Received: 14 March 2023 | Revised: 23 October 2023 | Accepted: 24 October 2023

DOI: 10.1002/erv.3047

WILEY

RESEARCH ARTICLE

Efficacy of a therapist-guided smartphone-based intervention to support recovery from bulimia nervosa: Study protocol of a randomized controlled multi-centre trial

Sandra Schlegl[1] | **Julia Maier**[1] | **Anna Dieffenbacher**[1] | **Ulrich Voderholzer**[1,2,3]

[1]Department of Psychiatry and Psychotherapy (LMU), University Hospital of Munich (LMU), Munich, Germany

[2]Department of Psychiatry and Psychotherapy, University Hospital of Freiburg, Freiburg, Germany

[3]Schoen Clinic Roseneck, Prien am Chiemsee, Germany

Correspondence
Sandra Schlegl, Department of Psychiatry and Psychotherapy, University Hospital of Munich (LMU), Nussbaumstrasse 7, Muenchen 80336, Germany.
Email: sandra.schlegl@med.uni-muenchen.de

Handling Editor: Daniel, Le Grange

Funding information
Else Kröner-Fresenius-Stiftung

Abstract

Objective: Although inpatient treatment is highly effective for patients with bulimia nervosa (BN), some patients show a resurgence of symptoms and relapse after discharge. Therefore, the aim of this study is to evaluate the efficacy of a guided smartphone-based aftercare intervention following inpatient treatment to support recovery.

Method: 172 female patients with BN (DSM-5: 307.51) will be randomized to receive a 16-week smartphone-based aftercare intervention (German version of 'Recovery Record') with therapist feedback as an add-on element to treatment as usual (TAU) or TAU alone. Assessments will take place at baseline (discharge, T0), during the intervention (after 4 weeks, T1), post-intervention (after 16 weeks, T2) and at 6-month follow-up (T3). Primary outcome will be remission at T2. Moderator and mediator analyses will investigate for whom the aftercare intervention suits best and how it works.

Conclusions: This is the first randomized controlled trial to examine a guided smartphone-based aftercare intervention following inpatient treatment of patients with BN. We expect that this innovative aftercare intervention is highly accepted by the patients and that it has the potential to support recovery after inpatient treatment and thereby could contribute to improving aftercare for patients with BN.

KEYWORDS
aftercare, bulimia nervosa, inpatient, multi-centre, randomized controlled trial, smartphone

Highlights

- There are several studies reporting relapse rates for patients with bulimia nervosa (BN) after having received remission or abstinence at the end of treatment.

- This is the first randomized controlled trial (RCT) to investigate the effects of a guided smartphone-based aftercare following inpatient treatment of patients with BN.
- If this innovative aftercare intervention is accepted by the patients and supports recovery after inpatient treatment for patients with BN, it could contribute to improving aftercare for patients with BN.

1 | INTRODUCTION

Bulimia nervosa (BN) is a severe mental disorder with a lifetime prevalence up to 3% of females (Twisk et al., 2013; van Eeden, van Hoeken, & Hoek, 2021). It goes along with a high risk of chronification and increased mortality (Arcelus et al., 2011; Steinhausen & Weber, 2009; van Eeden et al., 2021). Core symptoms are recurrent episodes of binge eating and repetitive inappropriate compensatory behaviours to prevent weight gain. Furthermore, patients with BN overvalue body shape and weight. To target these symptoms, cognitive behavioural therapy (CBT) is currently the most recommended and evidence-based treatment (APA, 2023; Herpertz et al., 2018; Kaidesoja et al., 2023; Monteleone et al., 2022; NICE, 2020).

However, even if treatment is successful in reducing behaviours such as binge eating and purging, abstinence rates may remain low (Hay et al., 2014) and even if remission or abstinence have been received after treatment relapse rates are substantial. There are several studies reporting relapse rates of 28%–46% for patients with BN after having received remission or abstinence at the end of treatment (Halmi et al., 2002; Mitchell et al., 2004; Olmsted et al., 2005; Wilson et al., 2002).

Inpatient treatment for patients with BN may be considered if they (1) are severely disturbed regarding eating and compensatory behaviour, (2) are non-responding to previous outpatient treatment, (3) are suffering from severe comorbid conditions, and (4) live in a treatment impeding environment (Herpertz et al., 2018).

A study on the effectiveness of CBT-based inpatient treatment in adult patients with BN showed a responder rate regarding EDI-2 (Eating Disorder Inventory-2) global score (defined as reliable change according to the criteria of Jacobson et al., 1984) of 77% (Diedrich et al., 2018). A further study of Zeeck et al. (2009) showed that although 81% of inpatients no longer fulfiled diagnostic criteria of BN at discharge, at 3-month-follow-up 48% were again symptomatic. Three years after discharge, 36% met all BN criteria (Zeeck et al., 2011). In both studies of Zeeck et al., the small number of cases ($N = 17$ and $N = 14$ respectively) must be taken into account.

For the difficulties in maintaining achieved treatment success when returning to the home environment, several reasons can be hypothesised: (1) renewed confrontation with everyday stressors after discharge increases the risk for (re)lapse (2) excessive demands due to a rapid reduction of therapeutic contacts from daily in the inpatient setting to once a week in the outpatient setting (3) insufficient continuation of inpatient therapy content in the outpatient setting or inadequate transfer to everyday requirements (4) lack of specialised outpatient eating disorder (ED) treatment, especially in rural areas. A new and exciting opportunity to bridge this gap might be the use of technology-based interventions (TBIs). TBIs are gaining broad interest in the treatment of EDs (Ahmadiankalati et al., 2020; Anastasiadou et al., 2018; Fairburn & Murphy, 2015; Hay & Claudino, 2015; J. Linardon et al., 2020; Schlegl et al., 2015).

The use of TBIs in aftercare might be accompanied by several advantages: low-threshold and easy access, local independence, slight integration into everyday life, asynchronous communication (with lag between contacts, such as email, postings on a secure website, and text messaging).

So far, four studies evaluating TBIs in the context of aftercare in patients with BN were conducted, two evaluating a mobile, SMS-based aftercare (Bauer et al., 2012; Robinson et al., 2006) and two examining an internet-based aftercare (Gulec et al., 2014; Jacobi et al., 2017). Taken together, the studies showed preliminary evidence for efficacy regarding the potential of TBIs in aftercare for patients with BN.

The latest trend amongst TBIs for EDs are smartphone-based interventions (Fairburn & Rothwell, 2015; Juarascio et al., 2015; O'Leary & Torous, 2022; Wasil et al., 2021).

Although there are at least 65 different apps for EDs (O'Leary & Torous, 2022), only four apps accounted for 96% of all monthly active users (Wasil et al., 2021). Furthermore, most research focused on only four apps (O'Leary & Torous, 2022).

