BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2015-010845
Article Type:	Protocol
Date Submitted by the Author:	11-Dec-2015
Complete List of Authors:	Hilbert, Anja
Primary Subject Heading:	Nutrition and metabolism
Secondary Subject Heading:	Evidence based practice
Keywords:	Socio-ecological model, Weight loss maintenance, Interpersonal, Social network, Randomized-controlled trial, Obesity

Social Facilitation Maintenance Treatment for Adults with Obesity: Study Protocol for a Randomized-Controlled Feasibility Study (SFM)

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Running title: Social Facilitation Maintenance Treatment for Adults

Abstract

Introduction: The long-term success of conservative weight loss treatment in adults with obesity is limited by substantial relapse, and only a few evidence-based weight loss maintenance treatments exist. This clinical trial investigates the feasibility and efficacy of a Social Facilitation Maintenance program for weight loss maintenance tailored to obese adults who have undergone conservative weight loss treatment.

Methods and Analysis: In a single-center, open-label feasibility trial, 72 adults currently or previously obese or overweight who have undergone conservative weight loss treatment were centrally randomized to four months of Social Facilitation Maintenance treatment or treatment as usual control condition. Patients were assessed at pre-treatment, post-treatment, and 6-, 12-, and 24-month follow-up after the end of treatment. In 16 outpatient group sessions, the Social Facilitation Maintenance treatment focused on promoting interpersonal relationships to build up a healthy lifestyle for long-term weight loss maintenance. Primary endpoint was the amount of weight regain at 6-month follow-up, compared with pre-treatment weight, derived from measured body weight. Secondary endpoints addressed feasibility, including recruitment, attrition, assessment non-completion, compliance, and patients' program evaluation; and in comparison with pre-weight loss maintenance, social and interpersonal functioning, eating behavior and physical activity, psychological and physical symptoms, body composition and risk of co-morbidity, and quality of life at post-treatment and follow-up assessments.

Ethics and Dissemination: The study was approved by the Ethical Committee at the University of Leipzig (165-13-15072013). The study results will be disseminated through peer-reviewed publications.

Registration: German Clinical Trials Register: www.germanctr.de, DRKS00005182, August 09, 2013; Amendment 01, November 6, 2013

Funding: German Federal Ministry of Education and Research, Hannoversche Strasse 28-30, 10115 Berlin, Germany; 01EO1001 K7-62

Key words: Socio-ecological model, weight loss maintenance, interpersonal, social network, randomized-controlled trial, obesity

Strengths and Limitations

Strengths of this study are the randomized-controlled evaluation of the feasibility and efficacy of a weight loss maintenance treatment in adults with obesity that has a unique focus on the social network and has been proven to be efficacious in children with obesity. The SPIRIT guidelines are followed. Limitations are inherent to the feasibility focus of this study and include the small sample size, single-center conduct, treatment through one therapist, and no blinding of treatment to raters.

Background

Prevalence rates for obesity and overweight in adults have increased over the prior decades.[1 2] Obesity is a leading cause of mortality and health-related disorders, such as type 2 diabetes mellitus and coronary heart disease.[3 4] The majority of comorbidities are alleviated by modest weight loss.[5–7] However, it is not the attained body mass index (BMI, kg/m^2) itself, but the successful long-term maintenance of the reduced weight that is most important for the reduction of obesity-related health risks.[8] Meta-analyses, however, suggest that in the long-run, most adult patients in weight loss (WL) programs regain a majority of weight initially lost.[9 10] This turns weight loss maintenance (WLM) into a major challenge in obesity management.

Reviews on the efficacy of WLM programs provide evidence of the efficacy of behavioral interventions,[9 11 12] although a delayed weight regain may occur. Predictor analyses of WLM indicate that psychosocial problems that often co-occur with obesity, including a lack of social support, social isolation, interpersonal distress, low self-esteem, low self-efficacy, and decreased coping skills, represent major barriers to its achievement.[13–16] Several studies have documented psychosocial and interpersonal difficulties encountered by obese individuals, especially in clinical settings.[17] Obese individuals face stigma and negative social interactions with strangers, acquaintances, and friends in multiple domains of life,[18] which may lead to social isolation and withdrawal.[19 20] Furthermore, social impairments are frequent (e.g., low socio-economic status, poor neighborhoods).[21] These disadvantages are distressing and may be relevant from a psychopathological perspective, likely impairing weight management.[22 23] In contrast, an extended focus on weight maintenance skills is central for effective WLM: Healthy eating behaviors (e.g., regular meal patterns), self-monitoring, internal control of eating behavior, and sustained physical activity have shown

positive effects on WLM.[14 15 24] Therefore, improving psychosocial problems and weight maintenance skills may be beneficial for WLM.

Most WLM programs focus on weight maintenance skills in the individual patient, while psychosocial problems and difficulties within the social network are usually not comprehensively addressed. The socio-ecological model posits that facilitating factors and barriers of one's behavior reside on multiple levels[25] – intrapersonal, interpersonal, social network, and community. Based on this model, a social facilitation maintenance (SFM) program for WLM was developed for children using empirically supported techniques to facilitate social networks that support healthy eating and physical activity.[26] The SFM approach also targets inter- and intrapersonal factors identified as barriers to a healthy lifestyle. In a randomized-controlled comparison of an SFM program, a "traditional" behavioral management, and a no-treatment control group, 7-12 year old children in both active treatments maintained their relative weight better than children in the control group with medium-to-large effect sizes.[26] During the two years of follow-up, both active maintenance treatments' efficacy declined relative to the control group, but the effects of SFM alone were significantly better than that of the no-treatment control group. There was indication that social problems moderated the relative weight change from baseline to two years of follow-up, with low social problem children in SFM versus the control group having the best outcomes. Although these results are promising, SFM has not yet been adapted and evaluated for WLM in adults.

As the medical comorbidities of obesity increase health care costs,[27 28] WLM treatment with a focus on psychosocial problems has the potential to reduce these costs. It is thus a clinical and research priority to evaluate WLM treatments such as SFM treatment. In this context, the aim of this study is to evaluate the feasibility and efficacy of an SFM treatment for WLM in adults, relative to treatment as usual (TAU), in an exploratory, single-

center randomized trial. Additional objectives are to identify changes in: social and interpersonal functioning; eating behavior and physical activity; psychological and physical symptoms; body composition and risk of co-morbidity; and quality of life. Outcome predictors will also be determined. TAU was selected as the control condition for this first evaluation of feasibility and efficacy of an evidence-based child-focused program in an adult-adapted version.

Methods and Analysis

Hypotheses

(1) Patients receiving SFM treatment will sustain larger amounts of weight loss compared to patients receiving TAU at 6-month follow-up.

(2) SFM treatment in adults will be feasible.

(3) Patients receiving SFM treatment will sustain larger amounts of weight loss at 12- and 24-month follow-up and will show higher social and interpersonal functioning, improved eating behavior and physical activity, lower psychological and physical symptoms, lower body fatness and risk of co-morbidity, and greater quality of life at post-treatment and follow-up assessments.

Design, Participants, and Procedures

Study design. SFM Treatment for Adults is an exploratory, single-center, open-label, prospective, randomized trial, evaluating the feasibility and efficacy of SFM treatment (experimental condition) compared to TAU (control condition). The study design is depicted in Figure 1. The study period lasts four months per patient in both conditions (four months of SFM treatment and TAU, respectively). Following a conservative WL treatment, patients undergo a pre-treatment assessment (t0). Following SFM or TAU as WLM treatment over 4

months, a post-treatment assessment is conducted (t1), followed by 6-month (t2), 12-month (t3), and 24-month (t4) follow-up assessments.

Participants. A total of 72 adult patients within conservative WL treatment at the IFB outpatient unit are randomized to either SFM treatment or TAU. Inclusion criteria are summarized in Table 1. To ensure generalization of study results, exclusion criteria are kept to a minimum.

Recruitment. The ongoing study is conducted from September 2013 – June 2017 at the Outpatient Unit of the Integrated Research and Treatment Center (IFB) AdiposityDiseases at University of Leipzig Medical Center, Leipzig, Germany. All patients presenting at the IFB Outpatient Unit for conservative WL treatment and having consented to be contacted for participation in research studies are informed about the study and, if interested, screened for eligibility by telephone (-t2). They are offered – with a 50% chance – intensive WLM treatment at no cost, and financial incentives for participation in 12- and 24-month follow-up assessments (t3, t4 à 15 €). WL treatment at the IFB Outpatient Unit requires BMI ≥ 35.0 kg/m^2 and includes one consultation with a physician, three individual nutritional counseling sessions, and six, 90 min behavioral WL sessions in groups of 6-10 patients.

Procedures. During telephone screening (-t2), eligible patients are invited to a preparatory session (-t1). At this session, inclusion and exclusion criteria are evaluated, written informed consent is obtained, and patients are enrolled and centrally randomized into the SFM or TAU arm by trained study staff. After finishing the conservative WL treatment, a pre-treatment assessment (t0) is conducted during which sociodemographic, anamnestic, anthropometric, and clinical data are obtained using self-report questionnaires and objective measurement. Both SFM treatment and TAU are conducted over a 4-month period.

Ancillary study. An ancillary study investigates changes in pro-inflammatory cytokines, serotonin transporter availability, and sleep ratings as predictors of weight change

over SFM treatment (principal investigator: Hubertus Himmerich, MD). This study involves a separate consent procedure for voluntary participation offered to all patients at the preparatory session, and blood sampling and sleep-related self-report questionnaires at pre-treatment (t0) and post-treatment (t1).

