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Effectiveness of an internet-based self-help intervention for improving mental health in individuals with obesity: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Patients with chronic somatic diseases such as obesity often develop comorbid depressive symptoms. E-mental health interventions are an innovative and effective treatment option within a stepped care approach. Studies have shown that acceptance and adherence are higher when they are tailored to the specific needs of the target group. This study protocol describes a randomised controlled trial (RCT) of an internet-based self-help intervention, Fit4Mood, to improve mental health in the high-risk group of adults with obesity. The objective of the @ktivPLUS research project is to evaluate the effectiveness, acceptability and cost-effectiveness of the intervention in comparison to an online bibliotherapy.

Methods and analysis Eligible individuals will be randomly allocated to an intervention group (access to an internet-based intervention) or to an active control group (access to an online bibliotherapy). Assessments will be conducted before the start of the intervention (baseline (BL)) and 4 months after BL (follow-up (FU)). The primary outcome is the reduction in depressive symptoms (Beck Depression Inventory-II) in n=190 participants. Secondary outcomes are anxiety, quality of life, activity, self-efficacy, resilience, mental and digital health literacy, stress, sleep quality, weight loss, weight management activities and readiness to lose weight, weight self-stigma, uptake, adherence and satisfaction with the intervention, workability and cost-effectiveness at follow-up. Additionally, sociodemographics, health, comorbidities and disabilities, as well as internet-specific information, will be assessed at BL. Intention-to-treat analysis using generalised linear mixed models will be applied.

Ethics and dissemination Approval for this study has been granted by the ethics committee of the *University of Leipzig* (ID: 140/25-ek). All participants will provide informed consent prior to participation in the study. Results will be disseminated in peer-reviewed journals and presented at national and international conferences. In the case of a successful evaluation, the internet-based self-help intervention Fit4Mood will be provided as freeware, which will be easily accessible and free of charge.

Trial registration number The current RCT study has been registered at the German Clinical Trials Register (Identifier: DRKS00036178, Registered 24 June 2025; https://www.drks.de/search/de/trial/DRKS00036178).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The @ktivPLUS study uses a high-quality study design (RCT) and an active control group: participants are randomly assigned to either the internet-based intervention or an online-bibliotherapy (control condition).
⇒ Broad inclusion and exclusion criteria will be applied to strengthen external validity by ensuring that the trial closely mirrors real-world care structures.
⇒ To increase attrition in the unguided internet-based intervention, target-specific adherence-enhancing features will be applied.
⇒ Only short-term effects 4 months after intervention will be measured.

INTRODUCTION

Obesity is a major public health challenge due to its increasing prevalence and adverse impact on somatic and mental health.[1 2] The WHO defines obesity as 'abnormal or excessive fat accumulation that may impair health' and classifies adults with a body mass index (BMI) ≥30 as obese.[2 3] Worldwide, the proportion of people with obesity has tripled since 1975,[4] and nearly one in four adults has obesity,[5] with an increasing trend.[1] In Germany, about one in five adults (19.0%) report a BMI ≥30.[6] Obesity is an important risk factor for adverse health outcomes, eg, type 2 diabetes mellitus, stroke, osteoarthritis, coronary heart disease and functional impairments.[1 7 8]

Obesity can also affect mental health: evidence suggests that individuals with obesity are 50%–60% more likely to develop depressive symptoms than those of normal weight,[9–15] with a prevalence of 2.0% in women and 1.3% in men of comorbid depression and obesity.[13] The association between obesity and depression is bi-directional: not only does obesity contribute to the onset and persistence of depression, but depressive symptoms are also positively associated with weight gain.[9 13 16–18] Some depressive symptoms have been shown to have a direct negative impact on weight: for example, increased appetite and emotional eating as coping strategy,[19–22] social withdrawal and reduced physical activity[23 24] or poor sleeping quality.[25] In addition, some antidepressant medications promote weight gain.[8 26–29] There is evidence for shared biological mechanisms, for example, genetics or immuno-inflammatory activation.[30] Both obesity and depression are associated with negative societal attitudes and discrimination, so individuals with obesity and depression may experience a double or 'layered stigma'.[31–35]

The co-occurrence of obesity and depression creates a complex interaction that amplifies their combined impact on physical health, mental well-being and social life. It heightens the risk of a more severe progression and decreases the likelihood of recovery from both diseases. Therefore, the co-occurrence of obesity and depression can lead to a cycle of worsening health outcomes if not effectively managed.[11 14 36] This is a significant challenge in clinical practice: healthcare providers often prioritise weight loss treatment, while mental health impairments are often not adequately treated.[36–38] Emerging research suggests that integrated interventions addressing both obesity and depression concurrently show considerable potential.[39–41] There is a need to develop accessible and innovative approaches to promote the mental health of individuals with obesity: as an add-on in existing healthcare structures, as well as a self-management-promoting tool in primary and secondary prevention.[42]

A promising approach involves internet-based interventions, which include web-based programmes and mobile applications specifically designed for health promotion.[43–46] These tools are cost-effective, easily accessible and provide flexibility. They enable user engagement regardless of location or time, and they can complement traditional healthcare by filling gaps in therapy availability and integrating into blended care approaches.[47–49] Internet-based interventions also address specific barriers experienced by individuals with obesity, including social stigma, isolation and mobility challenges.[50] Research findings suggest that stigma related to obesity or depression is a major barrier to help-seeking, leading to delayed or avoided medical visits, reduced trust in healthcare providers and lower uptake of mental health services.[51 52] Internet-based interventions can reduce this barrier by offering privacy and minimising perceived stigma.[53] There is evidence that these interventions are effective for managing various mental health conditions, with outcomes comparable to those of in-person therapies.[48 54–58] Research shows that internet-based interventions can effectively improve the mental health of people with obesity.[39 59 60] They are highly accepted by individuals with obesity as well as healthcare providers.[61 62] Internet-based interventions can help to promote individuals' understanding and skills in dealing with mental health problems, which can increase mental health literacy, help-seeking behaviour and self-help strategies.[63–66]