The latest RCT investigated the effectiveness of a 4-week transdiagnostic cognitive-behavioural intervention for EDs using a smartphone app 'Break Binge Eating' (Linardon et al., 2022). Although at baseline 67% of the total sample ($N = 392$) did not have a diagnosed ED, 73% showed ED symptoms (Linardon et al., 2022). In the global ED symptomatology, the posttest showed a significantly greater reduction in the intervention group

(IG) than in the waitlist control group (CG) (strong effect), and medium effect sizes were found for the subscales of the Eating Disorder Examination-Questionnaire (EDE-Q) and objective binge episodes (Linardon et al., 2022). Hildebrandt et al. (2020) compared a smartphone-guided self-help with standard care for adults with binge eating ($N = 225$). Individuals who received the app 'Noom' for 12 weeks reported significant reductions in objective days of binge-eating (strong effect) and achieved higher remission rates (small effect) (Hildebrandt et al., 2020). Furthermore, in a multicentre RCT ($N = 106$) the IG received a mobile app intervention 'TC App' as an add-on to standard face-to-face CBT for a duration of 4 weeks (Anastasiadou et al., 2020). Patients in both groups showed improvements in EDE-Q total and subscale scores, but the differences between groups were not significant (Anastasiadou et al., 2020).

A recent review on internet- and mobile-based aftercare and relapse prevention in mental disorders (Hennemann et al., 2018) concludes that there is some evidence that such interventions are feasible instruments for maintaining treatment gains for some mental disorders, including EDs.

There is one pilot RCT evaluating the app 'Recovery Record' (RR) in the context of aftercare in inpatients with anorexia nervosa (AN) ($N = 40$) (Neumayr et al., 2019) suggesting that such an intervention is highly accepted by patients and that it could support symptom stabilisation or continued improvement which is currently also investigated in an RCT (Schlegl et al., 2020).

However, so far, there is no study investigating RR in a clinical sample of patients with BN and there is no study in general evaluating a smartphone-based aftercare intervention for patients with BN.

RCTs should not only evaluate the efficacy of an intervention, but should also include moderator and mediator analyses (Kraemer et al., 2002) to investigate for whom and how an intervention works. Since there is no evidence regarding moderators and mediators in smartphone-based studies in patients with BN or EDs and since there is scarce and mixed evidence regarding moderators and mediators in studies in patients with BN or EDs in general, we plan exploratory analyses. We will consider mainly variables previously reported by Linardon et al. (2017), Jacobi et al. (2017) as well as Wilson et al. (2002).

Linardon et al. (2017) did the most comprehensive review on predictors, moderators and mediators of treatment outcome for EDs. The authors did not identify any moderator for treatment outcome in BN, also most predictors were unrelated to outcome. Regarding mediators, they found that early behavioural and cognitive symptom change was associated with better behavioural and cognitive outcomes. Furthermore, reducing dietary restraint led to better behavioural outcomes. Jacobi et al. (2017) evaluated moderators for abstinence in a web-based aftercare RCT for women with BN and considered several possible moderators for abstinence from binge eating and compensatory behaviours. However, only abstinence from binge eating and compensatory behaviours at hospital discharge was identified as moderator. Wilson, 2002 examined possible mediators of change of CBT for BN. They found reduction in dietary restraint as well as self-efficacy (concerning eating behaviour, negative affect, and body shape and weight) as mediators of treatment outcome whereas therapeutic alliance did not mediate it.

1.1 | Aim and hypotheses

The aim of this study is to investigate the efficacy of a guided smartphone-based aftercare intervention as an add-on element to treatment as usual (TAU) (usually once a week outpatient psychotherapy, weekly weight checks with a primary care physician, if necessary occasional psychiatric appointments) compared to TAU alone in former inpatients with BN. Data will be collected at discharge (T0), after 4 weeks (T1), at the end of the intervention (T2) and at 6-month follow-up (T3).

Primary question: Does additional participation in a guided smartphone-based aftercare intervention result in a significantly higher remission rate at the end of the aftercare intervention (T2) compared to TAU?

Primary hypothesis: At T2, the IG shows a significantly higher remission rate than TAU.

Secondary questions: Does additional participation in a guided smartphone-based aftercare intervention result in a significantly higher remission rate at T3, a higher abstinence rate at T2 and T3, lower overall ED symptomatology, a lower frequency of binge eating and purging, lower depressive symptoms, higher levels of self-efficacy and a higher stage of change at T2 and T3 as well as a lower relapse and rehospitalisation rate at T2 and T3 compared to TAU? How well is the smartphone-based aftercare intervention accepted by patients with BN?

Furthermore, exploratory moderator and mediator analyses are planned to investigate for whom the aftercare intervention is best suited and how it works.

2 | METHOD

Ethics approval from University Hospital of Munich (LMU) has been obtained. Furthermore, the trial was registered at https://clinicaltrials.gov (NCT05728021).

2.1 | Study design

A prospective multi-centre RCT with two parallel arms will examine the efficacy of a guided smartphone-based aftercare intervention following inpatient treatment of patients with BN. $N = 172$ consecutive patients will be recruited at 4 centres, which all provide CBT-based inpatient treatment based on the same best practice guidelines for the treatment of EDs (internal document). One week before discharge, the recruitment, screening, and information of patients about the study will be carried out. Patients will receive a detailed information on the study and give written informed consent to participate. For minors, an additional briefing of their legal guardians will be provided via telephone. Following that, informed consent forms will be sent out to the legal guardians and will have to be signed and returned. After informed written consent was given, patients will be randomized by an independent researcher who is not involved in the recruiting nor data collection either to the IG or the CG. We will use block randomisation with computer-generated randomly varying block sizes (2, 4, or 8), stratified by type of study centre (due to partially existing differences in the therapeutic offer) and age group (minor vs. adults) (to promote equal distribution of variables such as length of illness, education level, etc.). Randomisation will be performed at a 1:1 ratio to the following two study conditions:

1) Intervention group (IG): patients randomized to IG receive a therapist-guided smartphone-based aftercare intervention for a period of 16 weeks. Our intervention duration was set based on research findings that remission becomes more likely if symptom improvement or abstinence could be maintained for 16 weeks (Kordy et al., 2002). The patients are invited to download the German version of RR at the App Store (iPhone) or the Google Play Store (android) to their smartphone for free and to link with the aftercare therapist. After discharge, patients are asked to monitor their meals at least three times per day (breakfast, lunch, and dinner), that is, to produce a minimum of three logs per day over the subsequent 16 weeks. Furthermore, patients are instructed to monitor their thoughts and feelings as well as their (eating disordered) behaviours. The aftercare therapist also sets the patients clinical post-discharge goals and makes coping skill suggestions. Individual therapist feedback is provided in-app twice per week during the first 4 weeks, once per week in weeks 5-8 and every other week in weeks 9–16.
2) Control group (CG): patients randomized to CG receive TAU that is, patients and their physicians or therapists decide on post-discharge treatment which is documented at T2 and T3. In Germany TAU usually consists of once a week outpatient psychotherapy, weekly weight checks with a primary care physician and if necessary, occasional psychiatric appointments. Patients from the CG are also assessed at all assessment points.

Assessment points are as follows: at hospital discharge (=baseline, T0), after 4 weeks (=during the intervention, T1), after 16 weeks (=end of the aftercare intervention, T2) and after 10 months (=6-month follow-up, T3). At all assessment points, a trained assessor blinded to patients' group assignment will conduct structured interviews to assess ED symptomatology. The interview at T0 will be face-to-face whereas interviews at T2 and T3 will be conducted via telephone since the clinics treat patients from all over Germany. Furthermore, the patients will fill out online questionnaires (via the portal Unipark) at all four assessment points. Patients will receive a compensation of 40 EUR at T2 and 35 EUR at T3. Figure 1 illustrates the study design of the RCT ($N = 172$).

