BMJ Open

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

Anja Hilbert [ORCID],[1] Adrienne Juarascio,[2] Christiane Prettin,[3] David Petroff [ORCID],[3] Haiko Schlögl,[4] Claudia Hübner[1]

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

ABSTRACT

Introduction Behavioural weight loss (BWL) treatment is the standard evidence-based treatment for severe obesity (SO; body mass index $\geq$40.0 kg/m^2 or $\geq$35.0 kg/m^2 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, acceptance, 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.

Trial registration number DRKS00026018

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/m^2, the most commonly used indicator for obesity.[3] With increasing prevalence rates, especially severe obesity[4–7] (SO,[8] ie, obesity class 3, BMI$\geq$40 kg/m^2 or class 2, BMI$\geq$35 kg/m^2 with obesity-related comorbidity) carries the risk of quality of life impairment, due to its association with non-communicable diseases, including type 2 diabetes mellitus and cardiovascular disease,[1 9] mental disorders such as depressive, anxiety and eating disorders[10] and social disadvantages.[11 12] Moreover, its high chronicity,[13] related morbidity and premature mortality[14] pose substantial challenges to healthcare systems and societies.[15 16]

Multicomponent behavioural weight loss (BWL) treatment is considered the standard intervention for obesity.[17] 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,[18] which was similarly demonstrated for SO.[19 20] This moderate, yet clinically significant weight loss leads to meaningful health benefits,[21 22] but usually cannot be sustained over the long term.[23 24] 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.[25–27] Moreover, in challenging life situations (eg, lack of time or motivation, negative mood) weight management skills use is less likely.[26–28] 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[29] 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.[30] Systematic reviews indicated some efficacy of eHealth interventions for weight loss when provided stand-alone,[31–33] but less than standard behavioural interventions.[32] In contrast, meta-analyses found mHealth interventions including smartphone applications (apps) on nutrition and weight loss to be efficacious.[34 35] However, a combination with other modes of delivery (eg, personal interaction) yielded only a significant boost for mobile weight loss interventions.[35] 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.[36 37] However, evidence-based weight loss strategies were not used comprehensively,[30] which is, however, crucial for successful weight loss and maintenance.[38] Furthermore, only a few smartphone apps for supporting skills use in BWL treatment delivered personalised interventions,[39–41] a prerequisite to ensure acceptance and user-friendliness.[42]

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.[43–45] 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.[46] However, only a few initial EMIs have been developed for weight loss, and these had limited disseminability.[39–41 47 48] 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[47] and superior weight loss when a personalised EMI component was added, allowing accurate predictions of dietary lapses.[49 50] 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 'trEATsmart' (experimental condition) as an adjunct to BWL treatment[51] 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 1 Schedule of enrolment, interventions and assessments

Assessment	Study period						
	Screening	Enrol-ment	Pretreatment (t0)	Weekly during therapy	Mid-treatment (t1)	Post-treatment (t2)	Follow-up (t3)
Time	Approx. −42−−1 days	Day 0	Day 0	Weeks 1–24	3 months±2 weeks	6 months±4 weeks	12 months±4 weeks
Enrolment							
Eligibility	X						
Informed consent		X					
Allocation		X					
Interventions							
Behavioural weight loss treatment with smartphone application			◆———————————◆				
Behavioural weight loss treatment without smartphone application			◆———————————◆				
Assessments							
Anthropometrics, well-being (psychopathology, eating behaviour, physical activity, self-efficacy, emotion regulation, quality of life)			X		X	X	X
Weight management skills use (self-monitoring, goal setting)			X	X	X	X	X
Acceptance				X	X	X	X
(Serious) adverse events				X	X	X	

Box 1 Inclusion and exclusion criteria.

Inclusion

Age ≥18 years.

Severe obesity defined as body mass index ≥40.0 kg/m² or ≥35.0 kg/m² with obesity-related comorbidity.

Presenting for behavioural weight loss treatment at the Obesity Outpatient Unit of University of Leipzig Medical Centre.

Availability of a smartphone for Android.

Permanent Internet access via smartphone.

Written informed consent.