Research suggests that individuals could benefit more if internet-based interventions are adequately tailored to their specific needs.[67–69] However, interventions targeting people with obesity and with a focus on improving mental health are limited and only available in English.[39 60] Some German digital programmes promote weight loss, have been evaluated in randomised controlled trials (RCTs), registered as digital health applications (DiHAs) and are being reimbursed by German health insurance companies.[70 71] They use self-management, self-monitoring, psychoeducation and motivational techniques to facilitate weight regulation and lifestyle changes. In addition to these established obesity care structures, there is a need for low-threshold digital mental health programmes that align with a public health approach. DiHA and freely accessible programmes for individuals with depressive symptoms are available.[56 72–74] Yet these programmes are not tailored to the target group and do not contain obesity-related topics, such as body image, weight-related external and self-stigmatisation, or movement restrictions. Previous research indicates that both individuals with obesity and their healthcare providers express a strong demand for digital programmes that strengthen mental health while simultaneously addressing obesity-related conditions and symptoms, as general programmes are not perceived as sufficient to meet these needs.[61 75 76]

To our knowledge, no internet-based intervention specifically targeting depressive symptoms in people with obesity and including obesity-related content has been evaluated in Germany.[77] The objective of the @ktivPLUS study is to evaluate the effectiveness and cost-effectiveness of an internet-based self-help intervention (Fit4Mood) for improving mental health in the high-risk group of adults with obesity.

METHODS AND ANALYSIS

Study design

The present study will conduct a monocentric RCT with a parallel-arm design, assigning participants to either an intervention group (IG) with access to the internet-based self-management intervention Fit4Mood, or a control group (CG) with access to an online-bibliotherapy (see figure 1). Following an eligibility screening, data will be collected from participants at baseline (BL), before being notified of their group allocation, and at follow-up after 4 months (FU). A detailed description of the study procedure is provided below. The RCT study is planned to start

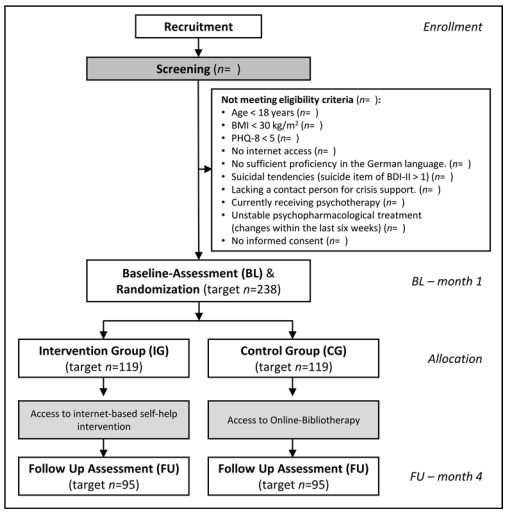

Figure 1 Flowchart of study design. BDI, Beck Depression Inventory; BMI, body mass index; PHQ, Patient Health Questionnaire.

in September 2025 and is expected to be completed by April 2027.

This RCT is part of a mixed-method design including qualitative work packages (development of intervention with planning groups, exploration of acceptability involving two focus groups of n=10 people with obesity and n=9 healthcare experts) as well as a pilot study with n=16 participants with obesity and comorbid depressive symptoms who had access to the intervention Fit4Mood.

Recruitment

Participants will be recruited German-wide using a variety of recruitment strategies: (1) Inpatient and outpatient healthcare providers working in the field of obesity and/or depression (such as psychology/psychotherapy, obesity ambulances, general practitioners, nutrition counselling and sports therapy) will be invited to distribute informational leaflets to eligible individuals. *The Institute of Social Medicine, Occupational Health and Public Health (ISAP*) at the *University of Leipzig* has already established a network of cooperating medical and mental health professionals (ISAP network), (2) Additionally, information about the study will be shared on relevant websites, internet forums and through social media (eg, *LinkedIn, Instagram, Facebook*), (3) Self-help networks for individuals with obesity will be contacted via telephone, email, recruitment flyers and information events. Furthermore, (4) local media and advertisements in public places, (5) snowball recruitment will be used to recruit participants and (6) Healthcare providers will be invited to actively recruit patients during consultations and will receive a €50 reimbursement per participant as compensation for the administrative effort involved.

Interested individuals will receive a comprehensive information sheet about the study as well as a screening questionnaire by postal mail. If they want to participate in the study, they will be asked to give written informed consent by signing a consent form, to complete the screening questionnaire and to return these documents by postal mail to the study team. They will also be informed that they need to provide contact details of their general practitioner/or equivalent health professional, who may be contacted in the event of a crisis (eg, worsening of symptoms). During the recruitment process and throughout the study, the research team will be available to answer any questions that participants may have.

Recruitment paths and materials, as well as study procedures, are based on experiences from previous studies[78] and were checked for feasibility in a previous pilot study and optimised.

Screening of inclusion and exclusion criteria

A brief screening questionnaire will be used to determine whether interested individuals meet the eligibility requirements for participation based on predefined inclusion and exclusion criteria. If the eligibility criteria are not met, participants are provided with information on alternative support services and an overview of mental health counselling centres. Those who qualify will be enrolled as study participants and randomly assigned to either IG or CG.

