Received: 9 December 2019 | Revised: 21 April 2020 | Accepted: 21 April 2020

DOI: 10.1002/eat.23286

ORIGINAL ARTICLE

International Journal of EATING DISORDERS WILEY

An mHealth intervention for the treatment of patients with an eating disorder: A multicenter randomized controlled trial

Dimitra Anastasiadou PhD[1,2] | Frans Folkvord PhD[2,3] | Agostino Brugnera PhD[4] | Laura Cañas Vinader PhD[5,6] | Eduardo SerranoTroncoso PhD[5,6] | Cristina Carretero Jardí MSc[7] | Raquel Linares Bertolin MSc[7] | Rudiger Muñoz Rodríguez MSc[8] | Beatriz Martínez Nuñez MD, MSc[8] | Montserrat Graell Berna MD, PhD[8] | Jordi Torralbas-Ortega MSc[9] | Lidia Torrent-Solà MSc[9] | Joaquim Puntí-Vidal PhD[9,10] | Maria Carrera Ferrer MSc[11] | Andrea Muñoz Domenjó MD[12] | Marina Diaz Marsa MD, PhD[13] | Katarina Gunnard PhD[14] | Jordi Cusido PhD[15,16] | Jordina Arcal Cunillera MSc[15,16] | Francisco Lupiañez-Villanueva PhD[1,2]

[1]Department of Information and Communication Sciences, Universitat Oberta de Catalunya, Barcelona, Spain

[2]Open Evidence Research Group, Universitat Oberta de Catalunya, Barcelona, Spain

[3]Tilburg School of Humanities and Digital Sciences, Tilburg University, Tilburg, The Netherlands

[4]Department of Human and Social Sciences, University of Bergamo, Bergamo, Italy

[5]Child and Adolescent Psychiatry and Psychology Department, Sant Joan de Déu Hospital of Barcelona, Esplugues de Llobregat, Spain

[6]Children and Adolescent Mental Health Research Group, Sant Joan de Déu Research Institut, Esplugues de Llobregat, Spain

[7]Eating Disorders Unit, ABB Center, Barcelona, Spain

[8]Child and Adolescent Psychiatry and Psychology Service, Niño Jesús University Children's Hospital, Madrid, Spain

[9]Child and Adolescent Mental Health Service, Parc Taulí Foundation, Research and Innovation Institute Parc Taulí (I3PT) - Autonomous University of Barcelona, Sabadell, Spain

[10]Department of Clinical and Health Psychology, Autonomous University of Barcelona, Bellaterra (Cerdanyola del Vallès), Spain

[11]Eating Disorders Programme IBSMIA, University Hospital Son Espases, Palma de Mallorca, Spain

[12]Department of Psychiatry, University Hospital Móstoles, Móstoles, Spain

[13]Eating Disorders Unit, San Carlos University Hospital, Madrid, Spain

[14]Eating Disorders Unit, Quirón Dexeus University Hospital, Barcelona, Spain

[15]Board Member, HealthApp SL, Sabadell, Spain

[16]Department of Engineering Projects, Universitat Politècnica de Catalunya, Barcelona, Spain

Correspondence
Dimitra Anastasiadou, Department of Information and Communication Sciences, Universitat Oberta de Catalunya, Barcelona, Spain.
Email: danastasiadou@uoc.edu

Action Editor: Tracey Wade

Funding information
RecerCaixa of "La Caixa" Foundation

Abstract

Objective: The current multicentre randomized controlled trial assessed the clinical efficacy of a combined mHealth intervention for eating disorders (EDs) based on cognitive behavioral therapy (CBT).

Method: A total of 106 ED patients from eight different public and private mental health services in Spain were randomly assigned to two parallel groups. Patients of the experimental group (N = 53) received standard face-to-face CBT plus a mobile intervention through an application called "TCApp," which provides self-monitoring and an online chat with the therapist. The control group (N = 53) received standard

face-to-face CBT only. Patients completed self-report questionnaires on ED symptomatology, anxiety, depression, and quality of life, before and after treatment.

Results: Significant reductions in primary and secondary outcomes were observed for participants of both groups, with no differences between groups. Results also suggested that the frequency with which patients attended their referral mental health institution after the intervention was lower for patients in the experimental group than for those in the control group.

Discussion: The current study showed that CBT can help to reduce symptoms relating to ED, regardless of whether its delivery includes online components in addition to traditional face-to-face treatment. Besides, the additional component offered by the TCApp does not appear to be promising from a purely therapeutic perspective but perhaps as a cost-effective tool, reducing thus the costs and time burden associated with weekly visits to health professionals.