The research assistants responsible for recruiting and data collection including conducting the structured interviews will be blind. As usual in psychotherapy trials, it will not be possible to blind patients and therapists (Munder & Barth, 2018). Aftercare therapists will be licenced psychotherapists highly experienced in the treatment of EDs and they will be trained using RR in general (manual available) and especially in the context of aftercare. Furthermore, they will receive a monthly supervision by a licenced senior therapist during the whole trial.

2.2 | Study participants

A total of $N = 172$ patients with BN will be randomized.

Patients will be eligible if they meet the following inclusion criteria:

1) primary diagnosis of BN (DSM-5: 307.51) at admission as assessed by the diagnostically relevant items from the Eating Disorder Examination (EDE) (Hilbert & Tuschen-Caffier, 2016b),
2) sex: female,
3) age: from 13 years onwards to 60 years,
4) regular completion of inpatient treatment,
5) at least a length of inpatient stay of 6 weeks,
6) remission at discharge, defined as less than once a week of binge eating and compensatory behaviour in the past 28 days thus no longer meeting the full criteria for BN according to DSM-5,

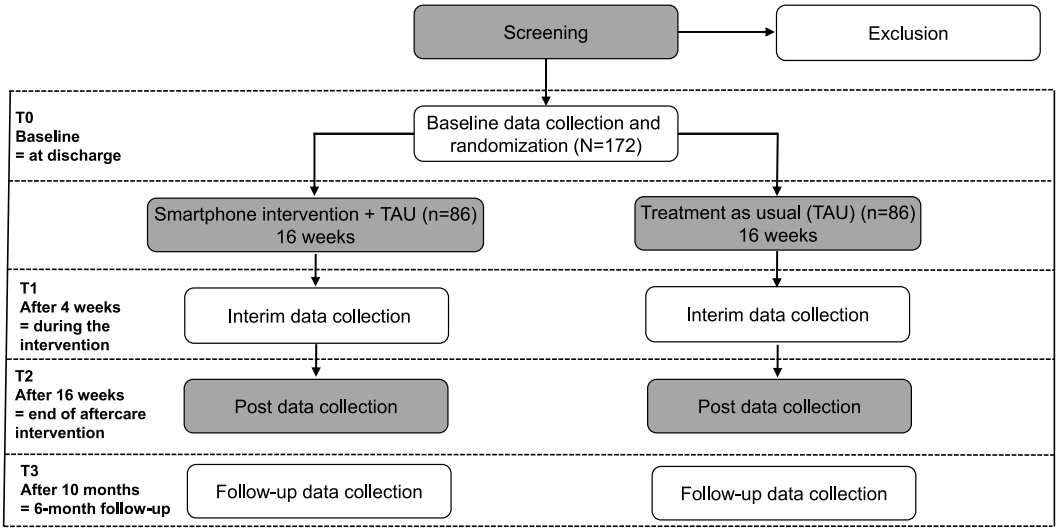

FIGURE 1 Study design of the main assessment timepoints of the randomized controlled trial ($N = 172$).

7) owner of a smartphone,
8) informed consent of the patient and, in case of minors, also of the parents.

Exclusion criteria are:

1) major depression (Beck Depression Inventory-II > 29 at discharge),
2) suicidal tendency (item 9 of BDI-II > 1 at discharge),
3) very high level of care after inpatient treatment (e.g., therapeutic living community, day clinic),
4) pregnancy.

Other psychiatric conditions such as drug/alcohol/medication abuse, acute suicidal tendencies, psychotic symptoms or a severe life-threatening somatic disorder are in general exclusion criteria for being treated in our clinic.

2.3 | Intervention

2.3.1 | Smartphone app RR

RR is an innovate smartphone app for EDs that enables linking of patients and clinicians. It comes in one version for patients and in another for therapists. It is available for Android and iOS. For therapists, there is also a web version. It includes content of evidence-based interventions such as elements of CBT, dialectical-behavioural therapy, acceptance and commitment therapy as well as motivational enhancement therapy.

The patient's app consists mainly of the following elements: self-monitoring of ED behaviours, thoughts, and feelings, positive reinforcement, meal planner, setting and tracking of individual goals, reminders, coping strategies, motivational slogans, positive affirmations, guided meditations, monthly in-app outcome questionnaires, and the ability to link with a clinician.

The functions of the therapist's app are access to all data logged by their patients and to graphical representations of their patients' data as well as secure in-app patient messaging. More detailed information on structure, features, and functions of RR can be found elsewhere (Tregarthen et al., 2015).

2.3.2 | Rationale for using RR as an aftercare tool

The basic RR app does not include specific features for aftercare. However, RR comprises several features that we assume as central elements for an aftercare intervention:

1) Self-monitoring: Self-monitoring is one of the core aspects of state of-the-art ED therapy (Fairburn, 2008) and relapse prevention in EDs (Legenbauer & Vocks, 2017). Self-monitoring can be used in aftercare with the aim to stabilise remission and to detect triggers as well as early (warning) signs of relapse (increase of ED thoughts, urges, or symptomatic behaviour). From our point of view, the transfer of a strict and sufficient meal structure to patients' everyday life is one of the most important post-discharge goals, as patients tend to lose their established meal routines after discharge from inpatient treatment and a regular, adequate meal structure prevents binge-eating and subsequent compensatory behaviour. Wilson et al. (2002) identified reduction in

dietary restraint as mediator of posttreatment improvement in both binge eating and vomiting. Continuing to adhere to a protocol regarding their food intake on a daily basis might help them to stay on track. Since RR includes these protocols and enquires for urges as well as disordered behaviour, both patients and therapists can detect early warning signs of relapse more easily. These features allow for timely intervention in the context of relapse prevention.

2) Thoughts and feelings: Besides food intake, a further core aspect of self-monitoring relates to thoughts and feelings (Fairburn, 2008). According to CBT, EDs are always associated with dysfunctional thoughts and feelings such as overvaluation of shape and weight as well as fear of gaining weight (Fairburn, 2008). These thoughts and feelings are addressed by creating functional analyses in the patients' everyday life. To that end, patients are asked to monitor shape and weight concerns, fears regarding meals, as well as other thoughts and feelings with RR. Reduced shape and weight concerns are supposed to decrease the pressure to diet which is the proximal cause of binge-eating (Wilson et al., 2002).
3) Personalised coping strategies and individual goals: Possessing coping strategies for maintaining meal structure and meal sizes, for risk situations, for maintaining remission, as well as for dealing with dysfunctional thoughts and feelings is important for relapse prevention. It is supposed that changes in self-efficacy for coping with situations that trigger binge-eating and purging is associated with decreases in binge-eating and purging (Wilson et al., 2002). Furthermore, concrete individual postdischarge goals might help patients in the transition phase from clinic to home. We defined a selection of coping strategies and clinical goals for each of the 16 weeks (n = 3–4 strategies/goals per week) of our aftercare intervention, which were partly chosen from the already existing ones and assumed to be most appropriate in the aftercare context for patients with BN.
4) Linking with a clinician/aftercare therapist: From our point of view, guidance from a therapist from the clinic might be an optimal way to transfer treatment goals that were achieved during inpatient treatment from the clinic to home.