Intervention

Experimental intervention – Social facilitation maintenance (SFM). For development of the SFM manual for adults, the existing evidence-supported SFM intervention manual for children by Wilfley and colleagues[26] was adapted for adults and German culture. The SFM treatment is based on the socio-ecological model,[25] targeting intra- and interpersonal factors identified as barriers to a healthy lifestyle in order to facilitate social networks that support healthy eating and physical activity.[26]

The overarching goal of SFM for adults is to promote interpersonal relationships to strengthen a healthy lifestyle (eating behavior and physical activity) for long-term WLM. The treatment consists of four phases with a focus on: (1) the patients themselves, (2) the patients' significant others, and (3) the community (e.g., work setting, neighborhood). The treatment is (4) concluded by a consolidation and relapse prevention phase. Across these phases, interpersonal problems (e.g., lack of social support, communication problems, stigma) and intrapersonal problems (e.g., negative thinking, self-stigma, negative body image) are addressed using empirically supported techniques (e.g., psychoeducation, self-monitoring, goal setting, self-reinforcement, problem-solving, communication training). Therapeutic phases, sessions, and topics are depicted in Table 2.

The SFM treatment is delivered in groups of 6-10 patients within 16 weekly sessions of 2 hours duration. SFM treatment is provided by a psychologist with training in behavior therapy and, specifically, SFM. Major differences between the adult SFM manual and the

child SFM manual reside in structure and content (e.g., group therapy vs. combined family and individual therapy; tailoring of exercises to group format; and adult-relevant topics, e.g., work setting). Treatment fidelity is ensured through regular supervision, also preventing drift in treatment delivery.

Control intervention – Treatment as usual (TAU). The TAU control condition consists of up to five individual sessions with a nutritionist and one visit with a physician over four months. This TAU is the commonly offered treatment at the IFB Outpatient Unit.

Measures

Primary and secondary outcomes. The primary outcome measure is the weight regain (kg) at 6-month follow-up (t2, 10 months after t0), compared with pre-treatment weight (t0), both derived from objectively measured body weight through calibrated instruments. Weight regain is consistently reported as the primary outcome measure in WLM trials.[9 11] The secondary outcome of measurement of weight at post-treatment (t1, 4 months after t0) will provide insight into the change of the primary outcome over WLM treatment. Self-report of weight at 12-month follow-up (t3, 16 months after t0) and at 24-month follow-up (t4, 28 months after t0) will provide evidence of the long-term maintenance of effects.

Feasibility, including recruitment, attrition, assessment completion, compliance, and patients' program evaluation are assessed as secondary outcome measures when appropriate (between pre-treatment and post-treatment). Further secondary endpoints include measures of: social and interpersonal functioning;[e.g., 29 30] eating behavior;[e.g., 31 32] physical activity;[33] psychological and physical symptoms;[e.g., 34–37] and quality of life.[38] The assessments are conducted at pre-treatment (t0), at post-treatment (t1), and at 6-, 12-, and 24-month follow-ups (t2, t3, t4). BMI (kg/m^2) is calculated from measured (t0, t1, t2) or self-reported (t3, t4) weight and height. Further indicators of body fatness and/or composition and cardiovascular risk are determined (e.g., waist circumference, blood pressure, skinfolds; t0, t1, t2).

We chose these outcome measures because they exhibit good psychometric properties, are well-established in German, and are used in international research studies. The raters have no therapeutic relationship with the patients. They underwent extensive training for conducting the assessments and receive ongoing supervision for standardized administration (drift prevention).

Predictor variables. Predictor variables, assessed at pre-treatment (t0) and post-treatment (t1), consist of all outcome variables, sociodemographic variables, compliance, and patient motivation and expectation ratings assessed through visual analogue scales.

Methodological Aspects

Power analysis. Because of the preliminary nature of this feasibility trial, estimation of sample size based on a power analysis was not deemed necessary. An analysis set consisting of 60 patients (30 patients per study arm) is expected to provide estimates for changes in weight with a 95% confidence interval of 5 kg. Such precision is more than adequate for a subsequent confirmatory trial. This sample calculation is based on a meta-analysis of extended WLM care versus no-intervention for which a Hedges g of .385 is expected.[39] The t test would then provide a power of approximately 55%. Assuming a drop-out rate of 20% of patients over the course of the study, 72 patients are recruited for the study. This rate is based on drop-out rates of 4-24% of previous WLM treatment studies.[40–42] For patients who discontinue or deviate from intervention protocol, it is nevertheless planned to conduct assessments and complete follow-ups. Efforts to retain as many participants as possible throughout the study period include information on the relevance and necessity of the study, use of continuity forms locating participants throughout the study period, and use of incentives for follow-up assessments.

Randomization. Patients meeting study criteria are enrolled and randomized by trained study staff after giving written informed consent. To ensure concealment of allocation, the randomization is centrally performed using an online randomization tool hosted by the Coordination Center for Clinical Trials of the University of Leipzig. Randomization is based on Pocock's minimization algorithm[43] and stratified by sex. The allocation ratio between the two study arms is 1:1.

Blinding. Assessments are performed by independent raters who have no therapeutic relationship with the patients. Blinding of treatment to raters and patients is not possible, because of the small scope of this study, and because patients know the study arm from the particular modes of delivery.

Data analytic plan. The primary outcome of "weight regain at 6-month follow-up (t2)", will be investigated by calculating an effect size with a 95% confidence interval for each arm separately. In addition, a mixed model will be used with weight at t2 as the dependent variable, and weight at t0 and study arm as fixed effects, with the group within study arm as a random effect. This confirmatory analysis follows the intent-to-treat principle and will be based on the full analysis set. Every attempt is made to acquire missing data. If data missing for the primary endpoint can be expected to bias results in a meaningful way, multiple imputation will be performed. Further, the analysis of the primary endpoint will be performed in the per-protocol set to evaluate the treatment effect for patients with good protocol adherence.

The primary endpoint will be further analyzed in an exploratory manner as in the primary analysis, but will also include sex and intervention group. Secondary endpoints will be analyzed in an exploratory, descriptive manner, and will be evaluated by means of effect sizes, presented with 95% confidence intervals, as well as parametric or non-parametric tests, depending on the scale level and type of distribution of the observed variables. Maintenance

of treatment success over time will be evaluated. Predictors of treatment outcome will be identified using regression analyses.

Monitoring and data management. The trial is performed in cooperation with the Coordination Center for Clinical Trials of the University of Leipzig, which is responsible for monitoring and data management. After data entry, data are monitored for completeness, consistency, and plausibility. Errors in data entry are determined in a step-wise procedure, examining all data of 5 patients and, depending on error rates, examining all data in up to an additional 25% of the patients. Data quality is ensured through plausibility checks (e.g., examination of ranges). During and after trial implementation, data will be collected and stored on servers of the Coordination Center for Clinical Trials, and thus behind the firewall of the University of Leipzig. Access to the servers is secured via https protocol, and requires user-specific login and password. Post-treatment data will be released only after study completion (i.e., after termination of the 24-month follow-up). No interim analyses are planned. AH will be granted access to the final trial dataset. The study data will be reported in accordance with the extended CONSORT guidelines for non-pharmacological treatment studies.[44]

Confidentiality. All clinical data recorded by the trial personnel at the trial site on paper CRFs will be entered into the data base at the Coordination Center for Clinical Trials Leipzig by using a trial identification number that does not reference the patient's personal identifiers (pseudonymized data). In the event of withdrawal of consent, the necessity for storing data will be evaluated. Data that are not needed will be deleted as requested, with full documentation of the reasons for deletion. Data analysis will be performed solely using de-identified data. After trial publication, trial data will be shared in de-identified form upon request.

Personal information about potential and enrolled participants collected during enrollment will only be stored at the trial site and be subject to the raters' and therapists' privacy obligation. Personal information will not be shared and will be deleted after the trial.

Ethics and Dissemination

Ethical approval. The study was approved by the Ethical Committee of the Medical Faculty at University of Leipzig (165-13-15072013). Written informed consent is obtained by trained staff after the study has been fully explained and prior to randomization (a model consent form is available upon request). Patients can withdraw at any time without any disadvantage. The trial is conducted in accordance to the guidelines for Good Clinical Practice (GCP).[45] All persons participating in the conduct of the trial commit themselves to the Declaration of Helsinki (Version Somerset West 1996),[46] as well as all pertinent national laws and the ICH guidelines for GCP and CPMP/ICH/135/95.[47] All protocol modifications including changes to eligibility criteria, outcomes, or analyses are reported to the Ethical Committee.

Safety. Adverse events are all unwanted medical events (e.g., emerging or aggravating symptoms) occurring throughout the trial, whether or not they have a causal association with the trial. Adverse events are documented at every assessment and at every week of treatment throughout the trial. They are rated according to severity: Serious adverse events are those that led to death, are life-threatening, make inpatient treatment necessary, lead to sustained harm, or cause birth defects or deformities. Serious adverse events include mental or physical decompensations that indicate a need for hospitalization (e.g., acute suicidality). Adverse events are recorded through a self-report assessment of somatic symptoms[35 36] at t0 through t2 and an unstandardized reporting of adverse events every week during treatment. Any serious adverse event is immediately reported to the Ethical Committee of the University of

Leipzig. In case of adverse events making ancillary or post-trial care necessary, participants are referred to local medical care services.

