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Smartphone-supported behavioural weight loss treatment in adults with severe obesity: study protocol for an exploratory randomised controlled trial (SmartBWL)

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ABSTRACT

Introduction Behavioural weight loss (BWL) treatment is the standard evidence-based treatment for severe obesity (SO: body mass index $\geq 40.0$ kg/m² or $\geq 35.0$ kg/m² with obesity-related comorbidity), leading to moderate weight loss which often cannot be maintained in the long term. Because weight loss depends on patients’ use of weight management skills, it is important to support them in daily life. In an ecological momentary intervention design, this clinical trial aims to adapt, refine and evaluate a personalised cognitive-behavioural smartphone application (app) in BWL treatment to foster patients’ weight management skills use in everyday life. It is hypothesised that using the app is feasible and acceptable, improves weight loss and increases skills use and well-being.

Methods and analysis In the pilot phase, the app will be adapted, piloted and optimised for BWL treatment following a participatory patient-oriented approach. In the subsequent single-centre, assessor-blind, exploratory randomised controlled trial, 90 adults with SO will be randomised to BWL treatment over 6 months with versus without adjunctive app. Primary outcome is the amount of weight loss (kg) at post-treatment (6 months), compared with pretreatment, derived from measured body weight. Secondary outcomes encompass feasibility, acceptability, weight management skills use, well-being and anthropometrics assessed at pretreatment, midtreatment (3 months), post-treatment (6 months) and 6-month follow-up (12 months). An intent-to-treat linear model with randomisation arm, pretreatment weight and stratification variables as covariates will serve to compare arms regarding weight at post-treatment. Secondary analyses will include linear mixed models, generalised linear models and regression and mediation analyses. For safety analysis, (serious) adverse events will be analysed descriptively.

Ethics and dissemination The study was approved by the Ethics Committee of the University of Leipzig (DE-21-00013674) and notified to the Federal Institute for Drugs and Medical Devices. Study results will be disseminated through peer-reviewed publications.

Registration This study was registered at the German Clinical Trials Register (DRKS00026018), www.drks.de.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the first assessor-blind randomised controlled study exploring the augmentation of group behavioural weight loss treatment in patients with severe obesity through a cognitive-behavioural smartphone app, providing personalised support for patients’ weight management skills use in everyday life for improving weight loss outcome.

⇒ Further distinctive features are the patient involvement in the iterative app adaptation and evaluation, the use of an ecological momentary intervention design and application of wearable sensors.

⇒ In a systematic intervention design framework, treatment mechanisms will be determined.

⇒ Limitations pertain to the single-centre design with a limited number of patients and study therapists involved.

⇒ Limitations further include that patients and therapists are not blinded.

INTRODUCTION

The worldwide prevalence of obesity, an ‘excessive fat accumulation that presents a risk to health’,1 has nearly tripled over the past 40 years,2 with 13% of the world population exceeding a body mass index (BMI) of 30 kg/m², the most commonly used indicator for obesity.3 With increasing prevalence rates, especially severe obesity4–7 (SO; i.e., obesity class 3, BMI $\geq 40$ kg/m² or class 2, BMI $\geq 35$ kg/m² with obesity-related comorbidity) carries excessive fat accumulation that presents a risk to health (decrease quality of life impairment, due to its association with non-communicable diseases, including type 2 diabetes mellitus and cardiovascular disease,8,9 mental disorders such as depressive, anxiety and eating disorders10 and social disadvantages.11 12 Moreover, its high chronicity,13 related morbidity and premature mortality14 pose substantial challenges to healthcare systems and societies.15 16
Multicomponent behavioural weight loss (BWL) treatment is considered the standard intervention for obesity. Meta-analytically, BWL treatment led to additional weight loss of 2.4 kg, ranging from 0.5 to 9.3 kg, over 12–18 months compared with control groups, which was similarly demonstrated for SO. This moderate, yet clinically significant weight loss leads to meaningful health benefits, but usually cannot be sustained over the long term. It is therefore imperative to further improve BWL treatment efficacy.