Exclusion

Serious mental illness (eg, psychotic disorder, suicidality and bipolar disorder).

Serious physical illness (eg, cancer).

Previous or planned bariatric surgery.

Current medical or psychological treatment impacting weight.

Current participation in other interventional trials.

Assumed lack of compliance.

Insufficient German language skills.

Planned or current pregnancy or lactation.

Fertile women (within 2 years of their last menstruation) without appropriate contraceptive measures (implanon, injections, oral contraceptives, intrauterine devices, partner with vasectomy),[78] while participating in the trial (participants using a hormone-based method have to be informed of possible effects of the trial device on contraception).

Psychological/mental or other inabilities to supply required informed consent.

Patients under legal supervision or guardianship.

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[51] 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 SO[8] 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[51] 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

Table 2 Weight management skills and assessments in the trEATsmart app

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

led to the development of the app with EMI system for adjunctive use in cognitive-behavioural therapy (CBT) for bulimia nervosa.[54 55] 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).[57] 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 with the patients randomised to the smartphone-supported BWL treatment in order to personalise the app to each patient's needs (eg, defining patient's goals; max. 15 min). Via the web-based portal, the study therapist can enter patient's individual goals linked to one of the weight management skills, select weight management skills according to patient's progress in the BWL treatment and

personalise wording. From a comprehensive list of interventions for each weight management skill with regard to different topics (eg, planning, problem-solving, accepting difficulties with regard to the weight management skill), personally relevant interventions can be selected by the study therapist (or deselected as needed).

For further personalisation, a built-in algorithm will analyse each app entry to determine if a just-in-time adaptive intervention would be helpful.[51 52] After completing an entry (eg, in the nutrition diary), an intervention on a specific selected weight management skill (eg, calorie-restricted eating), will be sent to the patient if the algorithm determined a problem with this skill (eg, calorie intake of the day so far exceeds target value) in relation to the patient's goals regarding this skill (eg, eating max. 1 handful of sweets per day).

Study therapist's fidelity to manual and procedures will be ensured through regular supervision by the PI (AH), also preventing drift.

Control intervention—BWL treatment as usual (without smartphone app)

The control group will receive the standard manualised BWL treatment[51 52] without trEATsmart app, which corresponds best to the research question of incremental efficacy of an adjunctive smartphone app. Usually, patients are not offered a smartphone app during BWL treatment at the IFB Outpatient Unit, therefore the control condition corresponds to a treatment as usual control condition. Duration, content and procedure of the BWL treatment will not differ between randomisation arms (BWL treatment with vs without smartphone app). In order to homogenise intervention time, the control group also will have the opportunity to discuss BWL-related questions with the study therapist group-wise after each behavioural and nutritional session.

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;[58] Eating Disorder Examination-Questionnaire),[59] 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-Lite)[67] 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.[47] 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 and processed information from the app can still be assigned to the individual patient at this point, which is necessary for clinical use of the information in BWL 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 data set. 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 Practice[72] 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 or 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[28 75] and smartphone-based interventions[39 42–44 54–56] 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,[76] and no professional writers will be involved. This manuscript was written according to the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines[77] 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.

Author affiliations
¹Integrated Research and Treatment Center AdiposityDiseases, Behavioural Medicine Research Unit, Department of Psychosomatic Medicine and Psychotherapy, University of Leipzig Medical Centre, Leipzig, Saxony, Germany
²Department of Psychological and Brain Sciences, Center for Weight, Eating and Lifestyle Science, Drexel University, Philadelphia, Pennsylvania, USA
³Clinical Trial Centre, University of Leipzig, Leipzig, Saxony, Germany
⁴Department of Endocrinology, Nephrology, Rheumatology, University Hospital Leipzig, Leipzig, Saxony, Germany

ORCID iDs
Anja Hilbert http://orcid.org/0000-0003-2775-1296
David Petroff http://orcid.org/0000-0002-6916-1465