Because of the small scope of this exploratory study and non-psychotherapeutic intervention, an independent Data Monitoring and Safety Committee was not deemed to be necessary.

Dissemination. The study results will be disseminated through peer-reviewed publications and conference presentations to the scientific community, and through further presentations to the public and health care professionals. No restrictions on publication exist. Authorship will follow the Rules of Good Scientific Practice of the German Research Foundation, and no professional writers will be used.

Authors' Contributions

AH conceived and designed the study and wrote this study protocol.

Funding

This work was supported by grant 01EO1001 from the German Federal Ministry of Education and Research. This funding body has no influence on the study design, data collection, writing of the manuscript, or in the decision to submit the manuscript for publication.

Competing Interests

None declared.

Trial Status

This study is ongoing and will continue until June 2017.

Acknowledgement

I am grateful to Nicole Koeppe-Bauernfeind and Petra Neuhaus for their input on the study protocol, preparation of case report forms, management of ethical requirements, and organization of randomization and data management; to David Petroff for his input on data analytic design; to Denise E. Wilfley for providing the SFM manual for children, granting the permission for and supporting the adaptation of the SFM manual to adults; to Claudia Hübner for her input on the study protocol, SFM manual for adults, and organization of the study; to her and to Lisa Schäfer for their contribution to the conduct of this study; and to all mentioned persons from University of Leipzig for their input on this paper. I am further grateful to Lisa Opitz and Jamie L. Manwaring for their editing of this paper.

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Table 1. Inclusion and exclusion criteria.

Inclusion
- Age ≥ 18 years - 25.0 kg/m^2 ≤ body mass index ≤ 45.0 kg/m^2 - Previous conservative WL treatment at the IFB outpatient unit with ≥ 50% attendance - Sufficient German language skills
Exclusion
- Serious unstable somatic conditions (e.g., cardiovascular disease) - Serious mental conditions (e.g., psychotic disorder, suicidality) - Bariatric surgery - Use of weight-impacting medication (e.g., antipsychotics) - Current psychotherapy - Current pregnancy or lactation

Notes. IFB, Integrated Research and Treatment Center AdiposityDiseases.

Table 2. Therapeutic phases, sessions and topics.

Phase	Sessions	Topics
Focus on self	(1) Introduction	- Introduction - Socio-ecological model
	(2) Healthy behaviors	- Meal routines - Physical activity and sleep routines
	(3) Healthy home environment	- Barriers and resources at home - Social support at home - Communication training
	(4) Self-reinforcement	- Negative thinking and self-verbalizations
Focus on significant others	(5) Social network support	- Barriers and resources in the social network
	(6) Changing the social network	- Planning and initiation of change regarding healthy eating and physical activity
	(7) Healthy meetings	- Arrange meetings in a healthy way regarding eating and physical activity
	(8) Communication	- Initiating and maintaining friendships - Communication training
Focus on community	(9) Work environment	- Barriers and resources at work - Planning and initiation of change
	(10) Neighborhood	- Barriers and resources in the neighborhood - Planning and initiation of change
	(11) Physical activity with others	- Relevance of physical activity with others - Planning and initiation of change

Table 2 (continued).

Phase	Sessions	Topics
Focus on consolidation and relapse prevention	(12) Stigma	- Weight related stigma (e.g., critical comments) and consequences for healthy lifestyle - Social competence training
	(13) Stigma and body image	- Media messages and stigma - Self-stigma and body image
	(14) Motivation and relapse prevention	- Relevance of motivation - Lapse and relapse - Coping with relapse
	(15) Consolidation	- Repetition of central behaviors for long-term WLM
	(16) Certification	- Farewell - Conferment of certificates

Figure 1. Schedule of enrolment, interventions, and assessments.

	Study period						
	Screening	Enrolment	Pre-treatment	Follow-up			
Time point	$-t_2$	$-t_1$	t_0	t_1	t_2	t_3	t_4
Enrollment							
Eligibility	X	X					
Informed consent		X					
Allocation		X					
Interventions							
Social Facilitation Maintenance Treatment			⟷	⟷			
Treatment as Usual			⟷	⟷			
Assessments							
Body weight, social and interpersonal functioning, eating behavior and physical activity, psychological and physical symptoms, body composition and risk of co-morbidity, quality of life			X	X	X	X	X
Recruitment, attrition, non-completion, compliance, patients' program evaluation			X	X			

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	1-3, 7-10, 14, 21-23
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	2
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	15
	5b	Name and contact information for the trial sponsor	3
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	14
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	6
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	21
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8, 22, 23
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	10
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	21
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9, 10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	24

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9, 10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	10

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	12
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	12
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	13
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	7
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	12,13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	12
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	13
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
	31b	Authorship eligibility guidelines and any intended use of professional writers	14
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	12
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	13
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	na

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Social Facilitation Maintenance Treatment for Adults with Obesity: Study Protocol for a Randomized-Controlled Feasibility Study (SFM Study)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2015-010845.R1
Article Type:	Protocol
Date Submitted by the Author:	31-Mar-2016
Complete List of Authors:	Hilbert, Anja
Primary Subject Heading:	Nutrition and metabolism
Secondary Subject Heading:	Evidence based practice
Keywords:	Socio-ecological model, Weight loss maintenance, Interpersonal, Social network, Randomized-controlled trial, Obesity

Social Facilitation Maintenance Treatment for Adults with Obesity: Study Protocol for a Randomized-Controlled Feasibility Study (SFM Study)

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Running title: Social Facilitation Maintenance Treatment for Adults

Abstract

Introduction: The long-term success of non-surgical weight loss treatment in adults with obesity is limited by substantial relapse, and only a few evidence-based weight loss maintenance treatments exist. This clinical trial investigates the feasibility and efficacy of a Social Facilitation Maintenance program for weight loss maintenance, tailored to obese adults who have undergone a lifestyle weight loss intervention.

Methods and Analysis: In a single-center, open feasibility trial, 72 adults currently or previously obese or overweight who have undergone a lifestyle weight loss intervention are centrally randomized to four months of Social Facilitation Maintenance treatment or treatment as usual control condition. Patients are assessed at pre-treatment, post-treatment, and 6-, 12-, and 24-month follow-up after the end of treatment. In 16 outpatient group sessions, the Social Facilitation Maintenance treatment, based on the socio-ecological model and on evidence supporting social facilitation as key process in maintaining weight loss, focuses on promoting interpersonal relationships to build up a healthy lifestyle for long-term weight loss maintenance. Primary outcome is the amount of weight regain at 6-month follow-up, compared with pre-treatment weight, derived from measured body weight. Secondary outcomes address feasibility, including recruitment, attrition, assessment non-completion, compliance, and patients' program evaluation; and in comparison with pre-weight loss maintenance, social and interpersonal functioning, eating behavior and physical activity, psychological and physical symptoms, body composition and risk of co-morbidity, and quality of life at post-treatment and follow-up assessments.

Ethics and Dissemination: The study was approved by the Ethical Committee at the University of Leipzig (165-13-15072013). The study results will be disseminated through peer-reviewed publications.

Registration: German Clinical Trials Register: www.germanctr.de, DRKS00005182, August 09, 2013; Amendment 01, November 6, 2013

Funding: German Federal Ministry of Education and Research, Hannoversche Strasse 28-30, 10115 Berlin, Germany; 01EO1001 K7-62

Key words: Socio-ecological model, weight loss maintenance, interpersonal, social network, randomized-controlled trial, obesity

Strengths and Limitations

Strengths of this study are the randomized-controlled evaluation of the feasibility and efficacy of a weight loss maintenance treatment in adults with obesity that has a unique focus on the social network and has been proven to be efficacious in children with obesity. The SPIRIT guidelines are followed. Limitations are inherent to the feasibility focus of this study and include the small sample size, single-center conduct, treatment through one therapist, and no blinding of treatment to raters.

Background

Prevalence rates for obesity and overweight in adults have increased over the prior decades.[1 2] Obesity is a leading cause of mortality and health-related disorders, such as type 2 diabetes mellitus and coronary heart disease.[3 4] The majority of comorbidities are alleviated by modest weight loss.[5–7] However, it is not the attained body mass index (BMI, kg/m^2) itself, but the successful long-term maintenance of the reduced weight that is most important for the reduction of obesity-related health risks.[8] Meta-analyses, however, suggest that in the long-run, most adult patients in weight loss (WL) programs regain a majority of weight initially lost.[9 10] This turns weight loss maintenance (WLM) into a major challenge in obesity management.

Reviews on the efficacy of WLM programs provide evidence of the efficacy of behavioral interventions,[9 11 12] although a delayed weight regain may occur. Predictor analyses indicate that psychosocial problems that often co-occur with obesity, including a lack of social support, social isolation, interpersonal distress, low self-esteem, low self-efficacy, and decreased coping skills, represent major barriers to WLM.[13–16] Their importance for maintaining behavior change in WLM, through fostering self-motivation, seems to exceed that for initiating behavior change in WL.[17] Several studies have documented psychosocial and interpersonal difficulties encountered by obese individuals, especially in clinical settings.[18] Obese individuals face stigma and negative social interactions with strangers, acquaintances, and friends in multiple domains of life,[19] which may lead to social isolation and withdrawal.[20 21] Furthermore, social impairments are frequent (e.g., low socio-economic status, poor neighborhoods).[22] These disadvantages are distressing and may be relevant from a psychopathological perspective, likely impairing weight management.[23 24] In contrast, an extended focus on weight maintenance skills is central for effective WLM: Healthy eating behaviors (e.g., regular meal patterns), self-monitoring, internal control of eating behavior,

and sustained physical activity have shown positive effects on WLM.[14 15 25] Therefore, improving psychosocial problems and weight maintenance skills may be beneficial for WLM.

