Received: 20 February 2020 | Revised: 14 July 2020 | Accepted: 14 July 2020

DOI: 10.1002/eat.23357

REGISTERED REPORT STAGE 1: STUDY DESIGN

International Journal of EATING DISORDERS WILEY

Therapist-guided smartphone-based aftercare for inpatients with severe anorexia nervosa (SMART-AN): Study protocol of a randomized controlled trial

Sandra Schlegl[1] | Christina Neumayr[2] | Ulrich Voderholzer[1,2,3]

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

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

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

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

Action Editor: Tracey Wade

Abstract

Objective: Inpatient treatment for patients with anorexia nervosa (AN) is recommended in extreme or severe cases after failure of outpatient treatment and is highly effective. However, a number of patients show symptom increase and relapse after discharge. The aim of this study is to evaluate the efficacy of a therapist-guided smartphone-based aftercare intervention for inpatients with AN to support symptom stabilization.

Method: A total of 186 female patients with a DSM-5 diagnosis of AN (307.1) will be randomized either to receive a 16-week smartphone-based aftercare intervention with therapist feedback as add-on to treatment as usual (TAU) or TAU alone. Data will be assessed at discharge (= baseline, T0), after 16 weeks (= end of the aftercare intervention, T1) and after 10 months (= 6-month follow-up, T2). Primary outcome will be overall eating disorder symptomatology (Eating Disorder Examination Global score). Secondary outcome measures will include body mass index, depression, motivation to change, self-efficacy, patient satisfaction with and adherence to the smartphone-based aftercare intervention as well as rehospitalization rate.

Discussion: This study will be the first randomized controlled trial to examine a therapist-guided smartphone-based aftercare intervention for inpatients with AN. Results may reveal whether and to which extent this novel intervention can support symptom stabilization after inpatient treatment.

KEYWORDS

aftercare, anorexia nervosa, inpatient, randomized controlled trial, smartphone

1 | INTRODUCTION

Anorexia nervosa (AN) is a severe, often chronic, and life-threatening disorder (Arcelus, Mitchell, Wales, & Nielsen, 2011; Steinhausen, 2002). Relapse after treatment is common with relapse rates ranging between 9% and 52% and being highest within the first year following treatment particularly as early as 3 months posttreatment (Berends, Boonstra, & van Elburg, 2018; Khalsa, Portnoff, McCurdy-McKinnon, & Feusner, 2017). Even if weight restoration is achieved, it is quite difficult for patients to sustain improvements after treatment. Maintaining change after discharge from inpatient treatment might be especially difficult since changes are achieved in a protected environment and discharge is a major disruption (Dalle Grave, Bohn, Hawker, & Fairburn, 2008). Patients with AN often show an ambivalence to recover, and adhering to a regular meal structure at home as well

as coping with old trigger situations in daily life can be challenging. Also, body dissatisfaction remains high after inpatient treatment, despite up to 70% of patients showing reliable change regarding overall eating disorder (ED) symptomatology (Schlegl et al., 2016; Schlegl, Quadflieg, Lowe, Cuntz, & Voderholzer, 2014). Besides, a discontinuity of care might negatively impact outcome after inpatient treatment.

A review on relapse in AN states that "there is a need for the development of sound, scientifically based interventions that contribute to relapse prevention" (Berends et al., 2018, p. 445). Furthermore, Zipfel, Giel, Bulik, Hay, and Schmidt (2015) state in their review that relapse prevention after inpatient treatment is one of the key unmet challenges in the management of AN.

E-mental health interventions are gaining broad interest, also in the treatment of EDs (Aardoom, Dingemans, & Van Furth, 2016; Anastasiadou, Folkvord, & Lupiañez-Villanueva, 2018; Fairburn & Murphy, 2015; Hay, Claudino, Touyz, & Abd Elbaky, 2015; Schlegl, Bürger, Schmidt, Herbst, & Voderholzer, 2015) and might have the potential to support patients with AN in the critical transition period from inpatient to outpatient treatment and to ensure continuity of care.