REFERENCES

1 World health organization (WHO). *Obesity* 2021. Available: https://www.who.int/health-topics/obesity#tab=tab_1
2 NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in body-mass index, underweight, overweight, and obesity from 1975 to 2016: a pooled analysis of 2416 population-based measurement studies in 128·9 million children, adolescents, and adults. *Lancet* 2017;390:2627–42.
3 World health organization (WHO). *Obesity and Overweight* 2021. Available: https://www.who.int/en/news-room/fact-sheets/detail/obesity-and-overweight
4 Williamson K, Nimegeer A, Lean M. Rising prevalence of BMI ≥40 kg/m2: a high-demand epidemic needing better documentation. *Obes Rev* 2020;21:e12986.
5 Hales CM, Fryar CD, Carroll MD, *et al*. Trends in obesity and severe obesity prevalence in US youth and adults by sex and age, 2007-2008 to 2015-2016. *JAMA* 2018;319:1723–5.

6 Ward ZJ, Bleich SN, Cradock AL, *et al*. Projected U.S. state-level prevalence of adult obesity and severe obesity. *N Engl J Med* 2019;381:2440–50.

7 Mensink GBM, Schienkiewitz A, Haftenberger M, *et al*. Overweight and obesity in Germany: results of the German health interview and examination survey for adults (degs1). *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 2013;56:786–94.

8 National Institute for Health and Clinical Excellence. *Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children*. National Institute for Health and Clinical Excellence, 2006.

9 GBD 2015 Obesity Collaborators, Afshin A, Forouzanfar MH, *et al*. Health effects of overweight and obesity in 195 countries over 25 years. *N Engl J Med* 2017;377:13–27.

10 Lin H-Y, Huang C-K, Tai C-M, *et al*. Psychiatric disorders of patients seeking obesity treatment. *BMC Psychiatry* 2013;13:1.

11 Effertz T, Engel S, Verheyen F, *et al*. The costs and consequences of obesity in Germany: a new approach from a prevalence and life-cycle perspective. *Eur J Health Econ* 2016;17:1141–58.

12 Lehnert T, Stuhldreher N, Streltchenia P, *et al*. Sick leave days and costs associated with overweight and obesity in Germany. *J Occup Environ Med* 2014;56:20–7.

13 Simmonds M, Llewellyn A, Owen CG, *et al*. Predicting adult obesity from childhood obesity: a systematic review and meta-analysis. *Obes Rev* 2016;17:95–107.

14 Flegal KM, Kit BK, Orpana H, *et al*. Association of all-cause mortality with overweight and obesity using standard body mass index categories: a systematic review and meta-analysis. *JAMA* 2013;309:71–82.

15 Withrow D, Alter DA. The economic burden of obesity worldwide: a systematic review of the direct costs of obesity. *Obes Rev* 2011;12:131–41.

16 Grieve E, Fenwick E, Yang H-C, *et al*. The disproportionate economic burden associated with severe and complicated obesity: a systematic review. *Obes Rev* 2013;14:883–94.

17 Bray GA, Frühbeck G, Ryan DH, *et al*. Management of obesity. *Lancet* 2016;387:1947–56.

18 LeBlanc ES, Patnode CD, Webber EM, *et al*. Behavioral and pharmacotherapy weight loss interventions to prevent obesity-related morbidity and mortality in adults: updated evidence report and systematic review for the US preventive services Task force. *JAMA* 2018;320:1172–91.

19 Hassan Y, Head V, Jacob D, *et al*. Lifestyle interventions for weight loss in adults with severe obesity: a systematic review. *Clin Obes* 2016;6:395–403.

20 Bauer K, Lau T, Schwille-Kiuntke J, *et al*. Conventional weight loss interventions across the different BMI obesity classes: a systematic review and quantitative comparative analysis. *Eur Eat Disord Rev* 2020;28:492–512.

21 Deutsche Adipositas-Gesellschaft (DAG) e.V. In: *Interdisziplinäre Leitlinie der Qualität S3 zur „Prävention und Therapie der Adipositas" [Interdisciplinary S3 Guideline on „Prevention and Treatment of Obesity]*. 2014. Available: https://register.awmf.org/assets/guidelines/050-001l_S3_Adipositas_Pr%C3%A4vention_Therapie_2014-11-abgelaufen.pdf [accessed 2 Dec 2022]

22 Jensen MD, Ryan DH, Apovian CM, *et al*. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of cardiology/american heart association Task force on practice guidelines and the obesity Society. *Circulation* 2014;129(25 Suppl 2):S102–38.