To be eligible for the study, participants must be at least 18 years old, have a *BMI* of ≥30 kg/m^2 (indicating obesity), and show at least mild depressive symptoms, indicated by a score of ≥5 on *the Patient Health Questionnaire 8 (PHQ-8)*.[79 80] Additionally, they must have access to the internet, have sufficient proficiency in the German language and provide informed consent. Exclusion criteria include displaying suicidal tendencies, identified by a score of >1 on the suicide item of the *Beck Depression Inventory (BDI-II),* or lacking a contact person, such as a general practitioner or equivalent medical specialist, for crisis support. Individuals currently receiving regular psychotherapeutic treatment or those with an unstable psychopharmacological treatment (defined by changes within the last 6 weeks) are also excluded from study participation.

Intervention

The internet-based self-help intervention Fit4Mood is designed to improve the mental health of individuals with obesity. It draws on established cognitive and behavioural therapy techniques, taking into account the specifics of obesity (eg, topics such as healthy eating, exercise therapy, negative body image, weight stigma, emotional eating and guideline-based treatment options for obesity). The online intervention consists of 14 modules and mental health crisis support contacts (see table 1). Quizzes, reflection, mindfulness and relaxation exercises are integrated into all modules. Users can reflect on how they are feeling at the beginning of a module to increase self-awareness. Six example characters with different degrees of obesity are included to illustrate strategies and to facilitate application to one's own situation. In addition, the intervention provides information about crisis support contact services in Germany, Austria and Switzerland, and

Table 1 Modules of the internet-based self-help intervention Fit4Mood

Module	Content
Introduction	Introduction to the programme's topics, benefits and limitations
Weight and mental well-being	Psychoeducation on the association between mood and weight
Self-care, stress and mindfulness	Perception and fulfilment of needs; techniques of self-care, relaxation, stress management, sleeping hygiene and mindfulness
My feelings	Functions of feelings and their influence on behaviour; strategies for dealing with unpleasant emotions
My thoughts	Association between thoughts, emotions and behaviour; impact of thought patterns on mood; strategies to develop mood-enhancing thoughts
I am getting active	Psychoeducation on the association between activities and mood; encouragement of weekly planning of activities
Getting started: physical activity and exercise	Encouragement of physical activity in daily life; exercises adapted for people with obesity
Feeling of self-worth and resources	Exploration of individual resources and strategies to promote self-worth
My body and me	Psychoeducation on the association between body perception and mood; strategies to adapt negative body perceptions
Social relationships and communication	Psychoeducation on social interactions and their association with mood; strategies for dealing with conflictual interactions
Nutrition and mental well-being	Healthy diet information and its positive effects on physical and mental well-being, weight and performance
Eating impulses	Differences between hunger, craving, appetite and the urge to eat; strategies to enhance control over eating behaviour
Obesity treatment	Overview of obesity treatment options according to clinical practice guidelines
My future path	Revision of individual progress and programme content

about psychotherapy, psychosocial counselling and peer support.

The intervention has been developed by experienced mental health professionals (eg, psychologists, psychotherapists, medical specialists, e-mental health specialists). Two planning groups of (1) Individuals with obesity and (2) Healthcare experts were involved in the development process. Development is based on *Bartholomew's intervention mapping (IM)*[81] in order to ensure that the intervention can be implemented in real-world settings. The IM is a six-step framework often used to guide behaviour change interventions and health education development, bridging the implementation gap between theory and practice. Moreover, the development process has been aligned to consider all three elements for self-management proposed by the *Corbin and Strauss Model on Self-Management-Framework*:[82] cognitive (eg, psychoeducation), emotional (eg, coping strategies) and behavioural (eg, lifestyle changes). The intervention includes modules that promote mental health (eg, cognitive restructuring and behavioural activation), as well as obesity-specific topics (such as negative body image and self-stigmatisation due to obesity), and weight management topics (eg, obesity treatment options and healthy nutrition). Additionally, obesity-specific aspects are incorporated into all modules, such as the selection of examples, eating for emotional regulation and weight-based discrimination.

The technical implementation was carried out by the local software company *Rhowerk*, with experience in the field of e-mental health interventions, which will also maintain the platform for the time of the study. If effective, the plan is to make the intervention available free of charge as part of a public health approach. To ensure this, we aim to attract interested partners, such as health insurance companies, or to secure financing from our own resources. Funding for maintenance is currently secured for 4 years. Fit4Mood can be accessed via URL or QR code and a standard internet browser on any computer, tablet or smartphone with personal login data provided by the study team. No installation will be necessary.

Before accessing the modules, participants will receive a brief introduction, including an overview of their contents, indications and limitations, as well as general information on terms of use and data protection. Users can work through modules in a flexible order and time. It is recommended that users complete one module per week (each module takes approximately 20 to 40 min to complete and can be processed in multiple sessions). Users will be encouraged to follow the sequence of modules. However, they are generally allowed to use the programme flexibly and adapt it to their individual needs. No in-app or email reminders are integrated, as the programme is purely browser-based and does not collect personal contact data such as email addresses or phone numbers. To enhance external validity, the study follows a pragmatic real-world