2.4 | Privacy and security of RR

The system complies with the requirements of the 'Privacy Rule' as defined by the 'Health Insurance Portability and Accountability Act' (HIPAA) of 1996 and the 'Health Information Technology for Economic and Clinical Health Act' (HITECH Act). Several steps are taken to ensure that patient data is treated securely and in accordance with these legal and ethical standards. Data is encrypted in transit (TLS) and encrypted at rest (AES), and the database is password-protected, regularly backed up and maintained on a secure server, located in Frankfurt, Germany to strictly comply with European privacy policy including the EU General Data Protection Regulation and the EU-US Privacy Shield. Only RR Inc. has access to the data.

2.5 | Outcome measures

2.5.1 | Primary outcome measure

Eating Disorder Examination (EDE)

We will use the EDE to assess remission status. The EDE (Hilbert & Tuschen-Caffier, 2016b) is a semi-structured interview to assess ED cognitions and behaviours experienced during the previous 28 days and consists of 40 items. 21 items build the 4 subscales (Restraint, Eating Concern, Weight Concern, and Shape Concern) and a Global Score.

2.5.2 | Secondary outcome measures

Eating Eisorder Examination-Questionnaire (EDE-Q)

The EDE-Q (Hilbert & Tuschen-Caffier, 2016a) is the self-rating version of the EDE (Hilbert & Tuschen-Caffier, 2016b). It consists of 28 items, 4 scales (Restraint, Eating Concern, Weight Concern, and Shape Concern) and a Global Score.

Eating Disorder Inventory-2 (EDI-2)

The EDI-2 (Garner, 1991) was used for the multidimensional assessment of the specific psychopathology of patients with BN. It consists of 11 scales with 91 items that can be answered on a 6-point scale from 1 (never) to 6 (always).

Body-mass-index (BMI)

BMI at admission and at discharge will be measured by a nurse, BMI at follow-up by self-report.

Beck Depression Inventory-II (BDI-II)

The BDI-II (Hautzinger et al., 2009) is a self-rating instrument to assess the severity of depressive symptoms. The 21 items can be rated in terms of their occurrence and intensity during the last 2 weeks.

Stages of Change Questionnaire for Eating Disorders (SOCQ-ED)

The SOCQ-ED (von Brachel et al., 2012) is a self-rating instrument assessing 6 stages of change

(Precontemplation, Contemplation, Preparation, Action, Maintenance, Termination) with regard to 13 ED behaviours.

General Self-efficacy Scale (GSE)

The GSE (Schwarzer & Jerusalem, 1999) consists of 10 items and assesses optimistic self-beliefs to cope with a variety of difficult demands in life.

Measures of self-efficacy concerning eating behaviour, negative affect, and body shape and weight

Following Wilson et al. (2002), a self-efficacy (SE) scale is used which provides measures of patients' confidence about resisting binge eating (a) in response to food cues and eating situations (SE–E), (b) when experiencing negative affect (SE–NA), (c) in response to shape and weight cues (SE–SW), and (d) in response to interpersonal situations (SE–I).

Helping Alliance Questionnaire (HAQ)

The HAQ (Bassler et al., 1995) is a self-rating instrument to evaluate the therapeutic process and comprises the two subscales 'relationship satisfaction' and 'satisfaction with therapeutic outcome'. The questionnaire consists of 12 questions about the therapeutic relationship and process variables, which can be answered by both the patient and the therapist.

Ratings of suitability of treatment and expectancy of treatment outcome

Ten-point visual analogue scales after 4 weeks will assess patients' perceptions of the suitability of the aftercare intervention and their expectations that they would maintain their remission status.

Acceptability of the smartphone app and the intervention (only at T2)

By using a self-developed questionnaire, we will assess design and user-friendliness of the app, overall acceptability, satisfaction and perceived helpfulness of the app, and of individual elements of the app as well as the acceptability of the app as an aftercare tool following inpatient treatment. Furthermore, satisfaction of patients with the therapist's feedback (content, frequency), with the duration of a 16-week aftercare intervention and with spending time using the app will be also evaluated.

Health care utilization after discharge (at T2 and T3)

Patients will be asked if they received outpatient treatment since discharge and if so, how many sessions they attended, when the first appointment with the potential outpatient therapist after discharge was, if they had had another inpatient (rehospitalisation) or day clinic admission since discharge, and if they used any additional health services (e.g., support groups).

Adherence to the smartphone-based aftercare intervention (measured from T0 to T2)

Adherence will be measured via dichotomous outcome of drop-out (individuals will be considered as drop-out if they fail to login to the app at all for a period of 14 consecutive days). Adherence will be assessed through application usage data.

Adherence to self-monitoring tasks (measured from T0 to T2)

Frequency of self-monitoring entries will be tracked automatically through the programme server.

Sociodemographic and clinical variables

Patients' socio-demographic data and clinical variables, such as illness duration and previous treatments, will be available from each patient's clinical record.

App usage

The tracking system Flurry Analytics will be used to track the patient's app usage behaviour. A log will be defined as the active and 'purposeful' usage of RR accompanied by an active entry. An active entry will be defined as logging a meal or photos, urges and disordered behaviours, using clinical goals or coping skills as well as interactions between the patient and the aftercare therapist.

Table 1 provides the schedule for enrolment, interventions and assessments according to SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement (Chan et al., 2013).

2.6 | (Serious) adverse events

The initial reporting of adverse events (serious or non-serious and related to research treatment or not) will take place with the study staff immediately notifying the Principal Investigator (PI). The PI will then decide whether the event is of such a severity that requires discontinuation of treatment, and whether the participant should remain in the study or be withdrawn. As serious events (SEAs) will be especially considered death and a life-threatening event. In the case of a SAE, we will report it to the ethics committee within 24 h of occurrence of the SAE.

TABLE 1 Schedule for enrolment, interventions, and assessments.

		STUDY PERIOD			
	Enrolment	**Baseline/Allocation**	***Intervention Period***		**Follow-up**
TIMEPOINT	***-T1***	**T0**	***T1***	***T2***	***T3***
ENROLMENT:					
Eligibility screening	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
Therapist-guided smartphone-based aftercare intervention + TAU		♦———	———	———♦	
TAU		♦———	———	———♦	
ASSESSMENTS:					
Sociodemographic and clinical variables		X			
EDE		X		X	X
EDE-Q		X	X	X	X
EDI-2		X		X	X
BMI		X		X	X
BDI-II		X		X	X
SOCQ-ED		X		X	X
GSE		X	X		
ED self-efficacy		X	X		
HAQ*			X	X	
Rating of suitability of treatment*			X		
Rating of expectancy of treatment outcome*			X		
Adherence		♦———	———	———♦	
Acceptability*				X	
Usage data*		♦———	———	———♦	
Health care utilization				X	X

Abbreviations: *, intervention group only; BDI-II, Beck Depression Inventory-II; BMI, Body Mass Index; ED self-efficacy, Measures of self-efficacy concerning eating behaviour, negative affect, and body shape and weight; EDE, Eating Disorder Examination; EDE-Q, Eating Disorder Examination-Questionnaire; EDI-2, Eating Disorder Inventory-2; GSE, General Self-Efficacy Scale; HAQ, Helping Alliance Questionnaire; SOCQ-ED, Stages of Change Questionnaire for Eating Disorders; TAU, Treatment as usual.