23 Diabetes Prevention Program Research Group. Long-term effects of lifestyle intervention or metformin on diabetes development and microvascular complications over 15-year follow-up: the diabetes prevention program outcomes study. *Lancet Diabetes Endocrinol* 2015;3:866–75.

24 Wing RR, Phelan S. Long-Term weight loss maintenance. *Am J Clin Nutr* 2005;82(1 Suppl):222S–225S.

25 Stubbs J, Whybrow S, Teixeira P, *et al*. Problems in identifying predictors and correlates of weight loss and maintenance. *Obes Rev* 2011;12:688–708.

26 Teixeira PJ, Carraça EV, Marques MM, *et al*. Successful behavior change in obesity interventions in adults: a systematic review of self-regulation mediators. *BMC Med* 2015;13:84.

27 Varkevisser RDM, van Stralen MM, Kroeze W, *et al*. Determinants of weight loss maintenance: a systematic review. *Obes Rev* 2019;20:171–211.

28 Burgess E, Hassmén P, Pumpa KL. Determinants of adherence to lifestyle intervention in adults with obesity: a systematic review. *Clin Obes* 2017;7:123–35.

29 Appelhans BM, French SA, Pagoto SL, *et al*. Managing temptation in obesity treatment: a neurobehavioral model of intervention strategies. *Appetite* 2016;96:268–79.

30 Pellegrini CA, Pfammatter AF, Conroy DE, *et al*. Smartphone applications to support weight loss: current perspectives. *Adv Health Care Technol* 2015;1:13–22.

31 Beleigoli AM, Andrade AQ, Cançado AG, *et al*. Web-Based digital health interventions for weight loss and lifestyle habit changes in overweight and obese adults: systematic review and meta-analysis. *J Med Internet Res* 2019;21:e298.

32 Podina IR, Fodor LA. Critical review and meta-analysis of multicomponent behavioral e-health interventions for weight loss. *Health Psychol* 2018;37:501–15.

33 Sorgente A, Pietrabissa G, Manzoni GM, *et al*. Web-Based interventions for weight loss or weight loss maintenance in overweight and obese people: a systematic review of systematic reviews. *J Med Internet Res* 2017;19:e229.

34 Villinger K, Wahl DR, Boeing H, *et al*. The effectiveness of app-based mobile interventions on nutrition behaviours and nutrition-related health outcomes: a systematic review and meta-analysis. *Obes Rev* 2019;20:1465–84.

35 Schippers M, Adam PCG, Smolenski DJ, *et al*. A meta-analysis of overall effects of weight loss interventions delivered via mobile phones and effect size differences according to delivery mode, personal contact, and intervention intensity and duration. *Obes Rev* 2017;18:450–9.

36 Thomas JG, Bond DS, Raynor HA, *et al*. Comparison of smartphone-based behavioral obesity treatment with gold standard group treatment and control: a randomized trial. *Obesity (Silver Spring)* 2019;27:572–80.

37 Goldstein SP, Goldstein CM, Bond DS, *et al*. Associations between self-monitoring and weight change in behavioral weight loss interventions. *Health Psychol* 2019;38:1128–36.

38 Stubbs RJ, Duarte C, Palmeira AL, *et al*. Evidence-Based digital tools for weight loss maintenance: the nohow project. *Obes Facts* 2021;14:320–33.

39 Ambeba EJ, Ye L, Sereika SM, *et al*. The use of mHealth to deliver tailored messages reduces reported energy and fat intake. *J Cardiovasc Nurs* 2015;30:35–43.

40 Burke LE, Zheng Y, Ma Q, *et al*. The smarter pilot study: testing feasibility of real-time feedback for dietary self-monitoring. *Prev Med Rep* 2017;6:278–85.

41 Forman EM, Goldstein SP, Zhang F, *et al*. OnTrack: development and feasibility of a smartphone APP designed to predict and prevent dietary lapses. *Transl Behav Med* 2019;9:236–45.