Weight loss and its maintenance essentially depend on the use of skills taught in BWL treatment, including self-monitoring, goal setting, reduced energy intake and increased physical activity. Systematic reviews and meta-analyses documented that low use of weight management skills predicts lesser weight loss and maintenance. Moreover, in challenging life situations (eg, lack of time or motivation, negative mood) weight management skills use is less likely. In order to ensure optimal weight loss, patients therefore need support to transfer skills from the BWL treatment setting to everyday life with its temptations and barriers.

Over the past years, there has been a proliferation of electronic health (eHealth) interventions for weight loss, including those delivered through mobile health (mHealth) technologies, to augment or extend the reach of BWL treatment—however, only a minority of these are evidence-based. Systematic reviews indicated some efficacy of eHealth interventions for weight loss when provided stand-alone, but less than standard behavioural interventions. In contrast, meta-analyses found mHealth interventions including smartphone applications (apps) on nutrition and weight loss to be efficacious. However, a combination with other modes of delivery (eg, personal interaction) yielded only a significant boost for mobile weight loss interventions. Most smartphone apps for weight loss provide self-monitoring tools (eg, for eating, physical activity and/or weight), as a greater use of self-monitoring skills has been linked to higher weight loss. However, evidence-based weight loss strategies were not used comprehensively, which is, however, crucial for successful weight loss and maintenance. Furthermore, only a few smartphone apps for supporting skills use in BWL treatment delivered personalised interventions, a prerequisite to ensure acceptance and user-friendliness.

A promising way to deliver personalised interventions is the use of ecological momentary interventions (EMIs), commonly supplied through smartphone apps. EMIs are real-time interventions providing personalised assistance in individually challenging situations in daily life. An EMI system that receives data about triggers and problem behaviours (eg, through self-monitoring of mood and overeating) could deliver automated interventions specific to the patient’s current experience (eg, tailoring type, dose and timing of intervention for using emotion regulation skills). Empirically, personalised EMIs have shown promise in the treatment of numerous physical and mental health disorders. However, only a few initial EMIs have been developed for weight loss, and these have limited disseminability.

For example, one recent randomised controlled trial (RCT) in 181 patients with overweight or obesity showed that a 10-week digital self-directed weight loss programme led to greater patient acceptance and superior weight loss when a personalised EMI component was added, allowing accurate predictions of dietary lapses. Despite these early successes, the ability of personalised EMI systems to affect complex behaviours such as weight management skills use or to complement a full BWL treatment protocol, remains largely untested.

Altogether, standard face-to-face BWL treatment teaching patients weight loss skills might be supported best through an app precisely tailored to a patient and his/her treatment providing personalised EMIs. To the best of our knowledge, such an augmentation of BWL treatment has not been investigated yet, especially in patients with SO. Thus, the aim of this exploratory clinical feasibility study is the adaptation and evaluation of a personalised cognitive-behavioural smartphone app tailored to BWL treatment to foster patients’ weight management skills use in daily life for improving weight loss outcome. We hypothesised that a smartphone app providing personalised support for BWL patients’ skills use in everyday life will improve short-term and long-term weight loss outcome, will be feasible and acceptable, and will increase weight management skills use and well-being.

METHODS AND ANALYSIS
Design, participants and procedures
Study design
The SmartBWL study is a single-centre, assessor-blind, randomised, two-armed parallel-group feasibility study, estimating the efficacy of the personalised, adaptive cognitive-behavioural smartphone app ‘tEATsmart’ (experimental condition) as an adjunct to BWL treatment compared with BWL treatment alone, corresponding to a treatment as usual control condition, in adults with SO. The study design is depicted in table 1.

