

BMJ Open Social facilitation maintenance treatment for adults with obesity: study protocol for a randomised-controlled feasibility study (SFM study)

Anja Hilbert

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Department of Medical Psychology and Medical Sociology, Integrated Research and Treatment Center AdiposityDiseases, University of Leipzig Medical Center, Leipzig, Germany

Correspondence to
Professor Anja Hilbert; anja.hilbert@medizin.uni-leipzig.de

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 programme for weight loss maintenance, tailored to meet the needs of obese adults who have undergone a lifestyle weight loss intervention.

Methods and analysis: In a single-centre, open feasibility trial, 72 adults currently or previously obese or overweight who have undergone a lifestyle weight loss intervention are centrally randomised to 4 months of social facilitation maintenance treatment or treatment as a usual control condition. In 16 outpatient group sessions, the social facilitation maintenance treatment, based on a socioecological model and on evidence supporting social facilitation as a 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' programme evaluation; and in comparison with pre-weight loss maintenance, social and interpersonal functioning, eating behaviour and physical activity, psychological and physical symptoms, body composition and risk of comorbidity, 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.

Trial registration number: DRKS00005182.

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

Strengths and limitations of this study

- The strengths of this study are the randomised-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-centre conduct, small sample size, no stratification for prior weight loss, treatment through one therapist and no blinding of treatment to raters.

disease.^{3 4} The majority of comorbidities are alleviated by modest weight loss (WL).^{5–7} However, it is not the attained body mass index (BMI, kg/m²) 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, the majority of adult patients in WL programmes regain most of the weight initially lost.^{9 10} This turns WL maintenance (WLM) into a major challenge in obesity management.

Reviews on the efficacy of WLM programmes provide evidence of the efficacy of behavioural 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 behaviour change in WLM, through fostering self-motivation, seems to exceed that for initiating behaviour 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 (eg, low socioeconomic status, poor neighbourhoods).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 behaviours (eg, regular meal patterns), self-monitoring, internal control of eating behaviour 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 programmes 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 behaviour reside on multiple levels²⁷—intrapersonal, interpersonal, social network and community. Social facilitation focuses on the enhancement of performance through interindividual influences such as the presence of others or modelling effects.²⁸ Based on these concepts, and against the background of the efficacy of interpersonal psychotherapy for stabilising body weight in eating and overweight disorders,^{29–31} a social facilitation maintenance (SFM) programme 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 interpersonal and intrapersonal factors identified as barriers to a healthy lifestyle. In a randomised-controlled comparison of an SFM programme, a 'traditional' behavioural management and a no-treatment control group, children aged 7–12 years in both active treatments maintained their relative weight better than children in the control group with medium-to-large effect sizes.³² During the 2 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 2 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.

Since the medical comorbidities of obesity increase healthcare 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 SFM treatment for WLM in adults, relative to treatment as usual (TAU), in an exploratory, single-centre randomised trial. Additional objectives are to identify changes in: social and interpersonal functioning; eating behaviour and physical activity; psychological and physical symptoms; body composition and risk of comorbidity; and quality of life. Pre-treatment and socio-demographic 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 programme in an adult-adapted version.

METHODS AND ANALYSIS

Hypotheses

1. Patients receiving SFM treatment will sustain larger amounts of WL compared with 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 WL at post-treatment and at 12-month 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-centre, open (ie, not blinded), prospective randomised trial, evaluating the feasibility and efficacy of SFM treatment (experimental condition) compared with TAU (control condition). The study design is depicted in figure 1. The study period lasts 4 months per patient in both conditions (4 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 randomised to either SFM treatment or TAU. Inclusion criteria are summarised in box 1. To ensure generalisation of study results, exclusion criteria are kept to a minimum.

Recruitment

The ongoing study is conducted from September 2013 to 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



Time point	Study period						
	Screening	Enrolment	Pre-treatment	Follow-up			
	-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 behaviour 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 enrolment, interventions and assessments. t₁, post-treatment; t₂, 6-month follow-up; t₃, 12-month follow-up; t₄, 24-month follow-up.

Box 1 Inclusion and exclusion criteria

Inclusion

- ▶ Age ≥18 years;
- ▶ $25.0 \text{ kg/m}^2 \leq \text{body mass index} \leq 45.0 \text{ kg/m}^2$;
- ▶ Previous lifestyle weight loss intervention at the Integrated Research and Treatment Center AdiposityDiseases (IFB) outpatient unit with ≥50% attendance;
- ▶ Sufficient German language skills.

Exclusion

- ▶ Serious unstable somatic conditions (eg, cardiovascular disease);
- ▶ Serious mental conditions (eg, psychotic disorder, suicidality);
- ▶ Bariatric surgery;
- ▶ Use of weight-impacting medication (eg, antipsychotics);
- ▶ Current psychotherapy;
- ▶ Current pregnancy or lactation.