2.7 | Data analyses

2.7.1 | Sample size calculation

The sample size calculation was based on previous studies that found that 54%–63% of patients who were abstinent at the end of treatment were still in remission at 16-week follow-up (Halmi et al., 2002; Olmsted et al., 2005; Wilson et al., 2002) in day clinic or outpatient settings. For our inpatients we assume a somewhat lower remission rate of 50%. Furthermore, we consider a difference of 25% in remission rates between groups as clinically relevant. This difference is somewhat higher than the expected difference in previous studies (Bauer et al., 2012; Jacobi et al., 2017), but due to the intensive therapist guidance we expect a higher difference in remission rates. The α-level was set to 5% (two-tailed) and the power (1—type II error) was set to 0.8. Using Fisher's exact test, a sample size of $n = 64$ patients per treatment arm is required, resulting in a total sample size of $N = 2 \times 64 = 128$. Assuming a non-compliance and loss to follow-up rate of 25% (Neumayr et al., 2019), in total a minimum of $N = 172$ patients have to be included in the study. Sample size estimation was calculated with G × Power (version 3.1.9.2) (Faul et al., 2007).

2.7.2 | Statistical analyses

Primary outcome

Remission at T2 as defined by less than once a week of binge eating and compensatory behaviour in the past 28 days thus no longer meeting the full criteria for BN according to DSM-5.

Secondary outcomes

Secondary outcomes are as follows:

- Remission at T3,
- Abstinence at T2 and T3 as defined by no binge eating or purging over the previous 28 days,
- Abstinence at T2 and T3 as defined by no binge eating or purging over the previous 28 days & Global EDE score <1 SD above community mean
- Changes in frequency of objective binge eating episodes, frequency of vomiting episodes, frequency of episodes of all compensatory behaviour, in EDE global score and subscales, in EDE-Q global score and subscales, in BMI, in depressive symptoms, in stages of change, in general and ED specific self-efficacy from T0-T2 and T0-T3,
- Rehospitalisation rate at T2 and T3,
- Rate and time to relapse as defined by again meeting the full criteria for BN according to DSM-5,
- Acceptability of the intervention at T2 in the IG,
- Drop-out rates at T2 in the IG,
- Suitability of treatment at week 4 in the IG,
- Expectancy of treatment outcome at week 4 in the IG,
- Health care utilization at T2 and T3.

2.8 | Statistical analyses

For the analyses, IBM SPSS Statistics 26 as well as Stata 16 will be used.

To detect eventual differences at baseline and drop-out rate differences between both study groups, *t*-tests for independent groups will be carried out for metric variables and chi-squared-tests for categorical variables. In case of significant differences between study groups, we will conduct regression analyses to examine whether the respective variable contributed significantly to the prediction of the primary outcome measure to then include it as covariate.

2.8.1 | Primary outcome

Remission rates between IG and CG will be compared using Fisher's exact test and odds ratios with respective confidence intervals. Conservatively, we will define all participants of whom no data is available at T2 regarding remission as non-remitted. Thus, for the primary efficacy outcome, we will have no missing data. Primary outcome will also be analysed using per protocol (PP) analysis which will include all patients that have completed at least 12 of the 16 weeks of the aftercare intervention and who completed EDE interview at T2.

2.8.2 | Secondary outcomes

Secondary outcomes will be analysed using linear mixed effects models for repeated measures with restricted maximum likelihood estimation. This approach has gained broad support for intention-to-treat (ITT) analyses in longitudinal clinical trials (Andersen & Millen, 2013). We will not impute missing values, as it was shown that multiple imputation of missing repeated outcome measurements did not add to linear mixed-effects models and was not necessary (Peters et al., 2012; Twisk et al., 2013). We will test the model with different covariance structures and will use the one who provides the best fit. The model will be based on 3 assessment time points (baseline (T0), post-intervention (T2), 6-month follow-up after post-intervention (T3)). Only in case of significant overall treatment effects (overall treatment group × time

interaction), post-hoc contrasts will be calculated to specify these effects by testing group differences over time. We will calculate effect sizes by dividing the difference of the model-estimated marginal means by the pooled pretest standard deviation (Morris, 2008). Standard deviations will be derived from the standard errors of the estimated marginal means.

Besides, differences in time to relapse or rehospitalisation between the two groups will be estimated using a Kaplan-Meier-Plot, differences in cumulated prevention of rehospitalisation will be tested using a log rank test.

As sensitivity analyses, we will impute missing data using multiple imputations (Jakobsen et al., 2017). Furthermore, PP analyses will be performed to investigate the influence of drop-outs on study results.

2.8.3 | Moderator and mediator analyses

For exploratory moderator and mediator analyses, the MacArthur Framework will be incorporated in the longitudinal modelling framework (Kraemer et al., 2008; Kraemer et al., 2002).

As potential moderators will be considered age, severity of BN at discharge (EDE global score), dietary restraint, weight concerns, shape concerns, abstinence at discharge, BMI, depression score (Jacobi et al., 2017; Linardon et al., 2017; Wilson et al., 2002). Furthermore, the following variables will be evaluated as moderators: length of inpatient stay (Andersson et al., 2023) as well as stage of change (Antichi & Giannini, 2023).

As potential mediators will be considered change in ED symptomatology (EDE global score, dietary restraint, weight concerns, shape concerns), changes in self-efficacy concerning eating behaviour, negative affect, and body shape and weight, ratings of suitability of treatment, and expectancy of treatment outcome as well as therapeutic alliance (Jacobi et al., 2017; Linardon et al., 2016; Wilson et al., 2002). Finally, changes in general self-efficacy (Antichi & Giannini, 2023; Ebert et al., 2013) will be considered as further potential mediator.

All potential moderators will be assessed at T0, potential mediator variables at T1.

3 | DISCUSSION

This study will be the first RCT to examine a guided smartphone-based aftercare intervention following inpatient treatment of patients with BN. Our research project addresses one of the most important unmet needs regarding maintaining remission and abstinence rates in patients with BN after successful treatment and represents an innovative approach to aftercare following inpatient treatment. Smartphone-based aftercare interventions can be of great value when the patient has to make the transition from treatment learnt in therapy outside the therapeutic context to daily life and maintain or consolidate the skills. Findings from this trial may yield important scientific and clinical implications for improving longer-term treatment outcome for BN. We assume that a therapist-guided smartphone-based aftercare intervention for patients with BN will be an effective way to support recovery after inpatient treatment. The results may also reveal the relative efficacy of such an intervention for patients with BN versus patients with AN (Schlegl et al., 2020).

The long-term goal of the project is to significantly contribute to the maintenance of the therapeutic success and to minimise the risk of relapse following inpatient treatment of patients with BN by implementing a smartphone-based aftercare intervention in routine care. By proving its efficacy, health insurances may consider taking over the costs for such an intervention that may be cost-effective in the long-run.