A recent review on internet- and mobile-based aftercare and relapse prevention in mental disorders (Hennemann, Farnsteiner, & Sander, 2018) concludes that there is some evidence that such interventions are feasible instruments for maintaining treatment gains for some mental disorders, including EDs. Furthermore, there is some preliminary evidence that technology-based aftercare/relapse prevention might be feasible and efficacious in patients with AN: Fichter et al. (2012) evaluated the efficacy of an internet-based relapse prevention and found an increased body mass index (BMI) in the intervention group (IG) while the control group (CG) had minimal weight loss. Furthermore, an uncontrolled pilot study evaluating relapse prevention via videoconference found an increased BMI at the end of the relapse prevention (Giel et al., 2015).

One of the newest approaches among e-mental health interventions are smartphone-based interventions (Bakker, Kazantzis, Rickwood, & Rickard, 2016; Linardon, Cuijpers, Carlbring, Messer, & Fuller-Tyszkiewicz, 2019). The potential of smartphone apps for the management and/or treatment of EDs has also received an increasing research interest (Aardoom et al., 2016; Agras, Fitzsimmons-Craft, & Wilfley, 2017; Anastasiadou et al., 2018; Bauer & Goldschmidt, 2019; Fairburn & Rothwell, 2015; Juarascio, Manasse, Goldstein, Forman, & Butryn, 2015).

So far, there is few empirical support for the efficacy of apps for EDs. There is an app called Noom Monitor which was evaluated in patients with binge eating: a pilot randomized controlled trial (RCT) (Hildebrandt et al., 2017) found a greater meal and snack adherence in the smartphone assisted self-help group compared to the traditional guided self-help which partially mediated treatment effects on objective bulimic episodes. Furthermore, an RCT (Hildebrandt et al., 2020) showed higher rates of remission in the smartphone-guided self-help group compared to standard care. There is a further app called TCApp which was evaluated in a qualitative study in patients with EDs (Anastasiadou, Folkvord, Serrano-Troncoso, & Lupiañez-Villanueva,- 2019) and was rated as easy to use and useful, from both patients and ED specialists. However, an RCT did not reveal an additional effect on outcome when comparing face-to-face cognitive-behavioral therapy (CBT) to face-to-face CBT + TCApp (Anastasiadou et al., 2020). Additionally, Juarascio, Goldstein, Manasse, Forman, and Butryn (2015) evaluated the potential feasibility and acceptability of a conceptualized app for binge-eating disorder which also was perceived as highly feasible and acceptable. Finally, there is the app "Recovery Record" (RR). There are several user analyses (Darcy, Tregarthen, & Lock, 2020; Kim et al., 2018; Sadeh-Sharvit et al., 2018; Tregarthen, Lock, & Darcy, 2015) suggesting broad acceptability of RR. Furthermore, there is a recent RCT comparing a tailored version of RR with the standard version in users with ED symptoms (Tregarthen et al., 2019) showing a significantly higher rate of remission after 8 weeks in the group receiving the tailored version. Finally, there are four preliminary studies evaluating the app in clinical samples: There are two qualitative evaluations of patients as well as clinicians in a clinic setting (Lindgreen, Clausen, & Lomborg, 2018; Lindgreen, Lomborg, & Clausen, 2018) identifying supportive and obstructive experiences of the app. Furthermore, Keshen et al. (2020) compared self-monitoring via RR versus traditional paper records as add-on to an intensive outpatient ED treatment and found no significant differences. Finally, there is our pilot RCT (Neumayr, Voderholzer, Tregarthen, & Schlegl, 2019) investigating the feasibility, acceptability, and preliminary efficacy of an 8-week therapist-guided smartphone-based aftercare intervention for inpatients with AN. In summary, adherence to the app and acceptance of the aftercare intervention were very good. Furthermore, we found moderate effects on ED symptomatology and small effects on BMI in favor of the IG at the end of the 8-week intervention. However, at 6-month follow-up, the outcome of the IG was no longer superior to the CG. We concluded that a longer intervention period might be promising to produce more sustainable effects.

1.1 | Aim and hypotheses

The aim of this study is to evaluate the efficacy of an extended therapist-guided smartphone-based aftercare intervention as add-on to treatment as usual (TAU) compared to TAU alone in inpatients with AN. Our primary hypothesis is that at the end of the aftercare intervention (T1), the IG shows a significantly lower overall ED symptomatology than TAU.

Secondary hypotheses include a significantly lower overall ED symptomatology at 6-month follow-up (T2), a higher BMI, a lower frequency of binge eating and purging, a higher reduction regarding depression, a higher stage of change, a higher self-efficacy as well as a lower rehospitalization rate at T1 and T2 compared to TAU.