In the initial pilot phase, the personalised smartphone app is being adapted to BWL treatment (cf. Experimental intervention). Following a participatory, patient-oriented approach, patients in BWL treatment at the Obesity Outpatient Unit of the Integrated Research and Treatment Center (IFB) AdiposityDiseases, University of Leipzig Medical Centre, and representatives of patient advocacy groups and regional self-help groups, are being involved in this adaptation, in order to ensure optimal acceptance, utility and usability. The adaptation is being piloted in up to 12 patients with SO, following the procedure described below. Feasibility (eg, adherence; app entries per day; days with few app entries; entries in the nutrition, exercise, weight and body image diary; willingness to implement suggested interventions) and acceptance (ie, patient-perceived utility, usability...
<table>
<thead>
<tr>
<th>Study period</th>
<th>Assessment</th>
<th>Screening</th>
<th>Enrol-ment</th>
<th>Pretreatment (t0)</th>
<th>Weekly during therapy</th>
<th>Mid-treatment (t1)</th>
<th>Post-treatment (t2)</th>
<th>Follow-up (t3)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time</strong></td>
<td></td>
<td>Approx. −42−1 days</td>
<td>Day 0</td>
<td>Day 0</td>
<td>Weeks 1−24</td>
<td>3 months±2 weeks</td>
<td>6 months±4 weeks</td>
<td>12 months±4 weeks</td>
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<tr>
<td><strong>Enrolment</strong></td>
<td></td>
<td>Day 0</td>
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<tr>
<td>Eligibility</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Informed consent</td>
<td>X</td>
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<tr>
<td>Allocation</td>
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<tr>
<td><strong>Interventions</strong></td>
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<tr>
<td>Behavioural weight loss treatment with smartphone application</td>
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<td>Behavioural weight loss treatment without smartphone application</td>
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<tr>
<td><strong>Assessments</strong></td>
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<td></td>
</tr>
<tr>
<td>Anthropometrics, well-being (psychopathology, eating behaviour, physical activity, self-efficacy, emotion regulation, quality of life)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Weight management skills use (self-monitoring, goal setting)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Acceptance</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Serious) adverse events</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</table>
Box 1  Inclusion and exclusion criteria.

<table>
<thead>
<tr>
<th>Inclusion</th>
<th></th>
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<tbody>
<tr>
<td>Age ≥18 years.</td>
<td></td>
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<tr>
<td>Severe obesity defined as body mass index (BMI) ≥ 40.0 kg/m² or ≥ 35.0 kg/m² with obesity-related comorbidity.</td>
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<tr>
<td>Presenting for behavioural weight loss treatment at the Obesity Outpatient Unit of University of Leipzig Medical Centre.</td>
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<tr>
<td>Availability of a smartphone for Android.</td>
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<tr>
<td>Permanent Internet access via smartphone.</td>
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<td>Written informed consent.</td>
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</table>

<table>
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<tr>
<th>Exclusion</th>
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<tr>
<td>Serious mental illness (e.g., psychotic disorder, suicidality and bipolar disorder).</td>
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<tr>
<td>Serious physical illness (e.g., cancer).</td>
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<td>Previous or planned bariatric surgery.</td>
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<tr>
<td>Current medical or psychological treatment impacting weight.</td>
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<tr>
<td>Current participation in other interventional trials.</td>
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<tr>
<td>Assumed lack of compliance.</td>
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<tr>
<td>Insufficient German language skills.</td>
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<td>Planned or current pregnancy or lactation.</td>
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<td>Fertile women (within 2 years of their last menstruation) without appro-</td>
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<tr>
<td>priate contraceptive measures (implanon, injections, oral contracep-</td>
<td></td>
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<tr>
<td>tives, intrauterine devices, partner with vasectomy).</td>
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<tr>
<td>while participating in the trial (participants using a hormone-based method have to be informed of possible effects of the trial device on contraception).</td>
<td></td>
</tr>
<tr>
<td>Psychological/mental or other inabilities to supply required informed consent.</td>
<td></td>
</tr>
<tr>
<td>Patients under legal supervision or guardianship.</td>
<td></td>
</tr>
</tbody>
</table>

and satisfaction) will be examined in addition to patient-defined parameters in order to empirically inform iterative adaptations of the app throughout the pilot phase. Here, if feasibility is detected to being low for a patient, the study therapist will contact the patient by telephone, email or in person at the BWL treatment sessions in order to ask about potential app use issues and offer support.