Strengths of our study are the innovative treatment approach, the randomized controlled study design with a large sample size and a CG, structured interviews by blinded assessors at each timepoint, the therapist-guidance of the intervention, as well as a follow-up that allows tracking if results are sustained. Our results may be limited by the fact that they may be considered preliminary and will need replication and may not apply to BN patients in other countries and treatment settings. A further limitation of our study might be the mixed age sample: in general, adolescents might vary from adults in systematic ways in terms of their app usage and benefit from using the app. Furthermore, we only will include female patients. Finally, a further shortcoming is that we did not involve people with lived experience in the study design.

Future studies may want to further examine the efficacy of our intervention in other countries and treatment settings and validate the effects against different control conditions.

ACKNOWLEDGEMENTS

This research is funded by the Else Kröner-Fresenius-Stiftung.

Open Access funding enabled and organized by Projekt DEAL.

CONFLICT OF INTEREST STATEMENT

The authors declare no potential conflict of interest. The funder had no role in the design of the study; in the collection, analyses, or interpretation of data; in the

writing of the manuscript, or in the decision to publish the results.

DATA AVAILABILITY STATEMENT

This article describes a study protocol, and thus, no data are available for this study.

PATIENT CONSENT STATEMENT

Informed consent was obtained from all subjects involved in the study and their legal representatives (if patient <18 years).

CLINICAL TRIAL REGISTRATION

The trial was registered at https://clinicaltrials.gov (NCT05728021).

ORCID

Sandra Schlegl https://orcid.org/0000-0003-1791-7379
Ulrich Voderholzer https://orcid.org/0000-0003-0261-3145

REFERENCES

Ahmadiankalati, M., Steins-Loeber, S., & Paslakis, G. (2020). Review of randomized controlled trials using e-health interventions for patients with eating disorders. *Frontiers in Psychiatry*, *11*, 568. https://doi.org/10.3389/fpsyt.2020.00568

Anastasiadou, D., Folkvord, F., Brugnera, A., Canas Vinader, L., SerranoTroncoso, E., Carretero Jardi, C., Linares Bertolin, R., Muñoz Rodríguez, R., Martínez Nuñez, B., Torralbas-Ortega, J., Torrent-Solà, L., Puntí-Vidal, J., Carrera Ferrer, M., Muñoz Domenjó, A., Diaz Marsa, M., Gunnard, K., Cusido, J., Arcal Cunillera, J., Lupiañez-Villanueva, F., ..., & Graell Berna, M. (2020). An mHealth intervention for the treatment of patients with an eating disorder: A multicenter randomized controlled trial. *International Journal of Eating Disorders*, *53*(7), 1120–1131. https://doi.org/10.1002/eat.23286

Anastasiadou, D., Folkvord, F., & Lupiañez-Villanueva, F. (2018). A systematic review of mHealth interventions for the support of eating disorders. *European Eating Disorders Review*, *26*(5), 394–416. https://doi.org/10.1002/erv.2609

Andersen, S. W., & Millen, B. A. (2013). On the practical application of mixed effects models for repeated measures to clinical trial data. *Pharmaceutical Statistics*, *12*(1), 7–16. https://doi.org/10.1002/pst.1548

Andersson, P., Jamshidi, E., Ekman, C. J., Tedroff, K., Björkander, J., Sjögren, M., Lundberg, J., Jokinen, J., Desai Boström, A. E., & Desai Boström, A. E. (2023). Mapping length of inpatient treatment duration and year-wise relapse rates in eating disordered populations in a well-defined Western-European healthcare region across 1998–2020. *International Journal of Methods in Psychiatric Research*, e1960. https://doi.org/10.1002/mpr.1960

Antichi, L., & Giannini, M. (2023). An introduction to change in psychotherapy: Moderators, course of change, and change mechanisms. *Journal of Contemporary Psychotherapy: On the Cutting Edge of Modern Developments in Psychotherapy*, *53*(4), 315–323. https://doi.org/10.1007/s10879-023-09590-x

APA. (2023). *Practice guideline for the treatment of patients with eating disorders* (Vol. 4). American Psychiatric Association.

Arcelus, J., Mitchell, A. J., Wales, J., & Nielsen, S. (2011). Mortality rates in patients with anorexia nervosa and other eating disorders: A meta-analysis of 36 studies. *Archives of General Psychiatry*, *68*(7), 724–731. https://doi.org/10.1001/archgenpsychiatry.2011.74

Bassler, M., Potratz, B., & Krauthauser, H. (1995). Der 'Helping Alliance Questionnaire' (HAQ) von Luborsky: Möglichkeiten zur Evaluation des therapeutischen Prozesses von stationärer Psychotherapie. [The Helping Alliance Questionnaire (HAQ) by Luborsky: Possible evaluation of inpatient psychotherapy processes]. *Psychotherapeut*, *40*(1), 23–32.

Bauer, S., Okon, E., Meermann, R., & Kordy, H. (2012). Technology-enhanced maintenance of treatment gains in eating disorders: Efficacy of an intervention delivered via text messaging. *Journal of Consulting and Clinical Psychology*, *80*(4), 700–706. https://doi.org/10.1037/a0028030

Chan, A.-W., Tetzlaff, J. M., Altman, D. G., Laupacis, A., Gøtzsche, P. C., Krleža-Jerić, K., Hróbjartsson, A., Mann, H., Dickersin, K., Doré, C. J., Parulekar, W. R., Summerskill, W. S., Groves, T., Schulz, K. F., Sox, H. C., Rockhold, F. W., Rennie, D., Moher, D., & Berlin, J. A. (2013). SPIRIT 2013 statement: Defining standard protocol items for clinical trials. *Annals of Internal Medicine*, *158*(3), 200–207. https://doi.org/10.7326/0003-4819-158-3-201302050-00583

Diedrich, A., Schlegl, S., Greetfeld, M., Fumi, M., & Voderholzer, U. (2018). Intensive inpatient treatment for bulimia nervosa: Statistical and clinical significance of symptom changes. *Psychotherapy Research*, *28*(2), 297–312. Epub 2016 Jul 25.PMID: 27456048. https://doi.org/10.1080/10503307.2016.1210834

Ebert, D. D., Gollwitzer, M., Riper, H., Cuijpers, P., Baumeister, H., & Berking, M. (2013). For whom does it work? moderators of outcome on the effect of a transdiagnostic internet-based maintenance treatment after inpatient psychotherapy: Randomized controlled trial. *Journal of Medical Internet Research*, *15*(10), e191. https://doi.org/10.2196/jmir.2511. PMID: 24113764.

Fairburn, C. G. (2008). *Cognitive behavior therapy and eating disorders*. Guilford Publications.

Fairburn, C. G., & Murphy, R. (2015). Treating eating disorders using the internet. *Current Opinion in Psychiatry*, *28*(6), 461–467. https://doi.org/10.1097/yco.0000000000000195

Fairburn, C. G., & Rothwell, E. R. (2015). Apps and eating disorders: A systematic clinical appraisal. *International Journal of Eating Disorders*, *48*(7), 1038–1046. Epub 2015 Feb 27.PMID: 25728705. https://doi.org/10.1002/eat.22398

Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A. (2007). G-power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*, *39*(2), 175–191. https://doi.org/10.3758/bf03193146

Garner, D. M. (1991). *Eating disorder inventory-2: Professional manual*. Psychological Assessment Resources.