KEYWORDS

eating disorders, mental health, mHealth, randomized controlled trial

1 | INTRODUCTION

In current societies, eating disorders (EDs) are a major cause of physical and psychosocial disability and poor quality of life (Keski-Rahkonen & Mustelin, 2016; Klump, Bulik, Kaye, Treasure, & Tyson, 2009), and are associated with high mortality rates (Arcelus, 2011; Smink, van Hoeken, & Hoek, 2013). In Spain, EDs were the second cause of disability-adjusted life-years (DALY) among women in 2010 after anxiety disorders. This fact highlights the need to prioritize such disorders in the Spanish public health system (Lara et al., 2015), as well as to evaluate direct and indirect costs associated with the disease (Kordy, 2005).

In general, one of the forms of psychological therapy for patients with EDs that is recommended most highly is cognitive behavioral therapy (CBT) (National Institute for Health and Care Excellence, 2017). One important behavioral component in CBT for ED is the self-monitoring of nutritional intake, as well as the thoughts and feelings that go with it (Fairburn, 2008). Despite the increasing adoption of CBT principles and techniques, many patients fail to continue to apply the skills learned in treatment in their daily lives (Juarascio, Parker, Lagacey, & Godfrey, 2018). In specific, although adherence to self-monitoring is associated with better treatment outcomes in EDs (Darcy, Adler, Miner, & Lock, 2014), it is sometimes a challenging task for this group of patients, with many of them, mostly during adolescence, complaining about difficulties associated with the daily use of paper-and-pen records (i.e., forget to bring paper notes to therapy, fear of losing them, or do not want to carry them everywhere with them) (Anastasiadou, Folkvord, Serrano-Troncoso, & Lupiañez-Villanueva,- 2019; Lock, 2005). Taking also into account that this group of patients experiences difficulties associated with their specific condition, such as a low motivation for change and for receiving treatment, it is crucial to investigate alternative methods for delivering self-monitoring techniques based on CBT principles to these patients, such as through mobile interventions (Casasnovas et al., 2007; Kazdin & Blase, 2011). In addition, empirically supported treatment for EDs is only available to a limited number of patients, making it important to explore ways to expand the availability and reach of evidence-based psychological treatments for EDs (Cooper & Bailey-Straebler, 2015; Kass, Kolko, & Wilfley, 2013; Kazdin & Blase, 2011; Kazdin, Fitzsimmons-Craft, & Wilfley, 2017; Simon & Ludman, 2009).

mHealth interventions for EDs hold a great promise for reaching those in need of psychological treatment (Holmes et al., 2018). Multiple studies have shown that both patients and clinicians consider mHealth techniques that support and facilitate ED symptoms monitoring as highly acceptable and feasible—either as a sole or additional treatment tool for EDs (Anastasiadou, Folkvord, & Lupiañez-Villanueva, 2018; Darcy et al., 2014; Juarascio, Manasse, Goldstein, Forman, & Butryn, 2015; Lindgreen, Clausen, & Lomborg, 2018; Lindgreen, Lomborg, & Clausen, 2018). Up until now, however, the clinical utility of mHealth interventions for people with EDs is not fully clear, and high-quality research is largely lacking (Juarascio, Manasse, et al., 2015; Lui, Marcus, & Barry, 2017).

When accurately conducted, app-based treatments may lead to an improved form of traditional CBT by facilitating monitoring of symptoms, offering patients the opportunity to communicate and share difficulties and improvements with their therapist wherever and whenever, and improving access to psycho-education and skills materials (Fairburn & Patel, 2017; Fairburn & Rothwell, 2015; Juarascio, Goldstein, Manasse, Forman, & Butryn, 2015; Luxton, McCann, Bush, Mishkind, & Reger, 2011).

The mobile application that will be tested in this study, called TCApp, has been specifically developed for people with EDs and is based on the general principles of CBT. It represents a tool for connecting patients with therapists in the time in-between medical consultations using online food records, monitoring of thoughts, actions,

and emotions, and bidirectional messages via chat between patients and their therapists. Due to the principle 24 hr a day availability to chat with their therapist and possibility of continuous self-monitoring, patients may feel more accompanied in their treatment process and may experience more support and self-confidence in dealing with treatment challenges. Equally, by use of the app, therapists can track patients online and have the opportunity to visualize their patients' progress using graphs and reports, as well as to contact them via chat when the need arises. The TCApp has been developed as a result of fruitful partnership between technology experts from a company called HealthApp, patients with EDs and ED specialists from different mental health institutions in the area around Barcelona (Spain). It is considered to be a patient-centered tool which, through gamification elements (i.e., badges, points, scoreboards, alerts) increases patients' engagement and adherence with CBT treatment.