50% chance—intensive WLM treatment at no cost, and financial incentives for participation in 12-month and 24-month follow-up assessments (t₃, t₄ à €15). The lifestyle WL treatment at the IFB outpatient unit requires BMI ≥35.0 kg/m² 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 counselling sessions with a nutritionist in groups of 6–10 patients; and 60 min weekly or semiweekly 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 randomised 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 proinflammatory 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—SFM

For development of the SFM manual for adults, the existing evidence-supported SFM intervention manual for children by Wilfley *et al*³² was used. SFM treatment is based on the socioecological model,²⁷ targeting intrapersonal 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 reorganised and shortened in order to fit with the group format. Content of sessions was adapted to adults and German culture, and interventions to foster group cohesion were added (eg, group-based games).

Table 1 Therapeutic phases, sessions and topics

Phase	Sessions	Topics
Focus on self	(1) Introduction	► Introduction
	(2) Healthy behaviours	► Socioecological model
	(3) Healthy home environment	► Meal routines
Focus on significant others	(4) Self-reinforcement	► Physical activity and sleep routines
	(5) Social network support	► Barriers and resources at home
	(6) Changing the social network	► Social support at home
	(7) Healthy meetings	► Communication training
	(8) Communication	► Negative thinking and self-verbalisations
Focus on community	(9) Work environment	► Barriers and resources in the social network
	(10) Neighbourhood	► Planning and initiation of change regarding healthy eating and physical activity
	(11) Physical activity with others	► Arrange meetings in a healthy way regarding eating and physical activity
	(12) Stigma	► Initiating and maintaining friendships
Focus on consolidation and relapse prevention	(13) Stigma and body image	► Communication training
	(14) Motivation and relapse prevention	► Barriers and resources at work
	(15) Consolidation	► Planning and initiation of change
	(16) Certification	► Barriers and resources in the neighbourhood
		► Planning and initiation of change
		► Relevance of physical activity with others
		► Planning and initiation of change
		► Weight-related stigma (eg, critical comments) and consequences for healthy lifestyle
		► Social competence training
		► Media messages and stigma
		► Self-stigma and body image
		► Relevance of motivation
		► Lapse and relapse
		► Coping with relapse
		► Repetition of central behaviours for long-term WLM
		► Farewell
		► Conferment of certificates

WLM, weight loss maintenance.

The overarching goal of SFM for adults is to promote interpersonal relationships to strengthen a healthy lifestyle (eating behaviour and physical activity) for long-term WLM. Therapeutic phases, sessions and topics are depicted in [table 1](#). The treatment consists of four phases with a focus on: (1) the patients themselves, (2) the patients' significant others and (3) the community (eg, work setting, neighbourhood). The treatment is (4) concluded by a consolidation and relapse prevention phase. The first phase (sessions 1–4) guides patients to review their eating behaviour 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 the work environment and neighbourhood, 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 the management of anticipated relapse.

Across these phases, interpersonal problems (eg, lack of social support, communication problems, stigma) and intrapersonal problems (eg, negative thinking, self-stigma, negative body image) are addressed.

SFM treatment is delivered in groups of 6–10 patients within 16 weekly sessions of 2 hours duration. It is provided by a psychologist with training in behaviour therapy and, specifically, SFM. Empirically supported therapeutic techniques are used (eg, 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 (eg, group therapy vs combined family and individual therapy; tailoring of exercises to group format; and adult-relevant topics, eg, work setting). Treatment fidelity is ensured through regular supervision, also preventing a drift in treatment delivery.

Control intervention—TAU

The TAU control condition consists of one visit with a physician, and up to five 60 min individual nutritional

counselling sessions with a nutritionist over 4 months, in addition to 60 min weekly or semiweekly 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' programme 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 behaviour;^{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-month, 12-month and 24-month follow-ups (t2, t3, t4). BMI (kg/m²) 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 standardised 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

Owing to 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% CI 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 0.385 is expected.⁵¹ The t-test would then provide a power of ~55%. Assuming a dropout rate of 20% of patients over the course of the study, 72 patients are recruited for the study. This rate is based on dropout rates of 4–24% of previous WLM treatment studies.^{52–54} For patients who discontinue or deviate from the 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.

Randomisation

Patients meeting study criteria are enrolled and randomised by trained study staff after giving written informed consent. To ensure concealment of allocation, the randomisation is centrally performed using an online randomisation tool hosted by the Coordination Center for Clinical Trials of the University of Leipzig. Randomisation is based on Pocock's minimisation algorithm⁵⁵ 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% CI 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 analysed in an exploratory manner as in the primary analysis, but will also include sex and intervention group.

Secondary outcomes will be analysed in an exploratory, descriptive manner, and will be evaluated by means of effect sizes, presented with 95% CIs, 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 stepwise procedure, examining all data of five 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 (eg, 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 (ie, after termination of the 24-month follow-up). No interim analyses are planned. AH will be granted access to the final trial data set. 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 case report forms will be entered into the database at the Coordination Center for Clinical Trials Leipzig by using a trial identification number that does not reference the patient's personal identifiers (pseudonymised 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 on request.

Personal information about potential and enrolled participants collected during enrolment 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 randomisation (a model consent form is

available on 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 (eg, 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 hospitalisation (eg, 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 unstandardised 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.

Owing to 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 healthcare 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.

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Competing interests None declared.

Ethics approval Ethical Committee at the University of Leipzig.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The manuscript reports on a study protocol for a clinical trial. After trial publication, trial data will be shared in de-identified form on request.

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