2 | METHODS

Institutional review board approval for the study protocol was obtained. Furthermore, the trial was registered at https://clinicaltrials.gov (NCT04228939).

2.1 | Study design

A prospective RCT will examine the efficacy of a 16-week therapist-guided smartphone-based aftercare intervention for inpatients with AN. A total of 186 patients will be recruited at Schoen Clinic Roseneck, Prien am Chiemsee, Germany. All patients will receive a multimodal inpatient treatment program based on CBT with group and individual psychotherapy. In the week before discharge, the recruitment and screening of the patients will be carried out. Patients will receive detailed information on the study and will 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. Finally, an independent researcher of University Hospital of Munich (LMU) (neither involved in the recruiting nor the data collection) will randomize the patients into two groups. We will use block randomization with computer-generated randomly varying block sizes (2, 4, or 8), stratified by age group (minor vs. adults). Randomization will be performed at a 1:1 ratio to the following two study conditions:

1. *IG*: Patients from the IG will be offered a 16-week therapist-guided smartphone-based aftercare intervention. The patients will be asked to download for free the German version of "RR" app at the App Store or the Google Play Store. Via a code from the aftercare therapist, they can then link with him. After discharge, patients will be asked to monitor at least their three main meals per day as well as their thoughts, feelings and/or (ED) behaviors. An aftercare therapist will provide individual feedback via in-app messages. Frequency of therapist feedback will be twice per week in weeks 1–4, once per week in weeks 5–8, every other week in weeks 9–12, and once in week 16 (approximately 25 min per feedback). It will address meal structure, meal sizes, and meal composition. Furthermore, tasks of the aftercare therapist will be to encourage and motivationally reinforce patients. They also are to work with the patients on the ED cognitions and emotions they logged. Weekly goals and coping skills set by the aftercare therapist shall help the patients to transfer the skills learned from clinic to home and thereby maintain changes achieved during inpatient treatment and promote further recovery.
2. *CG*: Patients from the CG will continue with their standard treatment as usual after discharge. We expect a high percentage (>90%) of patients from the CG receiving outpatient psychotherapy (see Neumayr et al., 2019).

Data will be assessed at three time points: at discharge (= baseline, T0), after 16 weeks (= end of the aftercare intervention, T1) and after 10 months (= 6-month follow-up, T2). At all time points, a trained assessor will conduct structured interviews to assess ED symptomatology. The interview at T0 will be face-to-face whereas interviews at T1 and T2 will be conducted via telephone since the clinic treats patients from all over Germany. Furthermore, the patients will be asked to complete online questionnaires via Unipark (Questback GmbH, http://www.unipark.com). Finally, BMI will be assessed. Patients will receive a compensation of 30 Euro at both T1 and T2.

The research assistant responsible for recruiting and data collection including conducting the structured interviews will be blinded to patients' group assignment. As usual in psychotherapy trials, it will not be possible to blind patients and therapists (Munder et al., 2019). Licensed psychotherapists (with a university degree in psychology) from Schoen Clinic Roseneck will serve as aftercare therapists. They are highly experienced in the treatment of EDs and trained using "RR" app in the aftercare context since being already involved in our pilot RCT. Furthermore, a licensed senior psychotherapist will provide monthly group supervision during the whole trial.

Figure 1 illustrates the study design of the RCT.