Most WLM programs focus on weight maintenance skills in the individual patient, while psychosocial problems and difficulties within the social network are usually not comprehensively addressed.[17 26] The socio-ecological model posits that facilitating factors and barriers of one's behavior reside on multiple levels[27] – intrapersonal, interpersonal, social network, and community. Social facilitation focuses on the enhancement of performance through interindividual influences such as the presence of others or modeling effects.[28] Based on these concepts, and against the background of the efficacy of interpersonal psychotherapy for stabilizing body weight in eating and overweight disorders,[29–31] a social facilitation maintenance (SFM) program for WLM was developed for children using empirically supported techniques to facilitate social networks that support healthy eating and physical activity.[32] The SFM approach also targets inter- and intrapersonal factors identified as barriers to a healthy lifestyle. In a randomized-controlled comparison of an SFM program, a "traditional" behavioral management, and a no-treatment control group, 7-12 year old children in both active treatments maintained their relative weight better than children in the control group with medium-to-large effect sizes.[32] During the two years of follow-up, both active maintenance treatments' efficacy relative to the no-treatment control group declined, but the effects of SFM alone were significantly better than those of the no-treatment control group ($d = 0.45$). There was indication that social problems moderated the relative weight change from baseline to two years of follow-up, with low social problem children in SFM versus the control group having the best outcomes. Although these results are promising and a family-based follow-up trial and an employee wellness application are underway,[33 34] SFM has not yet been adapted and evaluated for WLM in adults.

As the medical comorbidities of obesity increase health care costs,[35 36] WLM treatment with a focus on psychosocial problems has the potential to reduce these costs. It is thus a clinical and research priority to evaluate WLM treatments such as SFM treatment. In this context, the aim of this study is to evaluate the feasibility and efficacy of an SFM treatment for WLM in adults, relative to treatment as usual (TAU), in an exploratory, single-center randomized trial. Additional objectives are to identify changes in: social and interpersonal functioning; eating behavior and physical activity; psychological and physical symptoms; body composition and risk of co-morbidity; and quality of life. Pre-treatment and sociodemographic variables, compliance, and patient motivation and expectation will be considered as outcome predictors. TAU was selected as the control condition for this first evaluation of feasibility and efficacy of an evidence-based child-focused program in an adult-adapted version.

Methods and Analysis

Hypotheses

(1) Patients receiving SFM treatment will sustain larger amounts of weight loss compared to patients receiving TAU at 6-month follow-up.

(2) SFM treatment in adults will be feasible.

(3) Patients receiving SFM treatment will sustain larger amounts of weight loss at post-treatment, and 12- and 24-month follow-up and will show greater improvements in health at post-treatment and follow-up assessments.

Design, Participants, and Procedures

Study design. SFM Treatment for Adults is an exploratory, single-center, open (i.e., not blinded), prospective, randomized trial, evaluating the feasibility and efficacy of SFM

treatment (experimental condition) compared to TAU (control condition). The study design is depicted in Figure 1. The study period lasts four months per patient in both conditions (four months of SFM treatment and TAU, respectively). Following a lifestyle WL intervention, patients undergo a pre-treatment assessment (t0). Following SFM or TAU as WLM treatment over 4 months, a post-treatment assessment is conducted (t1), followed by 6-month (t2), 12-month (t3), and 24-month (t4) follow-up assessments.

Participants. A total of 72 adult patients within the lifestyle WL intervention are randomized to either SFM treatment or TAU. Inclusion criteria are summarized in Table 1. To ensure generalization of study results, exclusion criteria are kept to a minimum.

Recruitment. The ongoing study is conducted from September 2013 – June 2017 at the Outpatient Unit of the Integrated Research and Treatment Center (IFB) AdiposityDiseases at University of Leipzig Medical Center, Leipzig, Germany. All patients presenting at the IFB Outpatient Unit for lifestyle WL intervention and having consented to be contacted for participation in research studies are informed about the study and, if interested, screened for eligibility by telephone (-t2). They are offered – with a 50% chance – intensive WLM treatment at no cost, and financial incentives for participation in 12- and 24-month follow-up assessments (t3, t4 à 15 €). The lifestyle WL treatment at the IFB Outpatient Unit requires BMI $\geq$ 35.0 kg/m^2 for admission. The WL treatment is provided under medical supervision, focuses on diet and nutrition, and includes: one consultation with a physician; three, 60 min individual and six, 90 min nutritional counseling sessions with a nutritionist in groups of 6-10 patients; and 60 min weekly or semi-weekly group-based exercise sessions for strength and/or endurance training.

Procedures. During telephone screening (-t2), eligible patients are invited to a preparatory session (-t1). At this session, inclusion and exclusion criteria are evaluated, written informed consent is obtained, and patients are enrolled and centrally randomized into

the SFM or TAU arm by trained study staff. After finishing the lifestyle WL intervention, a pre-treatment assessment (t0) is conducted during which sociodemographic, anamnestic, anthropometric, and clinical data are obtained using self-report questionnaires and objective measurement. Both SFM treatment and TAU are conducted over a 4-month period.

Ancillary study. An ancillary study investigates changes in pro-inflammatory cytokines, serotonin transporter availability, and sleep ratings as predictors of weight change over SFM treatment (principal investigator: Hubertus Himmerich, MD). This study involves a separate consent procedure for voluntary participation offered to all patients at the preparatory session, and blood sampling and sleep-related self-report questionnaires at pre-treatment (t0) and post-treatment (t1).

Intervention

Experimental intervention – Social facilitation maintenance (SFM). For development of the SFM manual for adults, the existing evidence-supported SFM intervention manual for children by Wilfley and colleagues[32] was used. The SFM treatment is based on the socio-ecological model,[27] targeting intra- and interpersonal factors identified as barriers to a healthy lifestyle in order to facilitate social networks that support healthy eating and physical activity.[32] For this study, the SFM manual for children was re-organized and shortened in order to fit with the group format. Session content was adapted to adults and German culture, and interventions to foster group cohesion were added (e.g., group-based games).

The overarching goal of SFM for adults is to promote interpersonal relationships to strengthen a healthy lifestyle (eating behavior and physical activity) for long-term WLM. Therapeutic phases, sessions, and topics are depicted in Table 2. The treatment consists of four phases with a focus on: (1) the patients themselves, (2) the patients' significant others, and (3) the community (e.g., work setting, neighborhood). The treatment is (4) concluded by

a consolidation and relapse prevention phase. The first phase (sessions 1-4) guides patients to review their eating behavior and physical activity routines for long-term WLM, and addresses changes in the physical and social home environment. The second phase (sessions 5-8) focuses on changes in the social network fostering healthful eating and physical activity. The third phase (sessions 9-11) addresses changes in work environment and neighborhood, with a concentration on the promotion of social physical activity. The fourth phase (sessions 12-16) focuses on coping with weight-related stigma as a barrier to healthful eating and physical activity, on the consolidation of therapeutic gains, and on management of anticipated relapse. Across these phases, interpersonal problems (e.g., lack of social support, communication problems, stigma) and intrapersonal problems (e.g., negative thinking, self-stigma, negative body image) are addressed.

The SFM treatment is delivered in groups of 6-10 patients within 16 weekly sessions of 2 hours duration. SFM treatment is provided by a psychologist with training in behavior therapy and, specifically, SFM. Empirically supported therapeutic techniques are used (e.g., psychoeducation, self-monitoring, goal setting, self-reinforcement, problem-solving, communication training). Major differences between the adult SFM manual and the child SFM manual reside in structure and content (e.g., group therapy vs. combined family and individual therapy; tailoring of exercises to group format; and adult-relevant topics, e.g., work setting). Treatment fidelity is ensured through regular supervision, also preventing drift in treatment delivery.

Control intervention – Treatment as usual (TAU). The TAU control condition consists of one visit with a physician, and up to five, 60 min individual nutritional counseling sessions with a nutritionist over four months, in addition to 60 min weekly or semi-weekly physical activity sessions as described. This TAU is the commonly offered treatment at the IFB Outpatient Unit.

Measures

Primary and secondary outcomes. The primary outcome measure is the weight regain (kg) at 6-month follow-up (t2, 10 months after t0), compared with pre-treatment weight (t0), both derived from objectively measured body weight through calibrated instruments. Weight regain is consistently reported as the primary outcome measure in WLM trials.[9 11] The secondary outcome of measurement of weight at post-treatment (t1, 4 months after t0) will provide insight into the change of the primary outcome over WLM treatment. Self-report of weight at 12-month follow-up (t3, 16 months after t0) and at 24-month follow-up (t4, 28 months after t0) will provide evidence of the long-term maintenance of effects.