42 Lyzwinski LN, Caffery LJ, Bambling M, *et al*. Consumer perspectives on mHealth for weight loss: a review of qualitative studies. *J Telemed Telecare* 2018;24:290–302.

43 Heron KE, Smyth JM. Ecological momentary interventions: incorporating mobile technology into psychosocial and health behaviour treatments. *Br J Health Psychol* 2010;15(Pt 1):1–39.

44 Nahum-Shani I, Smith SN, Spring BJ, *et al*. Just-in-time adaptive interventions (jitais) in mobile health. *Ann Behav Med* 2018;52:446–62.

45 Spruijt-Metz D, Wen CKF, O'Reilly G, *et al*. Innovations in the use of interactive technology to support weight management. *Curr Obes Rep* 2015;4:510–9.

46 Hardeman W, Houghton J, Lane K, *et al*. A systematic review of just-in-time adaptive interventions (jitais) to promote physical activity. *Int J Behav Nutr Phys Act* 2019;16:31.

47 Forman EM, Goldstein SP, Crochiere RJ, *et al*. Randomized controlled trial of ontrack, a just-in-time adaptive intervention designed to enhance weight loss. *Transl Behav Med* 2019;9:989–1001.

48 Haapala I, Barengo NC, Biggs S, *et al*. Weight loss by mobile phone: a 1-year effectiveness study. *Public Health Nutr* 2009;12:2382–91.

49 Goldstein SP, Zhang F, Thomas JG, *et al*. Application of machine learning to predict dietary lapses during weight loss. *J Diabetes Sci Technol* 2018;12:1045–52.

50 Goldstein SP, Thomas JG, Foster GD, *et al*. Refining an algorithm-powered just-in-time adaptive weight control intervention: a randomized controlled trial evaluating model performance and behavioral outcomes. *Health Informatics J* 2020;26:2315–31.

51 Schwalm SV, Hilbert A, Stumvoll M, *et al*. Das leipziger adipositasmanagement. integrierte versorgung nach §140 SGB V [leipzig obesity management: an integrated health care concept]. *Adipositas* 2015;9:87–92.

52 Frenzel SV, Bach S, Ahrens S, *et al*. Ausweg aus der versorgungslücke: voll krankenkassen-finanzierte konservative adipositas-therapie [Closing the gap in conservative obesity therapy: a fully health insurance-financed obesity program - Prospective analysis of clinical real world data]. *Dtsch Med Wochenschr* 2020;145:e78–86.

53 Curry SJ, Krist AH, Owens DK, *et al*. Behavioral weight loss interventions to prevent obesity-related morbidity and mortality in adults: US preventive services task force recommendation statement. *JAMA* 2018;320:1163–71.

54 Juarascio AS, Parker MN, Lagacey MA, *et al*. Just-in-time adaptive interventions: a novel approach for enhancing skill utilization and acquisition in cognitive behavioral therapy for eating disorders. *Int J Eat Disord* 2018;51:826–30.

55 Juarascio A, Srivastava P, Presseller E, *et al*. Authorship correction: a clinician-controlled just-in-time adaptive intervention system (CBT+) designed to promote acquisition and utilization of cognitive behavioral therapy skills in Bulimia nervosa: development and preliminary evaluation study. *JMIR Form Res* 2021;5:e31964.

56 Juarascio AS, Goldstein SP, Manasse SM, *et al*. Perceptions of the feasibility and acceptability of a smartphone application for the treatment of binge eating disorders: qualitative feedback from a user population and clinicians. *Int J Med Inform* 2015;84:808–16.

57 Max Ruber-Institut (MRI). Bundeslebensmittelschlüssel [german nutrient data base]. 2021. Available: https://blsdb.de/bls?background

58 Kroenke K, Spitzer RL, Williams JBW, *et al*. The patient health questionnaire somatic, anxiety, and depressive symptom scales: a systematic review. *Gen Hosp Psychiatry* 2010;32:345–59.

59 Hilbert A, de Zwaan M, Braehler E. How frequent are eating disturbances in the population? norms of the eating disorder examination-questionnaire. *PLoS One* 2012;7:e29125.