Gulec, H., Moessner, M., Tury, F., Fiedler, P., Mezei, A., & Bauer, S. (2014). A randomized controlled trial of an internet-based posttreatment care for patients with eating disorders.

Telemedicine Journal and e-Health, *20*(10), 916–922. https://doi.org/10.1089/tmj.2013.0353

Halmi, K. A., Agras, W. S., Mitchell, J., Wilson, G. T., Crow, S., Bryson, S. W., & Kraemer, H. (2002). Relapse predictors of patients with bulimia nervosa who achieved abstinence through cognitive behavioral therapy. *Archives of General Psychiatry*, *59*(12), 1105–1109. https://doi.org/10.1001/archpsyc.59.12.1105

Hautzinger, M., Keller, F., & Kühner, C. (2009). *BDI-II. Beck-Depressions-Inventar. Revision* (Vol. 2). Pearson Assessment.

Hay, P. J., Chinn, D., Forbes, D., Madden, S., Newton, R., Sugenor, L., Touyz, S., & Ward, W. (2014). Royal Australian and New Zealand College of Psychiatrists clinical practice guidelines for the treatment of eating disorders. *Australian and New Zealand Journal of Psychiatry*, *48*(11), 977–1008. https://doi.org/10.1177/0004867414555814

Hay, P. J., & Claudino, A. M. (2015). Bulimia nervosa: Online interventions. *BMJ Clinical Evidence*, 1009. PMID: 25735611.

Hennemann, S., Farnsteiner, S., & Sander, L. (2018). Internet- and mobile-based aftercare and relapse prevention in mental disorders: A systematic review and recommendations for future research. *Internet Interv*, *14*, 1–17. eCollection 2018 Dec. PMID: 30510909. https://doi.org/10.1016/j.invent.2018.09.001

Herpertz, S., Fichter, M., Herpertz-Dahlmann, B., Hilbert, A., Tuschen-Caffier, B., Vocks, S., & Zeeck, A. (2018). Gemeinsame S3-Leitlinie 'Diagnostik und Therapie der Essstörungen'. Available online: https://www.awmf.org/leitlinien/detail/ll/051-026.html

Hilbert, A., & Tuschen-Caffier, B. (2016a). *Eating disorder examination-questionnaire: German translation [article in German* (2 ed.). dgvt-Verlag.

Hilbert, A., & Tuschen-Caffier, B. (2016b). *Eating disorder examination: German translation [article in German* (2 ed.). dgvt-Verlag.

Hildebrandt, T., Michaeledes, A., Mayhew, M., Greif, R., Sysko, R., Toro-Ramos, T., & DeBar, L. (2020). Randomized controlled trial comparing health coach-delivered smartphone-guided self-help with standard care for adults with binge eating. *American Journal of Psychiatry*, *177*(2), 134–142. https://doi.org/10.1176/appi.ajp.2019.19020184

Jacobi, C., Beintner, I., Fittig, E., Trockel, M., Braks, K., Schade-Brittinger, C., & Dempfle, A. (2017). Web-based aftercare for women with bulimia nervosa following inpatient treatment: Randomized controlled efficacy trial. *Journal of Medical Internet Research*, *19*(9), e321. https://doi.org/10.2196/jmir.7668

Jacobson, N. S., Follette, W. C., & Revenstorf, D. (1984). Psychotherapy outcome research: Methods for reporting variability and evaluating clinical significance. *Behavior Therapy*, *15*(4), 336–352. https://doi.org/10.1016/s0005-7894(84)80002-7

Jakobsen, J. C., Gluud, C., Wetterslev, J., & Winkel, P. (2017). When and how should multiple imputation be used for handling missing data in randomised clinical trials—a practical guide with flowcharts. *BMC Medical Research Methodology*, *17*(1), 162. https://doi.org/10.1186/s12874-017-0442-1

Juarascio, A. S., Manasse, S. M., Goldstein, S. P., Forman, E. M., & Butryn, M. L. (2015). Review of smartphone applications for the treatment of eating disorders. *European Eating Disorders Review*, *23*(1), 1–11. Epub 2014 Oct 10 PMID: 25303148. https://doi.org/10.1002/erv.2327

Kaidesoja, M., Cooper, Z., & Fordham, B. (2023). Cognitive behavioral therapy for eating disorders: A map of the systematic review evidence base. *International Journal of Eating Disorders*, *56*(2), 295–313. Epub 2022 Oct 31. PMID: 36315392. https://doi.org/10.1002/eat.23831

Kordy, H., Krämer, B., Palmer, R. L., Papezova, H., Pellet, J., Richard, M., Treasure, J., & Cost Action B6 (2002). Remission, recovery, relapse, and recurrence in eating disorders: Conceptualization and illustration of a validation strategy. *Journal of Clinical Psychology*, *58*(7), 833–846. https://doi.org/10.1002/jclp.2013

Kraemer, H. C., Kiernan, M., Essex, M., & Kupfer, D. J. (2008). How and why criteria defining moderators and mediators differ between the Baron & Kenny and MacArthur approaches. *Health Psychology*, *27*(2 Suppl), S101–S108. https://doi.org/10.1037/0278-6133.27.2(Suppl.).S101

Kraemer, H. C., Wilson, G. T., Fairburn, C. G., & Agras, W. S. (2002). Mediators and moderators of treatment effects in randomized clinical trials. *Archives of General Psychiatry*, *59*(10), 877–883. https://doi.org/10.1001/archpsyc.59.10.877

Legenbauer, T., & Vocks, S. (2017). Manual der kognitiven Verhaltenstherapie bei Anorexie und Bulimie.

Linardon, J., de la Piedad Garcia, X., & Brennan, L. (2017). Predictors, moderators, and mediators of treatment outcome following manualised cognitive-behavioural therapy for eating disorders: A systematic review. *European Eating Disorders Review*, *25*(1), 3–12. Epub 2016 Nov 16.PMID: 27862611. https://doi.org/10.1002/erv.2492

Linardon, J., Shatte, A., Messer, M., Firth, J., & Fuller-Tyszkiewicz, M. (2020). E-mental health interventions for the treatment and prevention of eating disorders: An updated systematic review and meta-analysis. *Journal of Consulting and Clinical Psychology*, *88*(11), 994–1007. https://doi.org/10.1037/ccp0000575

Linardon, J., Shatte, A., Rosato, J., & Fuller-Tyszkiewicz, M. (2022). Efficacy of a transdiagnostic cognitive-behavioral intervention for eating disorder psychopathology delivered through a smartphone app: A randomized controlled trial. *Psychological Medicine*, *52*(9), 1679–1690. https://doi.org/10.1017/s0033291720003426

Mitchell, J. E., Agras, W. S., Wilson, G. T., Halmi, K., Kraemer, H., & Crow, S. (2004). A trial of a relapse prevention strategy in women with bulimia nervosa who respond to cognitive-behavior therapy. *International Journal of Eating Disorders*, *35*(4), 549–555. https://doi.org/10.1002/eat.10265