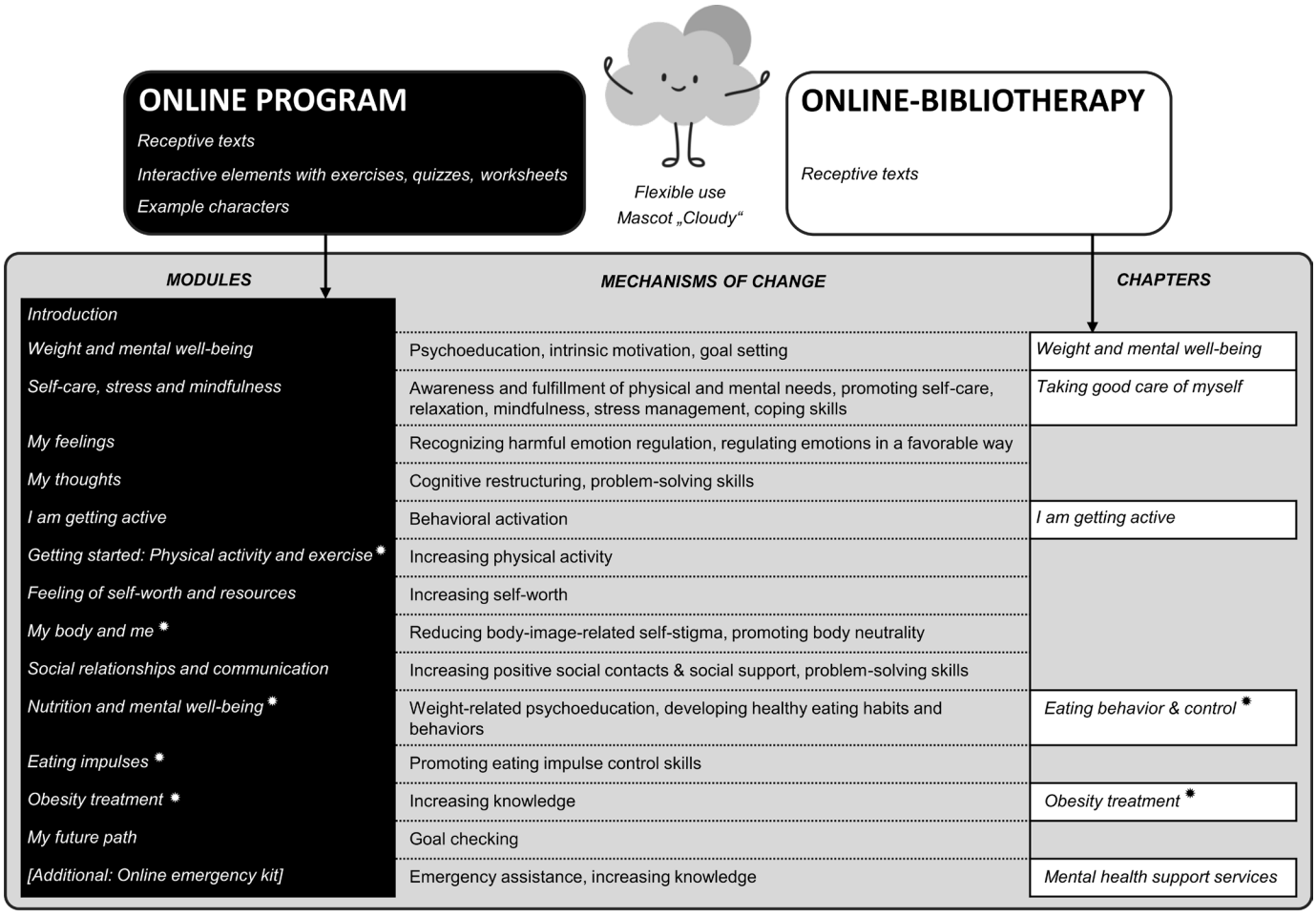

Figure 2 Comparison of @ktivPLUS study conditions and mechanisms of change. *Obesity specific, respectively, weight management-related modules or chapters.

design by refraining from reminders, thereby capturing adherence as it would occur in everyday use rather than in response to protocol-driven prompts. Design follows recommendations for non-discriminatory representations of people with obesity.[83–88] This includes content (body acceptance), language (people-first language) and presentation (appreciative imagery). A mascot, 'Cloudy', motivates users and suggests recovery breaks to avoid emotional and cognitive overload. To enhance accessibility for users who may experience visual impairments, the programme includes technical features such as adjustable text size, increased contrast and an audio option to read the text aloud.

A graphical summary of modules and the mechanism of change in comparison to the control condition can be found in figure 2.

Control condition

The online bibliotherapy has been developed using current literature and general didactic key rules referring to Grahlmann:[89] (1) Short, coherent, self-explanatory texts, (2) Concentration on important information (need-oriented), (3) Focus on topics of general relevance and (4) Risk-free recommendations for action with selection options. Therefore, the online bibliotherapy was developed as receptive bibliotherapy with short didactic texts on the topic of 'Obesity and mental health' in six chapters and a farewell section (see table 2).

The online bibliotherapy can also be accessed via URL or QR code and a standard internet browser on any computer, tablet or smartphone with personal login data provided by the study team.

Patient and public involvement in intervention design and optimisation

As patient and public involvement is crucial and forms an integral part of the project, Fit4Mood was developed by involving two planning groups throughout the entire development period, each consisting of n=11 representatives of the target group and n=11 healthcare experts as relevant stakeholders. Before development began, a needs analysis was conducted to identify relevant topics for the intervention, wishes and potential barriers. The planning groups received regular updates on the intermediate steps and provided feedback to influence the development. At the end of the development phase, a 'Strengths, Weaknesses, Opportunities and Threats' analysis was conducted with a focus on dissemination and

Table 2 Overview of the content of the online bibliotherapy

Chapter	Content
Weight and mental well-being	Psychoeducation on the association between mood and weight
Taking good care of myself	Information regarding sleeping hygiene, health-promoting nutrition, relaxation and mindfulness techniques
I am getting active	Encouragement of activities, incorporating movement into daily life and promoting physical activity
Eating behaviour and control	Strategies for enhancing control of eating behaviour
Obesity treatment	Overview of obesity treatment options according to clinical practice guidelines
Mental health support services	Crisis support contacts in Germany, Austria and Switzerland; information on psychotherapy and peer support

implementation. The intervention was thus optimised in terms of content and design for the target group according to the principle of patient-oriented design.