Feasibility of the study procedures in general and of delivering SFM to adults are evaluated by assessing recruitment, attrition, assessment completion, compliance, and patients' program evaluation as secondary outcome measures when appropriate (between pre-treatment and post-treatment). Further secondary outcomes include measures of: social and interpersonal functioning;[37–39] eating behavior;[40–42] physical activity;[43] psychological and physical symptoms; [44–49] and quality of life.[50] The assessments are conducted at pre-treatment (t0), at post-treatment (t1), and at 6-, 12-, and 24-month follow-ups (t2, t3, t4). BMI (kg/m^2) is calculated from measured (t0, t1, t2) or self-reported (t3, t4) weight and height. Further indicators of body fatness and/or composition and cardiovascular risk are determined (waist circumference, blood pressure, skinfolds, bioelectrical impedance analysis; t0, t1, t2).

We chose these outcome measures because they exhibit good psychometric properties, are well-established in German, and are used in international research studies. The raters have no therapeutic relationship with the patients. They underwent extensive training for conducting the assessments and receive ongoing supervision for standardized administration (drift prevention).

Predictor variables. Predictor variables, assessed at pre-treatment (t0) and post-treatment (t1), consist of all outcome variables, sociodemographic variables, compliance, and patient motivation and expectation ratings assessed through visual analogue scales.

Methodological Aspects

Power analysis. Because of the preliminary nature of this feasibility trial, estimation of sample size based on a power analysis was not deemed necessary. An analysis set consisting of 60 patients (30 patients per study arm) is expected to provide estimates for changes in weight with a 95% confidence interval of 5 kg. Such precision is more than adequate for a subsequent confirmatory trial. This sample calculation is based on a meta-analysis of extended WLM care versus no-intervention for which a Hedges g of .385 is expected.[51] The t test would then provide a power of approximately 55%. Assuming a drop-out rate of 20% of patients over the course of the study, 72 patients are recruited for the study. This rate is based on drop-out rates of 4-24% of previous WLM treatment studies.[52–54] For patients who discontinue or deviate from intervention protocol, it is nevertheless planned to conduct assessments and complete follow-ups. Efforts to retain as many participants as possible throughout the study period include information on the relevance and necessity of the study, use of continuity forms locating participants throughout the study period, and use of incentives for follow-up assessments.

Randomization. Patients meeting study criteria are enrolled and randomized by trained study staff after giving written informed consent. To ensure concealment of allocation, the randomization is centrally performed using an online randomization tool hosted by the Coordination Center for Clinical Trials of the University of Leipzig. Randomization is based on Pocock's minimization algorithm[55] and stratified by sex. The allocation ratio between the two study arms is 1:1.

Blinding. Assessments are performed by independent raters who have no therapeutic relationship with the patients. Blinding of treatment to raters and patients is not possible, because of the small scope of this study, and because patients know the study arm from the particular modes of delivery.

Data analytic plan. The primary outcome of "weight regain at 6-month follow-up (t2)", will be investigated by calculating an effect size with a 95% confidence interval for each arm separately. In addition, a mixed model will be used with weight at 6-month follow-up (t2) as the dependent variable, and weight at pre-treatment (t0) and study arm as fixed effects, with the group within study arm as a random effect. This confirmatory analysis follows the intent-to-treat principle and will be based on the full analysis set. Every attempt is made to acquire missing data. If data missing for the primary outcome can be expected to bias results in a meaningful way, multiple imputation will be performed. Further, the analysis of the primary outcome will be performed in the per-protocol set to evaluate the treatment effect for patients with good protocol adherence. The primary outcome will be further analyzed in an exploratory manner as in the primary analysis, but will also include sex and intervention group.

Secondary outcomes will be analyzed in an exploratory, descriptive manner, and will be evaluated by means of effect sizes, presented with 95% confidence intervals, as well as parametric or non-parametric tests, depending on the scale level and type of distribution of the observed variables. Maintenance of treatment success over time will be evaluated. Predictors of treatment outcome will be identified using regression analyses.

Monitoring and data management. The trial is performed in cooperation with the Coordination Center for Clinical Trials of the University of Leipzig, which is responsible for monitoring and data management. After data entry, data are monitored for completeness, consistency, and plausibility. Errors in data entry are determined in a step-wise procedure,

examining all data of 5 patients and, depending on error rates, examining all data in up to an additional 25% of the patients. Data quality is ensured through plausibility checks (e.g., examination of ranges). During and after trial implementation, data will be collected and stored on servers of the Coordination Center for Clinical Trials, and thus behind the firewall of the University of Leipzig. Access to the servers is secured via https protocol, and requires user-specific login and password. Post-treatment data will be released only after study completion (i.e., after termination of the 24-month follow-up). No interim analyses are planned. AH will be granted access to the final trial dataset. The study data will be reported in accordance with the extended CONSORT guidelines for non-pharmacological treatment studies.[56]

Confidentiality. All clinical data recorded by the trial personnel at the trial site on paper CRFs will be entered into the data base at the Coordination Center for Clinical Trials Leipzig by using a trial identification number that does not reference the patient's personal identifiers (pseudonymized data). In the event of withdrawal of consent, the necessity for storing data will be evaluated. Data that are not needed will be deleted as requested, with full documentation of the reasons for deletion. Data analysis will be performed solely using de-identified data. After trial publication, trial data will be shared in de-identified form upon request.

Personal information about potential and enrolled participants collected during enrollment will only be stored at the trial site and be subject to the raters' and therapists' privacy obligation. Personal information will not be shared and will be deleted after the trial.

Ethics and Dissemination

Ethical approval. The study was approved by the Ethical Committee of the Medical Faculty at University of Leipzig (165-13-15072013). Written informed consent is obtained by

trained staff after the study has been fully explained and prior to randomization (a model consent form is available upon request). Patients can withdraw at any time without any disadvantage. The trial is conducted in accordance to the guidelines for Good Clinical Practice (GCP).[57] All persons participating in the conduct of the trial commit themselves to the Declaration of Helsinki (Version Somerset West 1996),[58] as well as all pertinent national laws and the ICH guidelines for GCP and CPMP/ICH/135/95.[59] All protocol modifications including changes to eligibility criteria, outcomes, or analyses are reported to the Ethical Committee.

Safety. Adverse events are all unwanted medical events (e.g., emerging or aggravating symptoms) occurring throughout the trial, whether or not they have a causal association with the trial. Adverse events are documented at every assessment and at every week of treatment throughout the trial. They are rated according to severity: Serious adverse events are those that led to death, are life-threatening, make inpatient treatment necessary, lead to sustained harm, or cause birth defects or deformities. Serious adverse events include mental or physical decompensations that indicate a need for hospitalization (e.g., acute suicidality). Adverse events are recorded through a self-report assessment of somatic symptoms[45 46] at pre-treatment (t0) through 6-month follow-up (t2) and an unstandardized reporting of adverse events every week during treatment. Any serious adverse event is immediately reported to the Ethical Committee of the University of Leipzig. In case of adverse events making ancillary or post-trial care necessary, participants are referred to local medical care services.

Because of the small scope of this exploratory study and non-psychotherapeutic intervention, an independent Data Monitoring and Safety Committee was not deemed to be necessary.

Dissemination. The study results will be disseminated through peer-reviewed publications and conference presentations to the scientific community, and through further

presentations to the public and health care professionals. No restrictions on publication exist. Authorship will follow the Rules of Good Scientific Practice of the German Research Foundation, and no professional writers will be used.

Authors' Contributions

AH conceived and designed the study and wrote this study protocol.

Funding

This work was supported by grant 01EO1001 from the German Federal Ministry of Education and Research. This funding body has no influence on the study design, data collection, writing of the manuscript, or in the decision to submit the manuscript for publication.

Competing Interests

None declared.

Trial Status

This study is ongoing and will continue until June 2017.

Acknowledgement

I am grateful to Nicole Koeppe-Bauernfeind and Petra Neuhaus for their input on the study protocol, preparation of case report forms, management of ethical requirements, and organization of randomization and data management; to David Petroff for his input on data analytic design; to Denise E. Wilfley for providing the SFM manual for children, granting the permission for and supporting the adaptation of the SFM manual to adults; to Claudia Hübner

for her input on the study protocol, SFM manual for adults, and organization of the study; to her and to Lisa Schäfer for their contribution to the conduct of this study; and to all mentioned persons from University of Leipzig for their input on this paper. I am further grateful to Lisa Opitz and Jamie L. Manwaring for their editing of this paper.

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Table 1. Inclusion and exclusion criteria.

Inclusion
- Age ≥ 18 years
- 25.0 kg/m^2 ≤ body mass index ≤ 45.0 kg/m^2
- Previous lifestyle WL intervention at the IFB outpatient unit with ≥ 50% attendance
- Sufficient German language skills
Exclusion
- Serious unstable somatic conditions (e.g., cardiovascular disease)
- Serious mental conditions (e.g., psychotic disorder, suicidality)
- Bariatric surgery
- Use of weight-impacting medication (e.g., antipsychotics)
- Current psychotherapy
- Current pregnancy or lactation

Note. IFB, Integrated Research and Treatment Center AdiposityDiseases.

Table 2. Therapeutic phases, sessions and topics.