Monteleone, A. M., Pellegrino, F., Croatto, G., Carfagno, M., Hilbert, A., Treasure, J., Wade, T., Bulik, C. M., Zipfel, S., Hay, P., Schmidt, U., Castellini, G., Favaro, A., Fernandez-Aranda, F., Il Shin, J., Voderholzer, U., Ricca, V., Moretti, D., Busatta, D, ... Solmi, M. (2022). Treatment of eating disorders: A systematic meta-review of meta-analyses and network meta-analyses. *Neuroscience & Biobehavioral Reviews*, *142*, 104857. Epub 2022 Sep 6.PMID: 36084848 Review. https://doi.org/10.1016/j.neubiorev.2022.104857

Morris, S. B. (2008). Estimating effect sizes from pretest-posttest-control group designs. *Organizational Research Methods*, *11*(2), 364–386. https://doi.org/10.1177/1094428106291059

Munder, T., & Barth, J. (2018). Cochrane's risk of bias tool in the context of psychotherapy outcome research. *Psychotherapy Research*, *28*(3), 347–355. https://doi.org/10.1080/10503307.2017.1411628

Neumayr, C., Voderholzer, U., Tregarthen, J., & Schlegl, S. (2019). Improving aftercare with technology for anorexia nervosa after intensive inpatient treatment: A pilot randomized controlled trial with a therapist-guided smartphone app. *International Journal of Eating Disorders*, *52*(10), 1191–1201. https://doi.org/10.1002/eat.23152

NICE. (2020). *Eating disorders: Recognition and treatment*. Free Books & Documents. PMID: 33689256.

O'Leary, T., & Torous, J. (2022). Smartphone apps for eating disorders: An overview of the marketplace and research trends. *International Journal of Eating Disorders*. https://doi.org/10.1002/eat.23690

Olmsted, M. P., Kaplan, A. S., & Rockert, W. (2005). Defining remission and relapse in bulimia nervosa. *International Journal of Eating Disorders*, *38*(1), 1–6. https://doi.org/10.1002/eat.20144

Peters, S. A., Bots, M. L., den Ruijter, H. M., Palmer, M. K., Grobbee, D. E., Crouse, J. R., 3rd, O'Leary, D. H., Evans, G. W., Raichlen, J. S., Moons, K. G., & Koffijberg, H., & METEOR study group. (2012). Multiple imputation of missing repeated outcome measurements did not add to linear mixed-effects models. *Journal of Clinical Epidemiology*, *65*(6), 686–695. Epub 2012 Mar 27 PMID: 22459429. https://doi.org/10.1016/j.jclinepi.2011.11.012

Robinson, S., Perkins, S., Bauer, S., Hammond, N., Treasure, J., & Schmidt, U. (2006). Aftercare intervention through text messaging in the treatment of bulimia nervosa—feasibility pilot. *International Journal of Eating Disorders*, *39*(8), 633–638. https://doi.org/10.1002/eat.20272

Schlegl, S., Bürger, C., Schmidt, L., Herbst, N., & Voderholzer, U. (2015). The potential of technology-based psychological interventions for anorexia and bulimia nervosa: A systematic review and recommendations for future research. *Journal of Medical Internet Research*, *17*(3), e85. https://doi.org/10.2196/jmir.3554

Schlegl, S., Neumayr, C., & Voderholzer, U. (2020). Therapist-guided smartphone-based aftercare for inpatients with severe anorexia nervosa (SMART-AN): Study protocol of a randomized controlled trial. *International Journal of Eating Disorders*, *53*(10), 1739–1745. https://doi.org/10.1002/eat.23357

Schwarzer, R., & Jerusalem, M. (1999). *Scales for recording teacher and student characteristics. Documentation of the psychometric procedures in the context of the scientific monitoring of the pilot project 'Self-Effective Schools' [Book in German]*. Freie Universität Berlin.

Steinhausen, H.-C., & Weber, S. (2009). Outcome of eating disorders. *Child and Adolescent Psychiatric Clinics of North America*, *18*(1), 225–242. https://doi.org/10.1016/j.chc.2008.07.013

Tregarthen, J., Lock, J., & Darcy, A. (2015). Development of a smartphone application for eating disorder self-monitoring. *International Journal of Eating Disorders*, *48*(7), 972–982. https://doi.org/10.1002/eat.22386

Twisk, J., de Boer, M., de Vente, W., & Heymans, M. (2013). Multiple imputation of missing values was not necessary before performing a longitudinal mixed-model analysis. *Journal of Clinical Epidemiology*, *66*(9), 1022–1028. https://doi.org/10.1016/j.jclinepi.2013.03.017

van Eeden, A. E., van Hoeken, D., & Hoek, H. W. (2021). Incidence, prevalence and mortality of anorexia nervosa and bulimia nervosa. *Current Opinion in Psychiatry*, *34*(6), 515–524. https://doi.org/10.1097/yco.0000000000000739

von Brachel, R., Hotzel, K., Schlossmacher, L., Hechler, T., Kosfelder, J., Rieger, E., Rüddel, H., Braks, K., Huber, T., & Vocks, S. (2012). Development and validation of a German questionnaire assessing motivation to change in eating disorders - the Stages of Change Questionnaire for Eating Disorders (SOCQ-ED). *Psychotherapie, Psychosomatik, Medizinische Psychologie*, *62*(12), 450–455. [Article in German]. https://doi.org/10.1055/s-0032-1321882

Wasil, A. R., Patel, R., Cho, J. Y., Shingleton, R. M., Weisz, J. R., & DeRubeis, R. J. (2021). Smartphone apps for eating disorders: A systematic review of evidence-based content and application of user-adjusted analyses. *International Journal of Eating Disorders*, *54*(5), 690–700. https://doi.org/10.1002/eat.23478

Wilson, G. T., Fairburn, C. C., Agras, W. S., Walsh, B. T., & Kraemer, H. (2002). Cognitive-behavioral therapy for bulimia nervosa: Time course and mechanisms of change. *Journal of Consulting and Clinical Psychology*, *70*(2), 267–274. https://doi.org/10.1037/0022-006x.70.2.267

Zeeck, A., Weber, S., Sandholz, A., Joos, A., & Hartmann, A. (2011). Stability of long-term outcome in bulimia nervosa: A 3-year follow-up. *Journal of Clinical Psychology*, *67*(3), 318–327. https://doi.org/10.1002/jclp.20766

Zeeck, A., Weber, S., Sandholz, A., Wetzler-Burmeister, E., Wirsching, M., & Hartmann, A. (2009). Inpatient versus day clinic treatment for bulimia nervosa: A randomized trial. *Psychotherapy and Psychosomatics*, *78*(3), 152–160. https://doi.org/10.1159/000206869

How to cite this article: Schlegl, S., Maier, J., Dieffenbacher, A., & Voderholzer, U. (2024). Efficacy of a therapist-guided smartphone-based intervention to support recovery from bulimia nervosa: Study protocol of a randomized controlled multi-centre trial. *European Eating Disorders Review*, *32*(2), 350–362. https://doi.org/10.1002/erv.3047