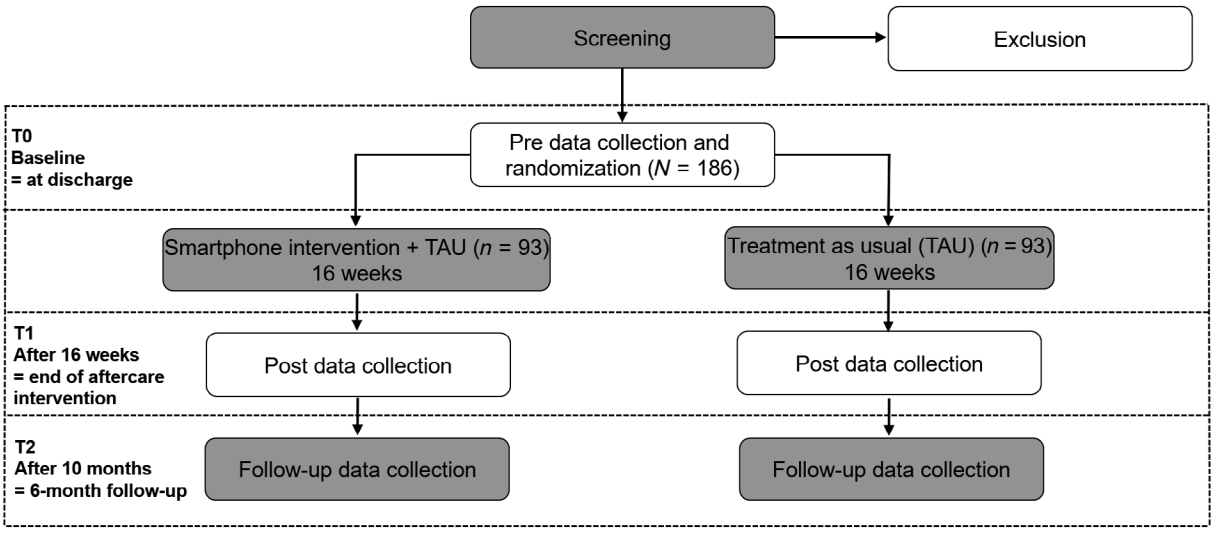

FIGURE 1 Study design of the randomized controlled trial (*N* = 186)

2.2 | Study participants

A total of 186 patients with AN will be randomized. Patients will be eligible if they meet the following inclusion criteria: (a) admission diagnosis of AN (DSM-5:307.1) as assessed by the diagnostically relevant items from the Eating Disorder Examination (EDE; Hilbert & Tuschen-Caffier, 2016b), (b) sex: female, (c) age: 12–60 years (including such a wide age range seems appropriate since there are no indications that age is associated with different attitudes and adherence to online- or smartphone-based interventions; Beatty & Binnion, 2016; Griffiths, Rossell, Mitchison, Murray, & Mond, 2018), (d) regular completion of inpatient treatment, (e) a minimum length of inpatient treatment of 6 weeks, (f) a BMI at discharge of at least 15 kg/m^2, (g) at least a 1-point BMI increase during inpatient treatment, (h) owner of a smartphone, (i) informed consent of both the patient and, in case of minors, the parents. Exclusion criteria are (a) major depression (Beck Depression Inventory-II [BDI-II] > 29 at discharge), (b) suicidal thoughts (Item 9 of BDI-II > 1 at discharge), (c) high level of aftercare (e.g., therapeutic living community, day clinic), and (d) pregnancy.

2.3 | Intervention

The smartphone app "RR" (https://www.recoveryrecord.com) has two versions: one for patients (free of charge) and another for clinicians (subject to license conditions). RR is primarily based on CBT, but also includes elements of dialectical behavioral therapy, acceptance and commitment therapy as well as motivational enhancement therapy. More detailed information on structure, features, and functions of RR can be found elsewhere (Tregarthen et al., 2015). Specific relapse prevention strategies are not included in the RR app. However, several features can be considered as useful elements also in the context of aftercare:

1. Self-monitoring of meals after discharge might help to transfer a regular meal structure with sufficient meal sizes and meal composition from clinic to home which might be essential for maintaining weight gain achieved during inpatient treatment. Self-monitoring of ED behaviors might help to detect early warning signs of relapse and offer the chance to intervene early.
2. Self-monitoring of thoughts and feelings might provide an insight into which challenges patients with AN face in the transition period from clinic to home and in general in their everyday life.
3. Weekly goals and coping strategies set by the aftercare therapist might help the patients transferring the skills learned from clinic to home. Having or learning further adaptive coping strategies is important for succeeding in transferring a regular meal structure, for dealing with risk situations and dysfunctional thoughts and feelings in the transition period from clinic to home. For our pilot study, we defined a selection of clinical goals and coping strategies for each of the 8 weeks of our aftercare intervention (n = 3–4 goals/strategies per week), which were partly chosen from the already existing ones and assumed to be the most appropriate in the aftercare context. We will use these in our RCT and also developed new ones for the extended intervention period.
4. Linking with an aftercare therapist: having support from a therapist from the clinic might be ideal to transfer the skills learned in the clinic to home.