Furthermore, acceptability was explored with two focus groups consisting of n=10 people with obesity and n=9 healthcare providers to further optimise the online programme. A pilot study with n=16 people with obesity and comorbid depressive symptoms was conducted.

A project advisory board will be established, consisting of representatives of the target group of people with obesity as well as healthcare experts. Project advisory group members will support the research team throughout the RCT study and help interpret and disseminate the findings.

Outcome measures and assessments

Participants enrolled in the study will complete assessments at the start (BL) and at a 4-month FU using questionnaires sent by postal mail. Table 3 provides an overview of all screening variables, outcomes and other measures, including their psychometric parameters that will be used.

Screening assessment

Depression severity will be assessed with the *PHQ-8*, a short 8-item self-report screening inventory for depression symptoms on a 4-point Likert scale from '0' (not at all) to '3' (nearly every day).[79] Eligible participants must report at least mild depressive symptoms, indicated by a PHQ-8 score ≥5.[79 80] Suicidal tendencies will be assessed using the suicide item of the *(BDI-II*, score >1).[90]

Primary outcome

Depression severity at 4 months (FU) after BL will be the primary outcome, as measured by the BDI-II.[90] The reliable and validated instrument is used in many studies, which enables comparability. The BDI-II consists of 21 questions covering the spectrum of depressive symptoms (eg, depressive mood, loss of joy and interest, and feelings of worthlessness) within the last 2 weeks. More severe perceived depressive symptoms are indicated by higher scores.

Secondary outcomes

The *Generalised Anxiety Disorder 2-item (GAD-2*) is a brief validated scale on the GAD-7.[91–94] Two symptoms (nervousness, anxiety or tension, worries) within the past 2 weeks are assessed on a 4-point Likert scale ranging from '0' (not at all) to '3' (nearly every day). A sum score from '0' (no anxiety) to '6' (high anxiety) will be derived, with higher scores indicating higher perceived anxiety symptoms.

The *Short Form Health Survey Questionnaire (SF-12*) is a validated short form of the SF-36[95] measuring health status covering both physical and mental aspects within the last 4 weeks.[96 97] The eight dimensions (physical functioning, physical role limitations, bodily pain, general health, vitality, social functioning, emotional role limitations and mental health) are assessed with twelve items. Two subscales for physical and mental health can be calculated, with higher scores indicating higher perceived health.[97]

Activities will be assessed using the 26-item *'Leisure and Sport' module of the German version of the International Social Survey Programme*[98] following adaptions from Weitzel *et al*.[99] Study participants will be asked how often they engage in a selection of 13 diverse sport and leisure activities with answers ranging from 'never' to 'daily' on a 6-point Likert scale. They will then be asked how much enjoyment they experience when engaging in these activities, with answers ranging from 'no enjoyment' to 'a great amount of enjoyment' on a 6-point Likert scale. Two scores for each of the two dimensions will be aggregated, with higher scores indicating greater activation and enjoyment.

Self-efficacy will be assessed using the *Hope and Self-efficacy subscale from the Questionnaire for the Assessment of Empowerment in Patients with Affective and Schizophrenic Disorders*,[100] with six items on a 5-point Likert Scale ranging from '1' (strongly disagree) to '5' (strongly agree). A higher score indicates greater self-efficacy.

Resilience will be measured with the *Brief Resilience Scale*[101 102], a 6-item instrument on a 5-point Likert scale from '1' (strongly disagree) to '5' (strongly agree), with a higher score indicating greater resilience.[102]

Mental Health literacy will be assessed with the *Mental Health Literacy Scale Germany-Questionnaire 24*,[103 104] an

Table 3 Instruments to measure primary and secondary outcomes and other variables

Instruments	Psychometric validation	Screening	BL	FU (4 months after BL)
Primary outcome				
Beck's Depression Inventory-II (BDI II)[90 143 144]	α=0.84[143]		x	x
Secondary outcomes				
Generalised Anxiety Disorder 2-item (GAD-2)[91–94]	α=0.75[93]		x	x
Quality of life Short Form (SF-12)[96 97]	Physical health scale: α=0.89 Mental health scale: α=0.89[97]		x	x
Leisure and Sport Activity Questionnaire from GESIS report[98 99]	Engagement scale: α=0.59–0.67 Pleasure scale: α=0.77–0.80[99]		x	x
Self-efficacy (EPAS)[100]	α=0.94[100]		x	x
Brief Resilience Scale (BRS)[101 102]	α=0.85[101]		x	x
Mental Health Literacy Survey-Germany-Questionnaire 24 (MHLS-Q24)[103 104]	α=0.96[103]		x	x
eHealth Literacy Scale (eHEALS)[106–108]	Information-seeking scale: α=0.88 information-appraisal scale: α=0.83[107]		x	x
Perceived Stress Questionnaire (PSQ-20)[109 110]	a=0.80–0.86		x	x
COPD and Asthma Sleep Impact Scale (CASIS)[111]	α=0.90–0.92[111]		x	x
Work-related questions: sick leave days,[113] presenteeism[114]	NA		x	x
Subjective Prognostic Employment Scale (SPE)[115]	Guttman scaling=0.99[115]		x	x
Weight and height (BMI)	NA	x	x	x
Readiness to achieve weight reduction (Readiness Ruler)[117–119]	NA		x	x
Weight management activities[119]	NA		x	x
Weight Self-Stigma Questionnaire (WSSQ)[120 121]	a=0.84[120]		x	x
Acceptability (SUS)[145] of intervention/control condition	α=0.911[145]		x	x
Satisfaction with intervention/control condition	NA			x
Uptake/adherence of intervention/control condition	NA		x	x
Healthcare utilisation, medication and costs (FIMA)[124 125] (short adapted version)	NA		x	x
Other variables				
Sociodemographics	NA	x (age, gender)	x	x
Patient Health Questionnaire (PHQ-8)[79]	a=0.89[79]	x		
Comorbidities,[128] disabilities[129]	NA		x	x
Internet-specific information	NA	x (internet access)	x	x
Suicidal tendencies (suicidal item in BDI-II >1)[90]	NA	x	x	x

