physician during the last 6 months?'

[9]'Did you have inpatient treatment in the hospital during the past 6 months?'

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Safety

We observed no serious adverse events during the trial period. 26 participants reported a total of 37 adverse events (manual-based low-level intervention: 19 events (nasopharyngitis and insomnia most frequently (3×) reported); TAU: 18 events (nasopharyngitis and headache most frequently (3×) reported). None was judged as likely related to the intervention.

Discussion

This trial investigated the adherence to six sessions, efficacy and safety of a manual-based low-level intervention aimed at coping with obesity and its acceptance compared to TAU (weight loss treatment). Only a small proportion of adolescents and young adults participated in our program. Adherence was low and did not differ between the treatment groups. The participation rates were comparable to those in other RCTs. Recent systematic reviews [2, 3] reported 'drop-out' rates of up to 42% or 50%, and 'losses to follow-up' of up to 43% or 71%. The adherence of adolescents and young adults compared to children could be even lower because of less parental support. Similarly, prior trials have revealed a low treatment interest in families of obese children [25].

Center-specific subanalyses revealed that the unemployed adolescents and young adults recruited in the job center exhibited a relatively higher adherence than those recruited from the pediatric university hospitals (32.2% vs. 20.5%). Possible explanations might be that these unemployed subjects were substantially older (21.6 ± 2.3 vs. 16.2 ± 1.8 years) and could have been more motivated because of their difficult psychosocial situation. Another possible explanation may be the lower treatment barrier, as the intervention was offered at a job center, rather than in a medical institution. Contrastingly, in another study a small proportion of families with low socioeconomic status was enrolled into obesity treatment programs [26]. Indeed, the reduction of treatment barriers for individuals with low socioeconomic status forms an important issue for health care policies [27].

For the second primary and the secondary outcomes, we also observed no evidence for a treatment effect. The secondary primary outcome, the HRQoL global score measured by the DISABKIDS questionnaire, was slightly higher in the manual-based low-level intervention group but did not significantly differ between the treatment groups. For the DISABKIDS subscale 'social exclusion', we observed explorative evidence for a better performance of the manual-based low-level intervention. If not due to multiple testing, this result may be attributed to a reduction of social isolation achieved by teaching social competence in the manual-based low-level intervention. Besides that, a tendency for a better outcome of the manual-based low-level intervention was observed in most of the secondary psychosocial outcome measures based on the respective mean values. On the other hand, positive group interactions and thus reduction of social isolation could have led to a similar participation rate and improvement of psychosocial functioning in the TAU group. In a comparable trial [13], both treatment groups (social skills training + TAU vs. motivational interviewing + TAU) improved their self-efficacy after 6 months.

Strengths and Limitations

To our knowledge, this is the first RCT assessing adherence defined as the participation rate as a primary outcome measure in an intervention not aiming at weight loss. With our suggested multi-leveled program, consisting of the manual-based low-level intervention and

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a subsequent information and preparation program on bariatric surgery [17], we propose a novel treatment approach which might help identifying adolescents and young adults eligible for bariatric surgery. Only individuals exhibiting a solid pre-surgical adherence are presumed to be willing/able to undergo continuous post-surgical monitoring which may help to prevent long-term risks and complications of bariatric surgery, especially in adolescents and young adults. Besides this, helping this age group to cope with psychosocial impairments forms an important task as extreme obesity is a chronic condition. Further strengths of this study encompass the multi-centered randomized study design, the use of a TAU arm consistent with clinical guidelines of obesity treatment [18], the involvement of multiple recruitment pathways (including facilitation of treatment access for individuals with low socioeconomic status) and the involvement of a multidisciplinary team and a Data Safety and Monitoring Board with profound clinical trial experience.

The most important limitation was the small sample size leading to a substantial loss of statistical power. Despite the use of multiple recruitment pathways and initiatives to boost recruitment we did not reach the proposed sample size. Consequently, the application of statistical methods was limited. To allow for exploratory analyses of the secondary outcomes, we did not adjust them for multiple testing. Due to the small sample size and heterogeneity of the study centers (e.g. recruitment pathways, age), results cannot be generalized to adolescents/young adults with extreme obesity. A relatively high proportion of participants discontinued the intervention, and, even though this was addressed by our primary analysis strategy, it is still possible that an attrition bias impacted the questionnaire-related outcomes. A potential performance bias was reduced by a standardized manual-based approach carried out at all study centers. Due to a study without blinding, a detection bias cannot be ruled out.

Conclusion

Overall, this study revealed no evidence for treatment effects in adherence or HRQoL when comparing a manual-based psychological intervention against TAU for adolescents and young adults with extreme obesity. On one hand, the participation in a psychological intervention may help to overcome social isolation and cope with impairments in social life, but further confirmatory trials are needed to substantiate this explorative observation. On the other hand, the major problem of a low adherence rate in treatment programs for adolescents with (extreme) obesity [2, 3] could not be solved by offering a coping-oriented psychological treatment approach in our study. The low adherence rate highlights the importance of assessing adherence in future trials and clinical practice, especially for socioeconomically disadvantaged and those adolescents and young adults presenting for bariatric surgery. The subjective needs of adolescents and young adults with (extreme) obesity to feel supported and not stigmatized should form a major focus.

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Ethics Approval and Consent to Participate

The study protocol was approved by the human research ethics committees at the Universities of Ulm, Essen, Datteln, Berlin, and Leipzig. The STEREO trial is registered at 'clinicaltrials.gov' (identification number: NCT01703273; Registered 7 August, 2012). Parts of the trial protocol have been published [17].

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Disclosure Statement

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