In the evaluation phase, following enrolment in BWL treatment at the IFB AdiposityDiseases Obesity Outpatient Unit and after determining eligibility for the SmartBWL study, patients will be randomised to 6 months of BWL treatment with versus without smartphone app. Type and content of the intervention are similar for the pilot and evaluation phase.

Participants

A total of 90 adult patients with SO8 are planned to be enrolled in the RCT. Inclusion criteria are summarised in box 1. To ensure generalisability, clinical exclusion criteria are kept to a minimum.

Recruitment

This ongoing study is being conducted from February 2021 to March 2024 at the IFB AdiposityDiseases Obesity Outpatient Unit, Leipzig, Germany. The evaluation phase will start in May 2022. Patients waiting for the beginning of BWL treatment at the Outpatient Unit and consenting to be contacted for participation in clinical studies will be informed about the study via telephone. In addition, information material will be distributed publicly to raise awareness for the study. Patients will be offered a 50% chance of receiving the smartphone app adjunctive to BWL treatment at no cost, and financial incentives for participation in assessments will be provided (100€ total maximum).

Procedures

After enrolment for BWL treatment, patients will undergo a telephone screening determining eligibility. Eligible patients will be invited to the pretreatment assessment (t0), during which inclusion will be confirmed, written informed consent will be obtained and central randomisation to BWL treatment with versus without smartphone app will take place. After 3 months of treatment, a midtreatment assessment (t1) and after 6 months, a post-treatment assessment (t2) will be conducted. Furthermore, a follow-up assessment (t3) will take place 6 months after the end of BWL treatment (ie, 12 months following pretreatment assessment). Assessments will include anthropometrics, feasibility, acceptance, weight management skills use (self-monitoring, goal setting) and well-being (psychopathology, eating behaviour, physical activity, self-efficacy, emotion regulation and quality of life). The procedure for the pilot phase is similar to that described for the evaluation phase; however, the pilot study is uncontrolled and a 6-month follow-up assessment will not be conducted.

Interventions

Experimental intervention—smartphone-supported BWL treatment

The BWL treatment delivered as multicomponent manualised lifestyle intervention in groups combined with individual sessions will be conducted at the Obesity Outpatient Unit of the University of Leipzig Medical Centre as part of a 2-year treatment programme, financed by the largest public health insurance company in Saxony.52 The BWL treatment will include 18–26 group sessions of nutrition counselling and behaviour therapy; 2–6 individual sessions of nutritional counselling; 41–48 group exercise sessions and up to 12 individual sessions of behaviour therapy during the first year of treatment. Type, dose, mode, intervention scheme and duration will be within those reported in the literature.53 The SmartBWL study will focus on the first 6 months of BWL treatment with versus without adjunctive smartphone app ‘tREATsmart’. Treatment focus is the acquisition and application of BWL skills, in order to increase energy expenditure while reducing energy intake and to increase adaptive responses to cues. As depicted in table 2, the tREATsmart app aims at supporting weight management skills use in everyday life.

An EMI system comprising both the tREATsmart app and also a web-based portal through which study therapists have access to patients’ app entries was selected for its practical design, personalisation, mechanism-oriented set-up and scalability.54 55 The app development was based on a self-help app for the obesity-associated binge-eating disorder and an EMI system for obesity,41 47 56 which then...
led to the development of the app with EMI system for adjunctive use in cognitive-behavioural therapy (CBT) for bulimia nervosa. In an ongoing RCT, the app was translated into German and adapted to the adjunctive use in CBT of binge-eating disorder (DRKS00024597; www.drks.de). Technically, the EMI system is built as a mobile native app and programmed in HTML5, CSS and JavaScript for Android operating system. As described above, the trEATsmart app is being adapted to BWL treatment in SO in the pilot phase. The app will be downloadable to the patients’ smartphones via Google Play Store.