Phase	Sessions	Topics
Focus on self	(1) Introduction	- Introduction - Socio-ecological model
	(2) Healthy behaviors	- Meal routines - Physical activity and sleep routines
	(3) Healthy home environment	- Barriers and resources at home - Social support at home - Communication training
	(4) Self-reinforcement	- Negative thinking and self-verbalizations
Focus on significant others	(5) Social network support	- Barriers and resources in the social network
	(6) Changing the social network	- Planning and initiation of change regarding healthy eating and physical activity
	(7) Healthy meetings	- Arrange meetings in a healthy way regarding eating and physical activity
	(8) Communication	- Initiating and maintaining friendships - Communication training
Focus on community	(9) Work environment	- Barriers and resources at work - Planning and initiation of change
	(10) Neighborhood	- Barriers and resources in the neighborhood - Planning and initiation of change
	(11) Physical activity with others	- Relevance of physical activity with others - Planning and initiation of change

Table 2 (continued).

Phase	Sessions	Topics
Focus on consolidation and relapse prevention	(12) Stigma	- Weight related stigma (e.g., critical comments) and consequences for healthy lifestyle - Social competence training
	(13) Stigma and body image	- Media messages and stigma - Self-stigma and body image
	(14) Motivation and relapse prevention	- Relevance of motivation - Lapse and relapse - Coping with relapse
	(15) Consolidation	- Repetition of central behaviors for long-term WLM
	(16) Certification	- Farewell - Conferment of certificates

Figure 1. Schedule of enrolment, interventions, and assessments.

Notes. t1, post-treatment; t2, 6-month follow-up; t3, 12-month follow-up; t4, 24-month follow-up.

	Study period						
	Screening	Enrollment	Pre-treatment	Follow-up			
Time point	$-t_2$	$-t_1$	t_0	t_1	t_2	t_3	t_4
Enrollment							
Eligibility	X	X					
Informed consent		X					
Allocation		X					
Interventions							
Social Facilitation Maintenance Treatment			←	→			
Treatment as Usual			←	→			
Assessments							
Body weight, social and interpersonal functioning, eating behavior and physical activity, psychological and physical symptoms, body composition and risk of co-morbidity, quality of life			X	X	X	X	X
Recruitment, attrition, non-completion, compliance, patients' program evaluation			X	X			

Figure 1. Schedule of enrollment, interventions, and assessments.
Notes. t1, post-treatment; t2, 6-month follow-up; t3, 12-month follow-up; t4, 24-month follow-up.
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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	1-3, 7-10, 14, 15, 21-23
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	2
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	15
	5b	Name and contact information for the trial sponsor	3
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	6
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6, 7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	23
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8, 9, 24, 25
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	10
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	23
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	26

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12, 13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	13
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	12
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	13, 14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	14

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8, 13, 14
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	8
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	14
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14, 15
	31b	Authorship eligibility guidelines and any intended use of professional writers	15
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	13
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	14
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	na

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Social Facilitation Maintenance Treatment for Adults with Obesity: Study Protocol for a Randomized-Controlled Feasibility Study (SFM Study)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2015-010845.R2
Article Type:	Protocol
Date Submitted by the Author:	27-Apr-2016
Complete List of Authors:	Hilbert, Anja
Primary Subject Heading:	Nutrition and metabolism
Secondary Subject Heading:	Evidence based practice
Keywords:	Socio-ecological model, Weight loss maintenance, Interpersonal, Social network, Randomized-controlled trial, Obesity

Social Facilitation Maintenance Treatment for Adults with Obesity: Study Protocol for a Randomized-Controlled Feasibility Study (SFM Study)

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Running title: Social Facilitation Maintenance Treatment for Adults

Abstract

Introduction: The long-term success of non-surgical weight loss treatment in adults with obesity is limited by substantial relapse, and only a few evidence-based weight loss maintenance treatments exist. This clinical trial investigates the feasibility and efficacy of a Social Facilitation Maintenance program for weight loss maintenance, tailored to obese adults who have undergone a lifestyle weight loss intervention.

Methods and Analysis: In a single-center, open feasibility trial, 72 adults currently or previously obese or overweight who have undergone a lifestyle weight loss intervention are centrally randomized to four months of Social Facilitation Maintenance treatment or treatment as usual control condition. In 16 outpatient group sessions, the Social Facilitation Maintenance treatment, based on the socio-ecological model and on evidence supporting social facilitation as key process in maintaining weight loss, focuses on promoting interpersonal relationships to build up a healthy lifestyle for long-term weight loss maintenance. Primary outcome is the amount of weight regain at 6-month follow-up, compared with pre-treatment weight, derived from measured body weight. Secondary outcomes address feasibility, including recruitment, attrition, assessment non-completion, compliance, and patients' program evaluation; and in comparison with pre-weight loss maintenance, social and interpersonal functioning, eating behavior and physical activity, psychological and physical symptoms, body composition and risk of co-morbidity, and quality of life at post-treatment and follow-up assessments.

Ethics and Dissemination: The study was approved by the Ethical Committee at the University of Leipzig (165-13-15072013). The study results will be disseminated through peer-reviewed publications.

Registration: German Clinical Trials Register: www.germanctr.de, DRKS00005182, August 09, 2013; Amendment 01, November 6, 2013

Funding: German Federal Ministry of Education and Research, Hannoversche Strasse 28-30, 10115 Berlin, Germany; 01EO1001 K7-62

Key words: Socio-ecological model, weight loss maintenance, interpersonal, social network, randomized-controlled trial, obesity

Strengths and Limitations

Strengths of this study are the randomized-controlled evaluation of the feasibility and efficacy of a weight loss maintenance treatment in adults with obesity that has a unique focus on the social network and has been proven to be efficacious in children with obesity. The SPIRIT guidelines are followed. Limitations are inherent to the feasibility focus of this study and include the single-center conduct, small sample size, no stratification for prior weight loss, treatment through one therapist, and no blinding of treatment to raters.

Background

Prevalence rates for obesity and overweight in adults have increased over the prior decades.[1 2] Obesity is a leading cause of mortality and health-related disorders, such as type 2 diabetes mellitus and coronary heart disease.[3 4] The majority of comorbidities are alleviated by modest weight loss.[5–7] However, it is not the attained body mass index (BMI, kg/m^2) itself, but the successful long-term maintenance of the reduced weight that is most important for the reduction of obesity-related health risks.[8] Meta-analyses, however, suggest that in the long-run, most adult patients in weight loss (WL) programs regain a majority of weight initially lost.[9 10] This turns weight loss maintenance (WLM) into a major challenge in obesity management.

Reviews on the efficacy of WLM programs provide evidence of the efficacy of behavioral interventions,[9 11 12] although a delayed weight regain may occur. Predictor analyses indicate that psychosocial problems that often co-occur with obesity, including a lack of social support, social isolation, interpersonal distress, low self-esteem, low self-efficacy, and decreased coping skills, represent major barriers to WLM.[13–16] Their importance for maintaining behavior change in WLM, through fostering self-motivation, seems to exceed that for initiating behavior change in WL.[17] Several studies have documented psychosocial and interpersonal difficulties encountered by obese individuals, especially in clinical settings.[18] Obese individuals face stigma and negative social interactions with strangers, acquaintances, and friends in multiple domains of life,[19] which may lead to social isolation and withdrawal.[20 21] Furthermore, social impairments are frequent (e.g., low socio-economic status, poor neighborhoods).[22] These disadvantages are distressing and may be relevant from a psychopathological perspective, likely impairing weight management.[23 24] In contrast, an extended focus on weight maintenance skills is central for effective WLM: Healthy eating behaviors (e.g., regular meal patterns), self-monitoring, internal control of eating behavior,

and sustained physical activity have shown positive effects on WLM.[14 15 25] Therefore, improving psychosocial problems and weight maintenance skills may be beneficial for WLM.

Most WLM programs focus on weight maintenance skills in the individual patient, while psychosocial problems and difficulties within the social network are usually not comprehensively addressed.[17 26] The socio-ecological model posits that facilitating factors and barriers of one's behavior reside on multiple levels[27] – intrapersonal, interpersonal, social network, and community. Social facilitation focuses on the enhancement of performance through interindividual influences such as the presence of others or modeling effects.[28] Based on these concepts, and against the background of the efficacy of interpersonal psychotherapy for stabilizing body weight in eating and overweight disorders,[29–31] a social facilitation maintenance (SFM) program for WLM was developed for children using empirically supported techniques to facilitate social networks that support healthy eating and physical activity.[32] The SFM approach also targets inter- and intrapersonal factors identified as barriers to a healthy lifestyle. In a randomized-controlled comparison of an SFM program, a "traditional" behavioral management, and a no-treatment control group, 7-12 year old children in both active treatments maintained their relative weight better than children in the control group with medium-to-large effect sizes.[32] During the two years of follow-up, both active maintenance treatments' efficacy relative to the no-treatment control group declined, but the effects of SFM alone were significantly better than those of the no-treatment control group ($d = 0.45$). There was indication that social problems moderated the relative weight change from baseline to two years of follow-up, with low social problem children in SFM versus the control group having the best outcomes. Although these results are promising and a family-based follow-up trial and an employee wellness application are underway,[33 34] SFM has not yet been adapted and evaluated for WLM in adults.

As the medical comorbidities of obesity increase health care costs,[35 36] WLM treatment with a focus on psychosocial problems has the potential to reduce these costs. It is thus a clinical and research priority to evaluate WLM treatments such as SFM treatment. In this context, the aim of this study is to evaluate the feasibility and efficacy of an SFM treatment for WLM in adults, relative to treatment as usual (TAU), in an exploratory, single-center randomized trial. Additional objectives are to identify changes in: social and interpersonal functioning; eating behavior and physical activity; psychological and physical symptoms; body composition and risk of co-morbidity; and quality of life. Pre-treatment and sociodemographic variables, compliance, and patient motivation and expectation will be considered as outcome predictors. TAU was selected as the control condition for this first evaluation of feasibility and efficacy of an evidence-based child-focused program in an adult-adapted version.