BL, baseline; BMI, body mass index; COPD, Chronic Obstructive Pulmonary Disease; EPAS, Questionnaire for the Assessment of Empowerment in Patients with Affective and Schizophrenic Disorders; FIMA, Questionnaire for the Use of Medical and Non-Medical Services; FU, follow-up; GESIS, GESIS – Leibniz Institute for the Social Sciences; NA, not applicable or available; SUS, System Usability Scale; α, Cronbach's alpha.

extension of the *European Health Literacy Survey Questionnaire*.[105] It consists of 24 items on a 4-point Likert scale ranging from '1' (very difficult) to '4' (very easy). Higher scores indicate greater mental health literacy.

Digital health literacy will be assessed with the *eHealth Literacy Scale*,[106–108] an 8-item instrument on a 5-point Likert scale from '1' (strongly disagree) to '5' (strongly agree), with a higher score indicating higher digital health literacy.[106]

The *Perceived Stress Questionnaire*[109 110] will be used to measure subjective stress within the dimensions worries, tension, joy and demands[109] within the last 4 weeks with 20

items on a 4-point Likert Scale ranging from '1' (almost never) to '4' (usually). A higher score indicates greater perceived stress.

The *Chronic Obstructive Pulmonary Disease (COPD) and Asthma Sleep Impact Scale*[111] is a 7-item questionnaire designed to assess sleep disturbances and perceived sleep quality in the last week on a 5-point Likert scale ranging from '1' (never) to '5' (very often). A higher score indicates greater perceived sleep disturbance. Additionally, sleep satisfaction will be assessed on a visual analogue scale from '0' (= not confident at all) to '10' (= absolutely confident).[112]

Work-ability related questions will assess self-reported sick leave days and presenteeism following Broszeit[113] and Nübling.[114] The *Subjective Prognostic Employment Scale*[115 116] is an effective and efficient 3-item questionnaire to assess vocational ability. A higher score indicates a worse self-prognosis of gainful employment abilities.

The willingness to engage in weight management strategies will be measured using the *Readiness Ruler* adapted from Zimmermann *et al*[117] and Stott *et al*[118] analogue to Welzel *et al*.[119] This visual analogue scale assesses readiness on a scale from '0' (not ready to change) to '10' (very ready to change). Participants will also be asked to report their height and weight for BMI calculation, and, if applicable, previous weight management strategies[119] in the past 3 months.

The *Weight Self-Stigma Questionnaire,* an instrument for people with overweight or obesity, will be used to assess self-stigma caused by being overweight. It consists of twelve items on a 5-point Likert Scale from '1' (strongly disagree) to '5' (strongly agree), with a higher score indicating greater weight-related self-stigma.[120 121]

Satisfaction with the intervention and the online bibliotherapy will be assessed using items adapted from the study trauer@ktiv.[78] The *System Usability Scale* by Brooke,[122] translated by Rummel *et al*,[123] will be used to assess usability of Fit4Mood or the online bibliotherapy with five positively and five negatively formulated statements on a 5-point Likert Scale from '0' (strongly disagree) to '4' (strongly agree), with higher score indicating greater usability. Uptake and adherence in the intervention will be assessed via pseudonymised login data.

Pseudonymised metadata are collected to operationalise uptake and adherence. Uptake is operationalised as the presence of at least one login timestamp to the website (yes/no), indicating the initiation of use of the study condition. Adherence is operationalised as the number of modules completed, with a module considered completed when timestamps are available for both its first and last page. Based on module completion, participants of the intervention are further classified into five user groups:

- Test user: accessed the first page of a module but did not complete any module.
- Low user: completed 1 out of 14 modules (<10%).
- Moderate user: completed 2–4 modules (approx. 15% to <30%).
- High user: completed 5–7 modules (approx. 35% to 50%).
- Intensive user: completed ≥8 modules (>50%).

Analogue, participants of the control condition will be classified as follows:

- Test user: accessed the first page of a chapter but did not complete any chapter.
- Low user: completed 1 chapter out of 6 (approx. 15%).
- Moderate user: completed 2 chapters (approx. 30%).
- High user: completed 3 chapters (50%).
- Intensive user: completed ≥4 chapters (>50%).

Healthcare utilisation, medication and productivity losses will be assessed with an adapted shortened version of the *Questionnaire for the Use of Medical and Non-Medical Services (FIMA*), a generic questionnaire that measures the health-related resource use,[124 125] from which healthcare costs will be calculated by applying standardised unit costs.[126]

Other measures and covariates

To investigate potential confounders, *sociodemographic characteristics* will be assessed,[127] including sex, age, family status, living situation, income, education and employment status. In addition, information on comorbidities and disabilities will be assessed based on participants' self-reports.[128 129] Finally, internet access and familiarity with internet use will be assessed according to Welzel *et al*.[78]

Data collection, processing and data management

Prior to the study, data protection consultation was provided by an external company. The data protection concept, including all technical measures and processing steps, was reviewed by the data protection officer of the Medical Faculty of the University of Leipzig. A data processing agreement was signed with the software company.

BL will be conducted after randomisation and prior to the intervention. FU will take place 4 months after BL. All data will be gathered using standardised questionnaires sent by postal mail at each assessment point.