The trEATsmart app will support patients’ weight management skills use: for example, patients will be supported in planning and realising a regular, calorie-restricted diet. To this end, the trEATsmart app will implement easy-to-use electronic self-monitoring (eg, eating self-monitoring, conversion into kcal and macronutrients and micronutrients using the German Nutrient Data Base). Wearable sensors for recording physical activity are planned to be integrated. The use of weight management skills will be measured app-based for determining treatment mechanisms (table 2).

The personalisation of the app will be realised through study therapists. After the behavioural and nutritional group sessions, which comprise patients from both randomisation arms, a study therapist will meet group-wise after each behavioural and nutritional session.

Table 2 Weight management skills and assessments in the trEATsmart app

<table>
<thead>
<tr>
<th>Weight management skills</th>
<th>Assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan and realise regular eating</td>
<td>Self-monitoring eating</td>
</tr>
<tr>
<td>Plan and realise calorie-restricted eating</td>
<td>Self-monitoring eating</td>
</tr>
<tr>
<td>Plan and realise balanced eating</td>
<td>Self-monitoring eating</td>
</tr>
<tr>
<td>Allow enjoyment of food</td>
<td>Self-monitoring eating</td>
</tr>
<tr>
<td>Perceive hunger and satiety</td>
<td>Self-monitoring eating</td>
</tr>
<tr>
<td>Plan and realise regular physical activity</td>
<td>Self-monitoring physical activity and physical activity tracker</td>
</tr>
<tr>
<td>Plan and realise regular self-weighing</td>
<td>Self-monitoring weight</td>
</tr>
<tr>
<td>Identify triggers of urge to eat/ craving</td>
<td>Self-monitoring impulses</td>
</tr>
<tr>
<td>Tolerate urges to eat/craving without giving in</td>
<td>Self-monitoring impulses</td>
</tr>
<tr>
<td>Use emotion regulation to reduce negative affect</td>
<td>Self-monitoring impulses</td>
</tr>
<tr>
<td>Build a positive body image</td>
<td>Body image diary</td>
</tr>
</tbody>
</table>

primary outcome is the amount of weight loss (kg) at post-treatment (t2) compared with pretreatment (t0), both derived from objectively measured body weight.

Secondary outcomes include the following: (a) feasibility (t0–t2): % of patients prematurely dropping out, number of BWL sessions attended, % of patients with complete assessments for the primary outcome and use of the app for the intervention group (eg, app entries per day, days with few app entries, entries in the nutrition, physical activity, weight and body image diary, willingness to implement suggested interventions); (b) acceptance (t1–t3): patient and therapist perceived utility, usability and satisfaction (visual analogue scales); (c) weight management skills use (t0–t3, weekly): self-monitoring frequency and goal setting (visual analogue scales); (d) well-being (t0–t3): general and eating disorder psychopathology (Patient Health Questionnaire, Eating Disorder Examination-Questionnaire, eating behaviour (binge eating and overeating assessed via Eating Disorder

**MEASURES**

Primary outcome is the amount of weight loss (kg) at post-treatment (t2) compared with pretreatment (t0), both derived from objectively measured body weight.

Secondary outcomes include the following: (a) feasibility (t0–t2): % of patients prematurely dropping out, number of BWL sessions attended, % of patients with complete assessments for the primary outcome and use of the app for the intervention group (eg, app entries per day, days with few app entries, entries in the nutrition, physical activity, weight and body image diary, willingness to implement suggested interventions); (b) acceptance (t1–t3): patient and therapist perceived utility, usability and satisfaction (visual analogue scales); (c) weight management skills use (t0–t3, weekly): self-monitoring frequency and goal setting (visual analogue scales); (d) well-being (t0–t3): general and eating disorder psychopathology (Patient Health Questionnaire, Eating Disorder Examination-Questionnaire, eating behaviour (binge eating and overeating assessed via Eating Disorder
Examination,60 Dutch Eating Behaviour Questionnaire,61 Food Craving Questionnaire-Trait,62 physical activity (International Physical Activity Questionnaire),63 self-efficacy (Generalised Self-Efficacy Scale);64 expectations, that is, patient motivation, readiness and confidence (visual analogue scales), emotion regulation (Difficulties in Emotion Regulation Scale)65 and quality of life (12-item Short Form Health Survey).66 Impact of Weight on Quality of Life-Lite67 and (e) anthropometrics (t0–t3): for example, hip and waist circumference. These outcome measures were chosen due to their clinical relevance, well-established use in international obesity research, and/or availability in German language with good psychometric properties.