2.4 | Privacy and security of RR

Several steps are taken to ensure that patient data is treated securely and in accordance with legal and ethical standards. Data are encrypted in transit (TLS) and encrypted at rest (AES), and a password-protected database is used that is regularly backed up and maintained on a secure server, located in Frankfurt, Germany. RR complies with European privacy policy including the EU General Data Protection Regulation and the EU-U.S. Privacy Shield.

2.5 | Outcome measures

2.5.1 | Primary outcome measure

Eating Disorder Examination

The EDE (Hilbert & Tuschen-Caffier, 2016b) is a semi-structured interview that assesses ED cognitions and behaviors patients experienced in the past 28 days. Of the 40 items, 21 items build the 4 subscales (Restraint, Eating Concern, Weight Concern, and Shape Concern) and the EDE Global score.

2.5.2 | Secondary outcome measures

Body mass index

A nurse will measure the BMI at admission and at discharge, the patients' general practitioner the BMI at follow-up. There is evidence from previous RCTs in our clinic that BMI capture via general practitioners is feasible (Dittmer et al., 2020; Fichter et al., 2012).

EDE—Questionnaire

The EDE-Q (Hilbert & Tuschen-Caffier, 2016a) is the self-rating version of the EDE (Hilbert & Tuschen-Caffier, 2016b). It consists of 28 items, the same 4 subscales and a Global score.

Beck Depression Inventory-II

The BDI-II (Hautzinger, Keller, & Kühner, 2009) assesses depressive symptoms during the past 2 weeks. The 21 items are summed up to a total score.

Stages of Change Questionnaire for Eating Disorders

The SOCQ-ED (von Brachel et al., 2012) is a self-rating instrument assessing six stages of change (Precontemplation, Contemplation, Preparation, Action, Maintenance, Termination) with regard to 13 ED behaviors.

General Self-Efficacy Scale

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

Acceptability of the smartphone app and the aftercare intervention (only at T1)

We will use a self-developed questionnaire (see also Neumayr et al., 2019) to assess patients' acceptability of the app in general (e.g., perceived helpfulness of different elements) and of the smartphone-based aftercare intervention (e.g., satisfaction with the feedback from the aftercare therapist, duration of the aftercare intervention).

Health care utilization after discharge (at T1 and T2)

Additional outpatient and/or inpatient (rehospitalization) treatment of patients since discharge will be assessed. Besides, patients will be asked to report additional day clinic treatment and any use of other health services (e.g., support groups).

Sociodemographic and clinical variables (at T0)

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

App usage (measured from T0 to T1)

For the purposes of this study, a log entry will be considered meaningful when the utilization of the app is accompanied by active user-entered data (e.g., logs of meals, ED behaviors, thoughts, feelings, use of clinical goals and/or coping skills, interactions between patient and aftercare therapist). Active entries and their respective timestamps are collected on the RR platform and shared with the research team via encrypted authenticated TLS. If a patient does not log in for 14 consecutive days despite requests and reminders, then this patient is classified as intervention dropout.

2.6 | (Serious) adverse events

The initial reporting of adverse events (serious or nonserious and related to research treatment or not) will take place with the study staff immediately notifying the principal investigator. As serious events will be especially considered death, a life-threatening event or hospitalization. The principal investigator will then decide whether the event is of such a severity that it requires discontinuation of treatment, and whether the patient should remain in the study or be withdrawn.

2.7 | Data analyses

2.7.1 | Sample size calculation

Sample size calculation was based on the results of our pilot study (Neumayr et al., 2019) where we found a medium effect size of 0.5 regarding the difference in EDE-Q Global score between the two study groups at postintervention. We used Repeated Measures and Sample Size (RMASS) software to calculate sample size for mixed-effects linear regression models for the analysis of longitudinal data (http://www.rmass.org/). The α-level was set to 5% (two-tailed) and the power (1−Type II error) was set to 0.8. An AR1 structure with a correlation of .30 and an effect size of 0.50 at the last time point were chosen. Assuming an attrition rate between timepoints of each 25%, $N = 186$ patients has to be included in the study.

2.7.2 | 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 the two 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.