Once BL has been completed, subjects will receive a sealed envelope with personal login information for the internet-based self-help intervention (IG) or for the online-bibliotherapy (CG). Both groups enter their login information on the same study website and are automatically taken to the respective condition. All participants are allowed to use the online programme or online bibliotherapy flexibly and according to their individual needs. A motivational reminder to perform the study condition will be sent out 1 month after BL.

To maximise follow-up rates, prepaid return envelopes and monetary incentives will be provided. Participants will be compensated with €40 for two assessments and participation in the intervention/control condition. Additionally, reminders will be sent up to three times in the event of missing assessment responses.

Metadata on uptake and adherence for both study conditions will be collected through log files, which will store pseudonymised data. All collected data will be entered into a statistical database and stored locally with password protection on the server of the medical faculty of the university of Leipzig. A double-entry check will be performed to ensure the accuracy and completeness of data entry. Each participant will be assigned a pseudonym, allowing data to be analysed in a strictly pseudonymous format.

To safeguard data protection, *Secure Sockets Layer technology* will be used for the secure transmission of all user inputs and anonymous log files related to the use of the internet-based intervention and for the transfer of metadata. User input data that participants actively save will be stored on an encrypted database on a German web server. Neither the software company nor the study team will have access to the content.

Sample size

Power calculation was based on a previous research study[74] with regard to a self-management online programme for depression, showing an effect size of Cohen's d=0.41 for the primary outcome (BDI-II). The sample size calculation was performed using the programme G*Power.[130] Considering a significance level of α=0.05 (two-sided), a statistical power of 1-β=0.80 and an allocation ratio of 1:1, a proposed sample size of n=190 participants (n=95 per group) at FU is estimated. Anticipating a drop-out rate of 20%, based on experiences with previous clinical research projects,[74 131] the total sample size would have to comprise n=238 individuals at BL (n=119 per group).

Randomisation and blinding

Participants who consent to join the study will be randomly assigned to either IG or CG before BL assessment using a computerised block randomisation algorithm, aiming for an equal 1:1 distribution between the two groups. This process is stratified by (1) Gender (male, female), (2) Age (≥18–45, >45 years) and (3) Depression severity (PHQ-8-Score ≥5–9 mild, ≥10 at least moderate) to maintain a balance in sample size and key characteristics across groups. Stratified randomisation will be conducted using separate randomisation within each stratum. An external professional will manage the randomisation process, creating block lists with statistical software (eg, R or StataSE 16). Randomisation lists, which are specific to each group, will be concealed from the study coordinator and recruitment team. Healthcare providers recruiting participants will also remain unaware of group assignments. Participants in both the IG and CG cannot be blinded, as blinding is, per se, not feasible for an online intervention. However, the statistician and team members analysing the results will be blinded to group assignments to prevent bias.

Data analysis

Analyses of primary and secondary outcomes will be conducted using an intention-to-treat approach. Changes in outcomes will be reported using mean scores and SD. The treatment effects on primary and secondary outcomes at follow-up will be tested with generalised linear mixed models. Acceptability, uptake and adherence to the intervention will be assessed using descriptive and inferential statistics based on pseudonymised computer log-files. Statistical significance will be set at $p<0.05$ for all analyses.

The study results will be reported following the *Consolidated Standards of Reporting Trials 2025 guidelines*[132] and *Consolidated Health Economic Evaluation Reporting Standards*.[133] Intervention costs will be calculated based on accounting principles, including material and time costs. Cost-effectiveness will be evaluated using *quality-adjusted life years* based on the *SF-12 (SF-6D)*[134] *as a measure of effects*. Statistical uncertainty in the incremental cost-effectiveness ratio will be assessed by using the net benefit approach and constructing *cost-effectiveness acceptability curves*.[135] All data will be checked for inconsistencies and missing values. Missing BL data will be addressed through multiple imputation methods,[136] where applicable. To identify systematic differences between completers and non-completers, a dropout analysis will be performed.

Data monitoring

The study will establish an independent external *Data Monitoring Committee (DMC)* to monitor its progress. The DMC will conduct regular inspections and establish ongoing protocols throughout the trial to ensure compliance with the *Guidelines for Good Clinical Practice (ICH-GCP)* and the *Declaration of Helsinki*. In the event of serious or urgent adverse events (AEs), the DMC will be notified immediately. The DMC will be responsible for monitoring the trial's progress, adherence to protocol and safety. Any recommendations from the DMC to modify or discontinue the study will be directed to the study coordinator.

Harms

The likelihood of (AEs, such as an increase in symptom frequency or intensity) and *severe adverse events* (SAEs, such as suicidality, severe depressive symptoms or hospitalisation) occurring due to study participation is considered minimal. However, for safety reasons, only participants who can provide access to a healthcare professional (eg, general practitioner) in case of a crisis will be enrolled. Additionally, individuals with suicidal thoughts will be excluded from participation. A standardised protocol for managing contact with participants experiencing suicidal ideation will be implemented for all staff members involved in recruitment or assessments. Staff trained to handle suicidality and crisis situations will be present on-site. AEs and SAEs will be monitored and documented at each assessment. In the event of any AEs or SAEs, the principal investigator and DMC will be promptly notified using a standardised case-report form. A joint decision will then be made between the study centre and the DMC regarding the appropriate response. In case of emergency,

the participant's healthcare professional contact will be informed. Documented AEs and SAEs will be analysed and included in study outcome reports. Information about emergency hotlines and professional support will be provided to participants in both groups (IG and CG). IG participants will have access to emergency information through an online emergency kit included in the intervention, while CG participants will receive the same emergency information as part of the online bibliotherapy.