Methods and Analysis

Hypotheses

(1) Patients receiving SFM treatment will sustain larger amounts of weight loss compared to patients receiving TAU at 6-month follow-up.

(2) SFM treatment in adults will be feasible.

(3) Patients receiving SFM treatment will sustain larger amounts of weight loss at post-treatment, and 12- and 24-month follow-up and will show greater improvements in health at post-treatment and follow-up assessments.

Design, Participants, and Procedures

Study design. SFM Treatment for Adults is an exploratory, single-center, open (i.e., not blinded), prospective, randomized trial, evaluating the feasibility and efficacy of SFM

treatment (experimental condition) compared to TAU (control condition). The study design is depicted in Figure 1. The study period lasts four months per patient in both conditions (four months of SFM treatment and TAU, respectively). Following a lifestyle WL intervention, patients undergo a pre-treatment assessment (t0). Following SFM or TAU as WLM treatment over 4 months, a post-treatment assessment is conducted (t1), followed by 6-month (t2), 12-month (t3), and 24-month (t4) follow-up assessments.

Participants. A total of 72 adult patients within the lifestyle WL intervention are randomized to either SFM treatment or TAU. Inclusion criteria are summarized in Table 1. To ensure generalization of study results, exclusion criteria are kept to a minimum.

Recruitment. The ongoing study is conducted from September 2013 – June 2017 at the Outpatient Unit of the Integrated Research and Treatment Center (IFB) AdiposityDiseases at University of Leipzig Medical Center, Leipzig, Germany. All patients presenting at the IFB Outpatient Unit for lifestyle WL intervention and having consented to be contacted for participation in research studies are informed about the study and, if interested, screened for eligibility by telephone (-t2). They are offered – with a 50% chance – intensive WLM treatment at no cost, and financial incentives for participation in 12- and 24-month follow-up assessments (t3, t4 à 15 €). The lifestyle WL treatment at the IFB Outpatient Unit requires BMI $\geq$ 35.0 kg/m^2 for admission. The WL treatment is provided under medical supervision, focuses on diet and nutrition, and includes: one consultation with a physician; three, 60 min individual and six, 90 min nutritional counseling sessions with a nutritionist in groups of 6-10 patients; and 60 min weekly or semi-weekly group-based exercise sessions for strength and/or endurance training.

Procedures. During telephone screening (-t2), eligible patients are invited to a preparatory session (-t1). At this session, inclusion and exclusion criteria are evaluated, written informed consent is obtained, and patients are enrolled and centrally randomized into

the SFM or TAU arm by trained study staff. After finishing the lifestyle WL intervention, a pre-treatment assessment (t0) is conducted during which sociodemographic, anamnestic, anthropometric, and clinical data are obtained using self-report questionnaires and objective measurement. Both SFM treatment and TAU are conducted over a 4-month period.

Ancillary study. An ancillary study investigates changes in pro-inflammatory cytokines, serotonin transporter availability, and sleep ratings as predictors of weight change over SFM treatment (principal investigator: Hubertus Himmerich, MD). This study involves a separate consent procedure for voluntary participation offered to all patients at the preparatory session, and blood sampling and sleep-related self-report questionnaires at pre-treatment (t0) and post-treatment (t1).

Intervention

Experimental intervention – Social facilitation maintenance (SFM). For development of the SFM manual for adults, the existing evidence-supported SFM intervention manual for children by Wilfley and colleagues[32] was used. The SFM treatment is based on the socio-ecological model,[27] targeting intra- and interpersonal factors identified as barriers to a healthy lifestyle in order to facilitate social networks that support healthy eating and physical activity.[32] For this study, the SFM manual for children was re-organized and shortened in order to fit with the group format. Session content was adapted to adults and German culture, and interventions to foster group cohesion were added (e.g., group-based games).

The overarching goal of SFM for adults is to promote interpersonal relationships to strengthen a healthy lifestyle (eating behavior and physical activity) for long-term WLM. Therapeutic phases, sessions, and topics are depicted in Table 2. The treatment consists of four phases with a focus on: (1) the patients themselves, (2) the patients' significant others, and (3) the community (e.g., work setting, neighborhood). The treatment is (4) concluded by

a consolidation and relapse prevention phase. The first phase (sessions 1-4) guides patients to review their eating behavior and physical activity routines for long-term WLM, and addresses changes in the physical and social home environment. The second phase (sessions 5-8) focuses on changes in the social network fostering healthful eating and physical activity. The third phase (sessions 9-11) addresses changes in work environment and neighborhood, with a concentration on the promotion of social physical activity. The fourth phase (sessions 12-16) focuses on coping with weight-related stigma as a barrier to healthful eating and physical activity, on the consolidation of therapeutic gains, and on management of anticipated relapse. Across these phases, interpersonal problems (e.g., lack of social support, communication problems, stigma) and intrapersonal problems (e.g., negative thinking, self-stigma, negative body image) are addressed.

The SFM treatment is delivered in groups of 6-10 patients within 16 weekly sessions of 2 hours duration. SFM treatment is provided by a psychologist with training in behavior therapy and, specifically, SFM. Empirically supported therapeutic techniques are used (e.g., psychoeducation, self-monitoring, goal setting, self-reinforcement, problem-solving, communication training). Major differences between the adult SFM manual and the child SFM manual reside in structure and content (e.g., group therapy vs. combined family and individual therapy; tailoring of exercises to group format; and adult-relevant topics, e.g., work setting). Treatment fidelity is ensured through regular supervision, also preventing drift in treatment delivery.

Control intervention – Treatment as usual (TAU). The TAU control condition consists of one visit with a physician, and up to five, 60 min individual nutritional counseling sessions with a nutritionist over four months, in addition to 60 min weekly or semi-weekly physical activity sessions as described. This TAU is the commonly offered treatment at the IFB Outpatient Unit.

Measures

Primary and secondary outcomes. The primary outcome measure is the weight regain (kg) at 6-month follow-up (t2, 10 months after t0), compared with pre-treatment weight (t0), both derived from objectively measured body weight through calibrated instruments. Weight regain is consistently reported as the primary outcome measure in WLM trials.[9 11] The secondary outcome of measurement of weight at post-treatment (t1, 4 months after t0) will provide insight into the change of the primary outcome over WLM treatment. Self-report of weight at 12-month follow-up (t3, 16 months after t0) and at 24-month follow-up (t4, 28 months after t0) will provide evidence of the long-term maintenance of effects.

Feasibility of the study procedures in general and of delivering SFM to adults are evaluated by assessing recruitment, attrition, assessment completion, compliance, and patients' program evaluation as secondary outcome measures when appropriate (between pre-treatment and post-treatment). Further secondary outcomes include measures of: social and interpersonal functioning;[37–39] eating behavior;[40–42] physical activity;[43] psychological and physical symptoms; [44–49] and quality of life.[50] The assessments are conducted at pre-treatment (t0), at post-treatment (t1), and at 6-, 12-, and 24-month follow-ups (t2, t3, t4). BMI (kg/m^2) is calculated from measured (t0, t1, t2) or self-reported (t3, t4) weight and height. Further indicators of body fatness and/or composition and cardiovascular risk are determined (waist circumference, blood pressure, skinfolds, bioelectrical impedance analysis; t0, t1, t2).

We chose these outcome measures because they exhibit good psychometric properties, are well-established in German, and are used in international research studies. The raters have no therapeutic relationship with the patients. They underwent extensive training for conducting the assessments and receive ongoing supervision for standardized administration (drift prevention).

Predictor variables. Predictor variables, assessed at pre-treatment (t0) and post-treatment (t1), consist of all outcome variables, sociodemographic variables, compliance, and patient motivation and expectation ratings assessed through visual analogue scales.

Methodological Aspects

Power analysis. Because of the preliminary nature of this feasibility trial, estimation of sample size based on a power analysis was not deemed necessary. An analysis set consisting of 60 patients (30 patients per study arm) is expected to provide estimates for changes in weight with a 95% confidence interval of 5 kg. Such precision is more than adequate for a subsequent confirmatory trial. This sample calculation is based on a meta-analysis of extended WLM care versus no-intervention for which a Hedges g of .385 is expected.[51] The t test would then provide a power of approximately 55%. Assuming a drop-out rate of 20% of patients over the course of the study, 72 patients are recruited for the study. This rate is based on drop-out rates of 4-24% of previous WLM treatment studies.[52–54] For patients who discontinue or deviate from intervention protocol, it is nevertheless planned to conduct assessments and complete follow-ups. Efforts to retain as many participants as possible throughout the study period include information on the relevance and necessity of the study, use of continuity forms locating participants throughout the study period, and use of incentives for follow-up assessments.

Randomization. Patients meeting study criteria are enrolled and randomized by trained study staff after giving written informed consent. To ensure concealment of allocation, the randomization is centrally performed using an online randomization tool hosted by the Coordination Center for Clinical Trials of the University of Leipzig. Randomization is based on Pocock's minimization algorithm[55] and stratified by sex. The allocation ratio between the two study arms is 1:1.