Primary outcome

To test our primary hypothesis that patients receiving the RR aftercare intervention will report stability in symptoms relative to deterioration in the CG during the 16-week intervention period, we will carry out 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 conduct the primary analysis of EDE Global score according to an ITT approach including all patients who underwent randomization. We will not impute missing values, as it was shown that mixed models analysis without any imputation yields more powerful tests than analyses with ad hoc imputation (Chakraborty & Gu, 2009). We will test the model with different covariance structures and will use the one who provides the best fit according to Akaike's information criterion. The model will be based on three assessment time points (baseline [T0], postintervention [T1], 6-month follow-up [T2]). 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 *SD* (Morris, 2008). *SDs* will be derived from the *SEs* of the estimated marginal means.

Secondary outcomes

Secondary continuous outcome measures will be analyzed equally. Besides, differences in time to rehospitalization between the two groups will be estimated using a Kaplan–Meier plot, differences in cumulated prevention of rehospitalization will be tested using a log rank test.

3 | CONCLUSIONS

Our research project addresses one of the most important unmet needs regarding managing AN and represents a novel approach to aftercare for inpatients with AN. Based on promising results of our pilot RCT, we assume that a therapist-guided smartphone-based aftercare intervention for patients with AN will be an effective way to support symptom stabilization after inpatient treatment. If we can prove efficacy of our aftercare intervention it might be desirable to implement this treatment model into routine care.

Strengths of our study are the novel 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. Challenges and open questions will be attrition and adherence in the extended intervention period of 16 weeks compared to the 8 weeks in our pilot study as well as if this extended intervention will have more sustainable effects.

ACKNOWLEDGMENT

This research is funded by the Swiss Anorexia Nervosa Foundation. Open access funding enabled and organized by Projekt DEAL.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

DATA AVAILABILITY STATEMENT

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

ORCID

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

REFERENCES

Aardoom, J. J., Dingemans, A. E., & Van Furth, E. F. (2016). E-health interventions for eating disorders: Emerging findings, issues, and opportunities. *Current Psychiatry Reports*, *18*(4), 42.

Agras, W. S., Fitzsimmons-Craft, E. E., & Wilfley, D. E. (2017). Evolution of cognitive-behavioral therapy for eating disorders. *Behaviour Research and Therapy*, *88*, 26–36.

Anastasiadou, D., Folkvord, F., Brugnera, A., Cañas Vinader, L., SerranoTroncoso, E., Carretero Jardí, C., … Lupiañez-Villanueva, F. (2020). An mHealth intervention for the treatment of patients with an eating disorder: A multicenter randomized controlled trial. *International Journal of Eating Disorders*, *53*, 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.

Anastasiadou, D., Folkvord, F., Serrano-Troncoso, E., & Lupiañez-Villanueva, F. (2019). Mobile health adoption in mental health: User experience of a Mobile health app for patients with an eating disorder. *Journal of Medical Internet Research: mHealth and uHealth*, *7*(6), e12920. https://doi.org/10.2196/12920

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.

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

Bakker, D., Kazantzis, N., Rickwood, D., & Rickard, N. (2016). Mental health smartphone apps: Review and evidence-based recommendations for future developments. *Journal of Medical Internet Research: Mental Health*, *3*(1), e7. https://doi.org/10.2196/mental.4984

Bauer, S., & Goldschmidt, A. B. (2019). Introduction to the special issue on advancing assessment of, and interventions for, eating disorders via innovative uses of technology. *International Journal of Eating Disorders.*, *52*, 1073–1076.

Beatty, L., & Binnion, C. (2016). A systematic review of predictors of, and reasons for, adherence to online psychological interventions. *International Journal of Behavioral Medicine*, *23*(6), 776–794. https://doi.org/10.1007/s12529-016-9556-9

Berends, T., Boonstra, N., & van Elburg, A. (2018). Relapse in anorexia nervosa: A systematic review and meta-analysis. *Current Opinion in Psychiatry*, *31*(6), 445–455.

Chakraborty, H., & Gu, H. (2009). *A mixed model approach for intent-to-treat analysis in longitudinal clinical trials with missing values*. RTI Press Publication No. MR-0009-0903. Research Triangle Park, NC: RTI International.

Dalle Grave, R., Bohn, K., Hawker, D. M., & Fairburn, C. G. (2008). Inpatient, day patient and two forms of outpatient CBT-E. In C. G. Fairburn (Ed.), *Cognitive behavior therapy and eating disorders*. New York, NY: The Guilford Press.