All assessments will be performed by trained assessors who will be blinded to randomisation, will be extensively trained and will receive ongoing supervision to avoid drift.

Patient and public involvement
Following a participatory research framework, patients are being involved in study planning and conduct, and dissemination of the results. The patient advocacy groups Adipositas Verband Deutschland e.V. (www.adipositasverband.de) and AdipositasHilfe Deutschland e.V. (www.adipositashilfe-deutschland.de), the largest networks of obesity self-help groups in Germany, have been involved in the preparation of this study, as were representatives of regional self-help groups and patients and therapists of the Obesity Outpatient Unit of the University of Leipzig Medical Centre. For the pilot phase, in preparatory sessions, patients (and therapists) at our Obesity Outpatient Unit, regional self-help groups, and patient advocacy groups have been informed about the study; its design and participatory approach; and were asked to describe their needs, goals, concerns and preferences, informing the adaptation of the smartphone app to BWL treatment and assessment development. Furthermore, a study website (www.treatsmart.de) informs interested patients and the public about the smartphone app, the study, its progress and a study newsletter can be signed up to. Patient volunteers were included in the pilot study, in which patient-perceived utility, usability and satisfaction are being assessed along with objective usability and patient-defined parameters, in order to inform iterative adaptations of the app in a feedback loop. For the evaluation phase, patients at our Obesity Outpatient Unit, representatives of regional self-help groups and patient advocacy groups, and the public will be informed about the study through informational sessions, the study website, newsletter and advertisements. In the RCT, patient-perceived feasibility and acceptance data will be assessed, including patient-defined variables. In the dissemination of the results, patient advocacy groups and self-help groups will be asked to disseminate the results through their information channels to their membership, and interested patients can be offered active involvement in dissemination.

Methodological aspects

Power analysis
Weight loss is typically modest with BWL treatment and loss to follow-up is considerable. The BWL treatment at the IFB Outpatient Unit has been assessed for patients with SO and suggests that a weight loss of 1.8±6.7 kg can be expected for the control group within 6 months of BWL treatment with a drop-out rate of 20%.68 A similar estimate was found in a recent meta-analysis in which patients with obesity lost 2.4 kg more in 12–18 months of BWL treatment versus control.18 An experimental RCT comparing a commercial self-directed BWL programme with smartphone add-on to the BWL programme alone found a post-treatment effect of Cohen’s d=0.24.69 Hence, sample size is conservatively based on an effect size of 0.2. We intend to analyse at least 36 patients per group in order to have 80% probability of finding that weight loss in the intervention arm is numerically superior to that in the control arm, that is, that the effect is in the ‘correct’ direction, whereas the probability of showing this significantly is under 15% (The sample size calculation was performed with the software R V.4.2.0 and can be replicated with the commands ‘pnorm(0,mean=1,sd=5*sqrt(2)/sqrt(36))’ to show 80% power where the factor sqrt(2) comes from pooling and the factor sqrt(36) from the sample size. The power for showing a significant difference is given by power.t.test(delta=1,sd=5,n=36).). After taking a drop-out rate of about 20% at 6 months into account, we thus plan on randomising 45 patients per arm.68 One could then estimate drop-out with 80% probability to within 7.5 percentage points (ie, the width of the corresponding CI would be under 15 percentage points).

Randomisation
Randomisation will be performed by an electronic tool developed by the Clinical Trial Centre of the University of Leipzig to ensure allocation concealment. Randomisation will be stratified by sex and age (cut-off 40 years), using variable-length blocks. The allocation ratio between the two study arms will be 1:1.

Blinding
All assessments will be performed by blinded, independent assessors without therapeutic relationship with the patients. Blinding of patients and treatment will not be possible as patients and therapists are aware of the treatment conditions based on the specific modes of delivery.