Blinding. Assessments are performed by independent raters who have no therapeutic relationship with the patients. Blinding of treatment to raters and patients is not possible, because of the small scope of this study, and because patients know the study arm from the particular modes of delivery.

Data analytic plan. The primary outcome of "weight regain at 6-month follow-up (t2)", will be investigated by calculating an effect size with a 95% confidence interval for each arm separately. In addition, a mixed model will be used with weight at 6-month follow-up (t2) as the dependent variable, and weight at pre-treatment (t0) and study arm as fixed effects, with the group within study arm as a random effect. This confirmatory analysis follows the intent-to-treat principle and will be based on the full analysis set. Every attempt is made to acquire missing data. If data missing for the primary outcome can be expected to bias results in a meaningful way, multiple imputation will be performed. Further, the analysis of the primary outcome will be performed in the per-protocol set to evaluate the treatment effect for patients with good protocol adherence. The primary outcome will be further analyzed in an exploratory manner as in the primary analysis, but will also include sex and intervention group.

Secondary outcomes will be analyzed in an exploratory, descriptive manner, and will be evaluated by means of effect sizes, presented with 95% confidence intervals, as well as parametric or non-parametric tests, depending on the scale level and type of distribution of the observed variables. Maintenance of treatment success over time will be evaluated. Predictors of treatment outcome will be identified using regression analyses.

Monitoring and data management. The trial is performed in cooperation with the Coordination Center for Clinical Trials of the University of Leipzig, which is responsible for monitoring and data management. After data entry, data are monitored for completeness, consistency, and plausibility. Errors in data entry are determined in a step-wise procedure,

examining all data of 5 patients and, depending on error rates, examining all data in up to an additional 25% of the patients. Data quality is ensured through plausibility checks (e.g., examination of ranges). During and after trial implementation, data will be collected and stored on servers of the Coordination Center for Clinical Trials, and thus behind the firewall of the University of Leipzig. Access to the servers is secured via https protocol, and requires user-specific login and password. Post-treatment data will be released only after study completion (i.e., after termination of the 24-month follow-up). No interim analyses are planned. AH will be granted access to the final trial dataset. The study data will be reported in accordance with the extended CONSORT guidelines for non-pharmacological treatment studies.[56]

Confidentiality. All clinical data recorded by the trial personnel at the trial site on paper CRFs will be entered into the data base at the Coordination Center for Clinical Trials Leipzig by using a trial identification number that does not reference the patient's personal identifiers (pseudonymized data). In the event of withdrawal of consent, the necessity for storing data will be evaluated. Data that are not needed will be deleted as requested, with full documentation of the reasons for deletion. Data analysis will be performed solely using de-identified data. After trial publication, trial data will be shared in de-identified form upon request.

Personal information about potential and enrolled participants collected during enrollment will only be stored at the trial site and be subject to the raters' and therapists' privacy obligation. Personal information will not be shared and will be deleted after the trial.

Ethics and Dissemination

Ethical approval. The study was approved by the Ethical Committee of the Medical Faculty at University of Leipzig (165-13-15072013). Written informed consent is obtained by

trained staff after the study has been fully explained and prior to randomization (a model consent form is available upon request). Patients can withdraw at any time without any disadvantage. The trial is conducted in accordance to the guidelines for Good Clinical Practice (GCP).[57] All persons participating in the conduct of the trial commit themselves to the Declaration of Helsinki (Version Somerset West 1996),[58] as well as all pertinent national laws and the ICH guidelines for GCP and CPMP/ICH/135/95.[59] All protocol modifications including changes to eligibility criteria, outcomes, or analyses are reported to the Ethical Committee.

Safety. Adverse events are all unwanted medical events (e.g., emerging or aggravating symptoms) occurring throughout the trial, whether or not they have a causal association with the trial. Adverse events are documented at every assessment and at every week of treatment throughout the trial. They are rated according to severity: Serious adverse events are those that led to death, are life-threatening, make inpatient treatment necessary, lead to sustained harm, or cause birth defects or deformities. Serious adverse events include mental or physical decompensations that indicate a need for hospitalization (e.g., acute suicidality). Adverse events are recorded through a self-report assessment of somatic symptoms[45 46] at pre-treatment (t0) through 6-month follow-up (t2) and an unstandardized reporting of adverse events every week during treatment. Any serious adverse event is immediately reported to the Ethical Committee of the University of Leipzig. In case of adverse events making ancillary or post-trial care necessary, participants are referred to local medical care services.

Because of the small scope of this exploratory study and non-psychotherapeutic intervention, an independent Data Monitoring and Safety Committee was not deemed to be necessary.

Dissemination. The study results will be disseminated through peer-reviewed publications and conference presentations to the scientific community, and through further

presentations to the public and health care professionals. No restrictions on publication exist. Authorship will follow the Rules of Good Scientific Practice of the German Research Foundation, and no professional writers will be used.

Authors' Contributions

AH conceived and designed the study and wrote this study protocol.

Funding

This work was supported by grant 01EO1001 from the German Federal Ministry of Education and Research. This funding body has no influence on the study design, data collection, writing of the manuscript, or in the decision to submit the manuscript for publication.

Competing Interests

None declared.

Trial Status

This study is ongoing and will continue until June 2017.

Acknowledgement

I am grateful to Nicole Koeppe-Bauernfeind and Petra Neuhaus for their input on the study protocol, preparation of case report forms, management of ethical requirements, and organization of randomization and data management; to David Petroff for his input on data analytic design; to Denise E. Wilfley for providing the SFM manual for children, granting the permission for and supporting the adaptation of the SFM manual to adults; to Claudia Hübner

for her input on the study protocol, SFM manual for adults, and organization of the study; to her and to Lisa Schäfer for their contribution to the conduct of this study; and to all mentioned persons from University of Leipzig for their input on this paper. I am further grateful to Lisa Opitz and Jamie L. Manwaring for their editing of this paper.

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Table 1. Inclusion and exclusion criteria.

Inclusion
- Age ≥ 18 years
- 25.0 kg/m^2 ≤ body mass index ≤ 45.0 kg/m^2
- Previous lifestyle WL intervention at the IFB outpatient unit with ≥ 50% attendance
- Sufficient German language skills
Exclusion
- Serious unstable somatic conditions (e.g., cardiovascular disease)
- Serious mental conditions (e.g., psychotic disorder, suicidality)
- Bariatric surgery
- Use of weight-impacting medication (e.g., antipsychotics)
- Current psychotherapy
- Current pregnancy or lactation

Note. IFB, Integrated Research and Treatment Center AdiposityDiseases.

Table 2. Therapeutic phases, sessions and topics.

Phase	Sessions	Topics
Focus on self	(1) Introduction	- Introduction - Socio-ecological model
	(2) Healthy behaviors	- Meal routines - Physical activity and sleep routines
	(3) Healthy home environment	- Barriers and resources at home - Social support at home - Communication training
	(4) Self-reinforcement	- Negative thinking and self-verbalizations
Focus on significant others	(5) Social network support	- Barriers and resources in the social network
	(6) Changing the social network	- Planning and initiation of change regarding healthy eating and physical activity
	(7) Healthy meetings	- Arrange meetings in a healthy way regarding eating and physical activity
	(8) Communication	- Initiating and maintaining friendships - Communication training
Focus on community	(9) Work environment	- Barriers and resources at work - Planning and initiation of change
	(10) Neighborhood	- Barriers and resources in the neighborhood - Planning and initiation of change
	(11) Physical activity with others	- Relevance of physical activity with others - Planning and initiation of change

Table 2 (continued).

Phase	Sessions	Topics
Focus on consolidation and relapse prevention	(12) Stigma	- Weight related stigma (e.g., critical comments) and consequences for healthy lifestyle - Social competence training
	(13) Stigma and body image	- Media messages and stigma - Self-stigma and body image
	(14) Motivation and relapse prevention	- Relevance of motivation - Lapse and relapse - Coping with relapse
	(15) Consolidation	- Repetition of central behaviors for long-term WLM
	(16) Certification	- Farewell - Conferment of certificates

Figure 1. Schedule of enrolment, interventions, and assessments.

Notes. t1, post-treatment; t2, 6-month follow-up; t3, 12-month follow-up; t4, 24-month follow-up.

	Study period						
	Screening	Enrollment	Pre-treatment	Follow-up			
Time point	$-t_2$	$-t_1$	t_0	t_1	t_2	t_3	t_4
Enrollment							
Eligibility	X	X					
Informed consent		X					
Allocation		X					
Interventions							
Social Facilitation Maintenance Treatment			←	→			
Treatment as Usual			←	→			
Assessments							
Body weight, social and interpersonal functioning, eating behavior and physical activity, psychological and physical symptoms, body composition and risk of co-morbidity, quality of life			X	X	X	X	X
Recruitment, attrition, non-completion, compliance, patients' program evaluation			X	X			

Figure 1. Schedule of enrollment, interventions, and assessments.
Notes. t1, post-treatment; t2, 6-month follow-up; t3, 12-month follow-up; t4, 24-month follow-up.
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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	1-3, 7-10, 14, 15, 21-23
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	2
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	15
	5b	Name and contact information for the trial sponsor	3
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	6
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6, 7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	23
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8, 9, 24, 25
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	10
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	23
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	26

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12, 13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	13
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	12
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	13, 14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	14

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8, 13, 14
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	8
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	14
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14, 15
	31b	Authorship eligibility guidelines and any intended use of professional writers	15
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	13
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	14
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	na

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.