Darcy, A., Tregarthen, J., & Lock, J. (2020). Can smartphones be used to improve eating disorder symptoms? An exploration of outcome and symptom profiles. Unpublished manuscript.

Dittmer, N., Voderholzer, U., Monch, C., Cuntz, U., Jacobi, C., & Schlegl, S. (2020). Efficacy of a specialized group intervention for compulsive exercise in inpatients with anorexia nervosa: A randomized controlled trial. *Psychotherapy and Psychosomatics*, *89*, 1–13. https://doi.org/10.1159/000504583

Fairburn, C. G., & Murphy, R. (2015). Treating eating disorders using the internet. *Current Opinion in Psychiatry*, *28*(6), 461–467.

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

Fichter, M. M., Quadflieg, N., Nisslmuller, K., Lindner, S., Osen, B., Huber, T., & Wunsch-Leiteritz, W. (2012). Does internet-based prevention reduce the risk of relapse for anorexia nervosa? *Behavior Research and Therapy*, *50*(3), 180–190. https://doi.org/10.1016/j.brat.2011.12.003

Giel, K., Leehr, E. J., Becker, S., Herzog, W., Junne, F., Schmidt, U., & Zipfel, S. (2015). Relapse prevention via videoconference for anorexia nervosa—Findings from the RESTART pilot study. *Psychotherapy and Psychosomatics*, *84*(6), 381–383. https://doi.org/10.1159/000431044

Griffiths, S., Rossell, S. L., Mitchison, D., Murray, S. B., & Mond, J. M. (2018). Pathways into treatment for eating disorders: A quantitative examination of treatment barriers and treatment attitudes. *Eating Disorders*, *26*(6), 556–574. https://doi.org/10.1080/10640266.2018.1518086

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

Hay, P. J., Claudino, A. M., Touyz, S., & Abd Elbaky, G. (2015). Individual psychological therapy in the outpatient treatment of adults with anorexia nervosa. *Cochrane Database of Systematic Reviews*, *7*, CD003909.

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 Interventions*, *24*(14), 1–17.

Hilbert, A., & Tuschen-Caffier, B. (2016a). *Eating Disorder Examination—Questionnaire: German translation* [Article in German] (2nd ed.). Tübingen: dgvt-Verlag.

Hilbert, A., & Tuschen-Caffier, B. (2016b). *Eating Disorder Examination: German translation* [Article in German] (2nd ed.). Tübingen: 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. *The American Journal of Psychiatry*, *177*(2), 134–142. https://doi.org/10.1176/appi.ajp.2019.19020184

Hildebrandt, T., Michaelides, A., Mackinnon, D., Greif, R., DeBar, L., & Sysko, R. (2017). Randomized controlled trial comparing smartphone assisted versus traditional guided self-help for adults with binge eating. *International Journal of Eating Disorders*, *50*(11), 1313–1322. https://doi.org/10.1002/eat.22781

Juarascio, A. S., Goldstein, S. P., Manasse, S. M., Forman, E. M., & Butryn, M. L. (2015). Perceptions of the feasibility and acceptability of a smartphone application for the treatment of binge eating disorders: Qualitative feedback from a user population and clinicians. *International Journal of Medical Informatics*, *84*(10), 808–816. https://doi.org/10.1016/j.ijmedinf.2015.06.004

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. https://doi.org/10.1002/erv.2327

Keshen, A., Helson, T., Ali, S., Dixon, L., Tregarthen, J., & Town, J. (2020). Efficacy and acceptability of self-monitoring via a smartphone application versus traditional paper records in an intensive outpatient eating disorder treatment setting. *European Eating Disorders Review*, *28*, 473–479. https://doi.org/10.1002/erv.2727

Khalsa, S. S., Portnoff, L. C., McCurdy-McKinnon, D., & Feusner, J. D. (2017). What happens after treatment? A systematic review of relapse, remission, and recovery in anorexia nervosa. *Journal of Eating Disorders*, *5*(1), 20.

Kim, J. P., Sadeh-Sharvit, S., Darcy, A. M., Neri, E., Vierhile, M., Robinson, A., … Lock, J. D. (2018). The utility and acceptability of a self-help smartphone application for eating disorder behaviors. *Journal of Technology in Behavioral Science*, *3*(3), 161–164.