Data analytic plan
For the primary outcome, a linear model with body weight at t2 as the dependent variable and randomisation arm, pretreatment weight and stratification variables as covariates will be used to estimate the efficacy of BWL treatment with versus without smartphone app. The difference between arms at t2 will be estimated with an 80% CI for the purposes of planning a subsequent confirmatory trial. A 95% CI will be used when performing significance tests.
corresponding to a 5% significance level. These analyses will follow the intent-to-treat principle and will be based on the full analysis set. To avoid attrition bias, multiple imputation will be performed. A linear mixed model with weight as the dependent variable, time point, randomisation arm, the interaction between time and arm and stratification variables as fixed effects and the patient ID as a random term will be used to analyse change in weight between the groups over time. Mixed models do not discount patients with missing data (in contrast to standard linear models). The primary outcome will also be examined in the per-protocol set including patients with good protocol adherence if this set should differ meaningfully from the full analysis set.

For the secondary outcomes involving proportions and differences in proportions, 80% and 95% CIs will be determined with a Wilson score. Comparisons between arms for other secondary outcomes will be performed with a linear mixed model as described above. No interim analysis is planned in this exploratory RCT. For safety analysis, adverse events (AEs) and serious adverse events (SAEs) will be analysed descriptively. The study will be reported according to the Consolidated Standards of Reporting Trials criteria.69

Monitoring
The cooperating Clinical Trial Centre of the University of Leipzig will be responsible for monitoring. Its standard operating procedures using a risk-based approach and the trial protocol will form the basis for monitoring, which will be independent of the study team and the PI and will consist of a combination of onsite and central monitoring. Details are specified in a monitoring manual.

Data management and confidentiality
Data management will be the responsibility of the Clinical Trial Centre of the University of Leipzig. Data assessed via self-report questionnaires at t0–t3 will be entered electronically by the patient via a secured online portal of the Clinical Trial Centre. These data will be transferred into the database using a patient identification number that has no relation to the patient’s personal identifiers (pseudonymised data). During and after trial implementation, the data will be stored on servers of the Clinical Trial Centre, and thus behind the firewall of the University of Leipzig. Access to the servers will be secured via https protocol and will require user-specific login.

All data collected via smartphone app and web-based portal will be temporarily stored on a secure and encrypted web server which is based in Germany (Microsoft Azure). The actively entered, automatically collected data will be the associated web-treatment. Therefore, access to the smartphone app and the associated web-based portal will be secured with a personal password for each study therapist. These data, regularly downloaded to a password-protected computer at the study centre and saved in a pseudonymised form, will remain on the web server until trial termination and will subsequently be deleted from the web server. The study centre ensures by contract that the operators of these servers do not carry out any further data processing. After trial completion, all relevant patient data will be stored for at least 10 years. Data processing will take place in accordance with the General Data Protection Regulation.70

Data analysis will be performed using deidentified data only. Post-treatment data will not be released until the study is completed (ie, after termination of the 6 month follow-up). The PI will be granted access to the final trial dataset. Trial data will be shared in deidentified form on reasonable request after publication of the study.

Ethics and dissemination
Ethical approval
According to the Medical Devices Regulation (MDR),71 the trEATsmart app is a medical device without CE certification. Therefore, the SmartBWL study was submitted for ethical approval via the German Medical Devices Information and Database System portal of the Federal Institute for Drugs and Medical Devices, received approval by the Ethics Committee of the University of Leipzig (Clinical Trial Identification Number: DE-21-00013674), and was notified to the Federal Institute for Drugs and Medical Devices.

The entire study procedure is consistent with the guidelines for Good Clinical Practice72 and the Declaration of Helsinki.73 Trial changes will be approved by the Ethics Committee of University of Leipzig and communicated to the trial register and, if necessary, to patients via supplement(s) to the consent form.