Auditing

Data auditing will be conducted through reviews of data collected at BL and during FU assessments. The auditing process will be carried out by external statisticians, who are independent of the investigators and staff involved in the study. Auditing will involve the examination of 5% of the questionnaires at each assessment point. The selected questionnaires will be randomly chosen and reviewed for consistency with the corresponding database entries.

ETHICS AND DISSEMINATION

Ethics approval

This study will adhere to the *Guidelines for ICH-GCP*, the *Declaration of Helsinki*, as well as applicable international and local regulations. Approval for this study was granted on 23 April 2025 by the ethics committee of the *University of Leipzig* (ID: 140/25-ek). All participants will provide informed consent prior to participation in the study. The ethics committee of the *University of Leipzig* will be notified of any major revisions to the trial protocol, including changes to the intervention plan, inclusion or exclusion criteria, outcome measures and adjustments to the sample size. Following approval, these modifications will be updated in the *German Clinical Trials Register* (https://www.drks.de/search/de/trial/DRKS00036178).

Dissemination

First, research findings of this study will be disseminated in peer-reviewed journals and presented at national and international conferences. Second, in case of a successful evaluation, the internet-based self-help intervention Fit4Mood will be provided as freeware, which will be easily accessible and free of charge. Dissemination strategies will be developed by involving representatives of the target group and healthcare experts and include information of relevant stakeholders (scientists, healthcare providers, self-help groups, etc) by providing information material (print and digital), for example, via forums, social media, postal mailings, newsletters, workshops, lectures and talks.

DISCUSSION

This RCT aims to evaluate the effectiveness of an internet-based self-help intervention compared with an online bibliotherapy on the primary outcome of depressive symptoms and secondary outcomes (eg, perceived health, anxiety, activities and stress) in a sample of adults ≥18 years with obesity (BMI ≥30 kg/m^2) and at least mild depressive symptoms (PHQ-8 ≥5). This study will add important results from a high-quality, adequately powered trial of a newly developed intervention in an area with limited prior evidence.[77] It will also examine acceptability, such as satisfaction with the intervention and adherence, to further refine the intervention. This approach is particularly important as the market for internet-based interventions, including self-management programmes, is rapidly expanding, but many of these solutions lack sufficient validation to ensure their effectiveness and reliability.

The intervention aims to improve mental well-being in a high-risk group for impaired mental health. It was developed by experienced mental health professionals, involving individuals with obesity and healthcare providers. The intervention is appropriately tailored to the needs of the target group by taking into account its specific needs and requirements: for example, in terms of imagery, content (eg, topics such as healthy eating, exercise therapy, negative body image, weight stigma, emotional eating and guideline-based treatment options for obesity), and technical features that allow users to enlarge the text, to increase contrast and to listen to text rather than read it. Additionally, six example characters with varying degrees of obesity are included for users to identify and relate to.

We anticipate that users of the internet-based intervention will improve their mental health and experience a reduction in depressive symptoms and other mental health-related outcomes (eg, quality of life, anxiety, self-efficacy, stress, sleep disturbances) to a greater extent than users of an online bibliotherapy. The intervention further aims at increasing readiness for weight loss and mental health literacy by raising knowledge with psychoeducation, introducing self-help strategies and supporting the application of new learnt self-management skills to everyday life. We also anticipate that users of the internet-based intervention will find it acceptable in terms of user satisfaction and adherence.

Limitations

A few limitations need to be taken into consideration. First, as with all unguided internet-based interventions, attrition needs to be taken into account.[137] To increase adherence,[138] the internet-based intervention uses adherence-enhancing features such as design elements (eg, the mascot 'Cloudy' that accompanies users), read-aloud function and options for adjusting the display to accommodate visual impairments. It allows highly flexible use in order and time to personalise utilisation and creates a sense of social connectedness facilitated by the intervention (eg, through example characters to identify with). Also, the use of the internet-based intervention will increase knowledge and insight into mental health and the feeling of being in control of one's own health.[138] The target group has been involved in the development process to ensure that the internet-based intervention is optimally tailored to their needs.[81]

Second, within our current study design, we will only conduct one FU assessment 4 months after BL assessment. Therefore, we will not be able to follow the long-term effects of the intervention. There is evidence that the superior effect of guidance diminishes 6–12 months after randomisation

and that unguided programmes may be as effective as guided programmes.[57 139] However, if other research funds are available at the given time, a long-term follow-up may be added to contribute to knowledge on the stability of effects.

Third, assessing the primary outcome of depressive symptoms based solely on self-report using the widely used instrument BDI-II may not accurately reflect clinical change, particularly in populations with somatic comorbidities. Future study designs could include additional assessments, such as clinician evaluations or diagnostic interviews. However, the BDI-II is a well-validated instrument widely used in clinical trials, including RCTs of digital mental health programmes.[140–142]

Strengths

There are also several strengths of this study. First, according to our knowledge, @ktivPLUS is the first study to evaluate the effectiveness of an unguided German internet-based intervention aiming at improving mental health in adults with obesity using a high-quality study design (RCT). Therefore, the study may add valuable insight to our knowledge of the effectiveness of mental health interventions in the target group of people with obesity.

Second, a key strength of this study lies in its tailored approach for adults with obesity, a group often underrecognised when it comes to customised internet-based mental health interventions. Another notable strength is the study's use of block randomisation, a method that ensures balanced sample sizes between IG and CG, while minimising imbalances in covariates across the groups.

Finally, several aspects of the study will increase internal validity: CG participants will complete the same self-report measures as IG participants at BL and FU (with acceptance and adherence items adapted to the group condition), an active CG design will be used, and the recruitment strategy will cover all areas in Germany as well as different settings and strategies (including primary care and all relevant healthcare and support sectors as well as self-help and peer support groups and social media).

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