Linardon, J., Cuijpers, P., Carlbring, P., Messer, M., & Fuller-Tyszkiewicz, M. (2019). The efficacy of app-supported smartphone interventions for mental health problems: A meta-analysis of randomized controlled trials. *World Psychiatry*, *18*(3), 325–336. https://doi.org/10.1002/wps.20673

Lindgreen, P., Clausen, L., & Lomborg, K. (2018). Clinicians' perspective on an app for patient self-monitoring in eating disorder treatment. *International Journal of Eating Disorders*, *51*(4), 314–321. https://doi.org/10.1002/eat.22833

Lindgreen, P., Lomborg, K., & Clausen, L. (2018). Patient experiences using a self-monitoring app in eating disorder treatment: Qualitative study. *Journal of Medical Internet Research: mHealth and uHealth*, *6*(6), e10253. https://doi.org/10.2196/10253

Morris, S. B. (2008). Estimating effect sizes from pretest-posttest-control group designs. *Organizational Research Methods*, *11*(2), 364–386.

Munder, T., Flückiger, C., Leichsenring, F., Abbass, A. A., Hilsenroth, M. J., Luyten, P., … Wampold, B. E. (2019). Is psychotherapy effective? A re-analysis of treatments for depression. *Epidemiology and Psychiatric Sciences*, *28*(3), 268–274. https://doi.org/10.1017/s2045796018000355

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*, 1191–1201. https://doi.org/10.1002/eat.23152

Sadeh-Sharvit, S., Kim, J. P., Darcy, A. M., Neri, E., Vierhile, M., Robinson, A., … Lock, J. D. (2018). Subgrouping the users of a specialized app for eating disorders. *Eating Disorders*, *26*(4), 361–372. https://doi.org/10.1080/10640266.2018.1440043

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., Diedrich, A., Neumayr, C., Fumi, M., Naab, S., & Voderholzer, U. (2016). Inpatient treatment for adolescents with anorexia nervosa: Clinical significance and predictors of treatment outcome. *European Eating Disorders Review*, *24*(3), 214–222. https://doi.org/10.1002/erv.2416

Schlegl, S., Quadflieg, N., Lowe, B., Cuntz, U., & Voderholzer, U. (2014). Specialized inpatient treatment of adult anorexia nervosa: Effectiveness and clinical significance of changes. *BMC Psychiatry*, *14*, 258. https://doi.org/10.1186/s12888-014-0258-z

Schwarzer, R., & Jerusalem, M. (1999). Scales for recording teacher and student characteristics. In *Documentation of the psychometric procedures in the context of the scientific monitoring of the pilot project "self-effective schools"* [Book in German]. Berlin: Freie Universität Berlin.

Steinhausen, H.-C. (2002). The outcome of anorexia nervosa in the 20th century. *The American Journal of Psychiatry*, *159*(8), 1284–1293. https://doi.org/10.1176/appi.ajp.159.8.1284

Tregarthen, J., Kim, J. P., Sadeh-Sharvit, S., Neri, E., Welch, H., & Lock, J. (2019). Comparing a tailored self-help mobile app with a standard self-monitoring app for the treatment of eating disorder symptoms: Randomized controlled trial. *Journal of Medical Internet Research: Mental Health*, *6*(11), e14972.

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

von Brachel, R., Hotzel, K., Schlossmacher, L., Hechler, T., Kosfelder, J., Rieger, E., … 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) [Article in German]. *Psychotherapie, Psychosomatik, Medizinische Psychologie*, *62*(12), 450–455. https://doi.org/10.1055/s-0032-1321882

Zipfel, S., Giel, K., Bulik, C. M., Hay, P., & Schmidt, U. (2015). Anorexia nervosa: Aetiology, assessment, and treatment. *The Lancet Psychiatry*, *2*, 1099–1111. https://doi.org/10.1016/S2215-0366(15)00356-9

How to cite this article: Schlegl S, Neumayr C, Voderholzer U. Therapist-guided smartphone-based aftercare for inpatients with severe anorexia nervosa (SMART-AN): Study protocol of a randomized controlled trial. *Int J Eat Disord*. 2020;53: 1739–1745. https://doi.org/10.1002/eat.23357