Safety
(S)AEs will be assessed in personal interviews at each patient contact and documented on corresponding forms. This includes, among other things, recording of onset and end, severity and causal relationship with the investigational product, as well as documentation in the study database. SAEs and serious device defects will be recorded electronically in a separate vigilance database. Notification and reporting will be in accordance with legal requirements (MDR)71 and Medizinprodukte-Durchführungsgesetz, MPDG.74

If central monitoring will indicate an unexpected accumulation of (S)AEs, a root-cause analysis will be performed to enable corrective and protective action (eg, adjustment of selection criteria, additional safety measurements or visits). If (S)AEs will require additional follow-up care, patients will be referred to the IFB Outpatient Unit or other local healthcare providers for psychological or medical treatment. Although SAEs have never been reported in comparable treatment trials,50 54 55 a special insurance will cover any potential risks for the patients caused by study-specific procedures.
Because of the preliminary nature of this exploratory trial, the single-centre design and the well-established safety of BWL treatment and smartphone-based interventions, focusing on weight management skills, but not on psychopathology, an external Data Safety and Monitoring Board was not deemed to be necessary. Instead, the PI, an external collaborator and expert specialising in the smartphone app and BWL treatment (AJ), and a Biometrician (DP) will regularly monitor and supervise progress of the trial (including data safety and main endpoints).

Discontinuation
A patient may withdraw from the study at any time at his or her own request for any reason. This discontinuation must not entail a penalty or loss of benefits to which the patient is otherwise entitled. Date and reasons for discontinuation will be documented on the CRFs if possible. In addition, treatment can be discontinued by the PI according discontinuation rules (eg, (S)AEs, unacceptable benefit/risk ratio, lack of compliance). According to the intent-to-treat principle, all patients will be followed up at each assessment time point after treatment discontinuation. Furthermore, the PI has the right to discontinue the trial, if information emerges that affects the benefit/risk ratio of the trial, if recruitment and follow-up rates do not guarantee the necessary statistical power or if there are repeated (S)AEs presumably associated with the trial. The PI will make the decision to discontinue the trial prematurely in consultation with AJ and DP.

Dissemination
The study results will be disseminated to the scientific community through peer-reviewed publications and conference presentations and to the public and healthcare professionals through further presentations. There are no restrictions on publication. Authorship will follow the Rules of Good Scientific Practice of the German Research Foundation, and no professional writers will be involved. This manuscript was written according to the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines and submitted for publication prior to the inclusion of the first patient in the evaluation phase of the SmartBWL study.

Subsequent confirmatory trial
Based on positive results of this exploratory trial, a confirmatory multicenter RCT on the efficacy of the app adjunctive to BWL treatment will be planned. The decision to conduct a confirmatory trial will be contingent on the following findings of this exploratory trial: (1) greater weight loss and (2) good feasibility as indicated by a lower drop-out rate in the intervention compared with the control group. These criteria are objectively measurable and reflect the primary and the main secondary outcomes, which would be targeted in the confirmatory trial. In addition, weight management skills use and well-being will be considered. The estimates for weight loss and drop-out along with 80% CI will be used in the planning of the subsequent trial. Overall, this exploratory trial will provide an opportunity to improve the app and analyse how to optimise recruitment.

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Contributors
AH (principal investigator) conceived and designed the study with input from AJ and DP (biometrician). AH, CH, CP and DP wrote the study protocol with contribution from AJ and HS.

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Competing interests
Professor Hilbert received: research grants on obesity and eating disorders from the German Federal Ministry of Education and Research, German Research Foundation, and Roland Ernst Foundation for Healthcare; royalties for books on the treatment of obesity and eating disorders with Hogrefe; honoraria for workshops and lectures on obesity and eating disorders and their treatment; honoraria as editor of the International Journal of Eating Disorders and the journal Psychotherapeut; honoraria as a reviewer from Mercator Research Centre Ruhr, Oxford University Press and the German Society for Nutrition; and honoraria as a consultant for WeightWatchers, Zweites Deutsches Fernsehen and Takeda.

Patient and public involvement
Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication
Consent obtained directly from patient(s).

Provenance and peer review
Not commissioned; externally peer reviewed.

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