60 Hilbert A, Tuschen-Caffier B. Eating disorder examination. In: *German translation*. 2nd edn. edn. Tübingen: dgvt-Verlag, 2016.

61 Nagl M, Hilbert A, de Zwaan M, *et al*. The German version of the Dutch eating behavior questionnaire: psychometric properties, measurement invariance, and population-based norms. *PLoS One* 2016;11:e0162510.

62 Meule A, Lutz A, Vögele C, *et al*. Food cravings discriminate differentially between successful and unsuccessful dieters and non-dieters. *Validation of the Food Cravings Questionnaires in German Appetite* 2012;58:88–97.

63 Wanner M, Probst-Hensch N, Kriemler S, *et al*. Validation of the long international physical activity questionnaire: influence of age and language region. *Prev Med Rep* 2016;3:250–6.

64 Hinz A, Schumacher J, Albani C, *et al*. Bevölkerungsrepräsentative normierung Der skala Zur allgemeinen selbstwirksamkeitserwartung. *Diagnostica* 2006;52:26–32.

65 Gratz KL, Roemer L. Multidimensional assessment of emotion regulation and dysregulation: development, factor structure, and initial validation of the difficulties in emotion regulation scale. *Journal of Psychopathology and Behavioral Assessment* 2004;26:41–54.

66 Morfeld M, Kirchberger I, Bullinger M. *SF-36 fragebogen zum gesundheitszustand*. 2nd ed. Göttingen: Hogrefe, 2011.

67 Mueller A, Holzapfel C, Hauner H, *et al*. Psychometric evaluation of the German version of the impact of weight on quality of life-lite (IWQOL-lite) questionnaire. *Exp Clin Endocrinol Diabetes* 2011;119:69–74.

68 Hilbert A, Neuhaus P, Köhler N, *et al*. Group cognitive remediation therapy prior to behavioral weight loss treatment for adults with severe obesity: a randomized clinical trial (crt study). *J Consult Clin Psychol* 2021;89:695–706.

69 Moher D. Consort: an evolving tool to help improve the quality of reports of randomized controlled trials. consolidated standards of reporting trials. *JAMA* 1998;279:1489–91.

70 Regulation (EU) 2016/679. *Official Journal of the European Union 2016* 2016;L119:1–88. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679

71 Regulation (EU) 2017/745. *Official journal of the european union*. 2017: L117–175. Available: https://www.medical-device-regulation.eu/wp-content/uploads/2019/05/CELEX_32017R0745_EN_TXT.pdf

72 Bundesministerium der Justiz und für. Verordnung über die anwendung der guten klinischen praxis bei der durchführung von klinischen prüfungen mit arzneimitteln zur anwendung am menschen [regulation on the application of good clinical practice in the conduct of clinical trials with medicinal products for human use] (GCP-verordnung - GCP-V). 2004. Available: https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/KlinischePruefung/GCP-Verordnung.pdf?__blob=publicationFile [Accessed 2 Dec 2022].

73 World Medical Association. World Medical association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013;310:2191–4.

74 Bundesministerium der Justiz. Gesetz zur durchführung unionsrechtlicher vorschriften betreffend medizinprodukte [law on the implementation of EU regulations concerning medical devices] (medizinprodukterecht-durchführungsgesetz – MPDG). 2020. Available: https://www.gesetze-im-internet.de/mpdg/MPDG.pdf [Accessed 2 Dec 2022].

75 World Health Organization (WHO). *International classification of diseases for mortality and morbidity statistics*. 2020. Available: https://icd.who.int/browse11/l-m/en

76 Deutsche Forschungsgemeinschaft DFG. *Sicherung guter wissenschaftlicher praxis [safeguarding good scientific practice]*. Weinheim, Germany, 2013.

77 Chan A-W, Tetzlaff JM, Gøtzsche PC, *et al*. Spirit 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013;346:e7586.

78 ICH guideline M3(R2) on non-clinical safety studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals, step 5, EMA/CPMP/ICH/286/1995. 2009. Available: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-m3r2-non-clinical-safety-studies-conduct-human-clinical-trials-marketing-authorisation_en.pdf [Accessed 2 Dec 2022].