The current study aims to assess the clinical efficacy of a combined intervention for EDs that includes a mobile intervention through the TCApp plus standard face-to-face CBT, in comparison to standard face-to-face CBT alone. Based on results from previous randomized controlled trials (RCT) showing more positive effects of mHealth interventions for patients with ED as compared to traditional treatment (Bauer, Percevic, Okon, Meermann, & Kordy, 2003; Hildebrandt et al., 2017), we hypothesized that patients with the TCApp plus standard face-to-face CBT would show more improvement on primary (ED pathology) and secondary outcomes (depression, anxiety, quality of life, total number of visits) than patients receiving standard face-to-face CBT alone.

2 | METHOD

2.1 | Design and participants

A multicentre RCT was carried out with two parallel groups (an intensive intervention group with standard CBT and TCApp, and a standard CBT control group) with a 1:1 allocation.

Participants were recruited between February and September 2018. The sample of patients with EDs was recruited from different public and private mental health services in Spain (Parc Taulí Hospital, Balearic Island Health Service-Son Espases University Hospital, Sant Joan de Déu Hospital, Niño Jesús University Children's Hospital, San Carlos Clinic Hospital, Quiron Dexeus University Hospital and ABB Center). All patients were over 12 years of age, had been diagnosed with an eating or feeding disorder according to DSM-V criteria, and were receiving a standard CBT treatment, with the support of a multidisciplinary team of different ED units (psychiatry, psychology, nutrition, and nursing).

2.2 | Procedure

The study was approved by the Ethical Committees of all participating hospitals. In addition, approval was obtained from the Ethical Committee of the University leading the study (Open University of Catalonia, UOC). The study was registered in ClinicalTrials.gov (Identifier NCT03197519), and its protocol was previously published elsewhere (Anastasiadou, Folkvord, & Lupiañez-Villanueva, 2018). Therefore, we will only describe the most important aspects of the study's procedure here.

Informed consent was obtained from all potential candidates for the study. Clinical interviews and assessment for eligibility were then carried out using the KSADS-PL or SCID-I interviews (First, Spitzer, Gibbon, & Williams, 2002; Kaufman et al., 1997). Patients who were identified as eligible, as well as their families, completed the baseline questionnaires (T0). Patients who did not return the documents within 2 weeks received a reminder call.

After completion of the baseline questionnaires (T0), patients were randomized across experimental group and control group. Patients were allocated their condition using a computer-generated randomization list (allocation ratio 1:1; block size of 10; stratified per hospital). Patients were notified regarding the outcome of the randomization in their next visit to the ED unit. Participants and ED specialists were since that moment aware of the allocated group, while data manager/analyst (DA) remained blinded.

Instructions on how to use the TCApp were given to patients from the experimental group by the ED specialist responsible for online monitoring. Then, each group of patients received the treatment that corresponded to their condition for a period of 12 weeks. At the end of the 12-week treatment, evaluation T1 was carried out. Due to high dropout rate from T0 to T1, no T2 evaluation was carried out (although it had been planned previously). For a detailed description of the study procedure, the definition of the study variables and assessment tools, the reader is referred to Figure 1 and Table 1 of the published protocol study (Anastasiadou, Lupiañez-Villanueva, Faulí, Arcal Cunillera, & Serrano-Troncoso, 2018).

2.3 | Interventions

The experimental group received a standard face-to-face CBT (treatment as usual, TAU) in addition to the mobile health intervention using the TCApp, for a time span of 12 weeks. During these 12 weeks, the patient should use the TCApp daily, completing the self-records and/or contacting his/her therapist via chat, when considered necessary. The therapist responsible for the online monitoring should connect to the online platform and perform the following actions at least once a week: follow the patient's daily self-records, generate personalized reports or graphs and communicate with him/her via chat. After a 12-week period, patients from the experimental group and their therapists will stop using the TCApp (they will be discharged).

The control group received standard treatment based on face-to-face CBT (TAU), offered by the ED units that participated in the study, for a similar amount of time. It is worth mentioning that the frequency and intensity of CBT treatment changed depending on whether the patient fulfilled the criteria for undergoing outpatient or day hospital treatment. If they so wished, participants in the

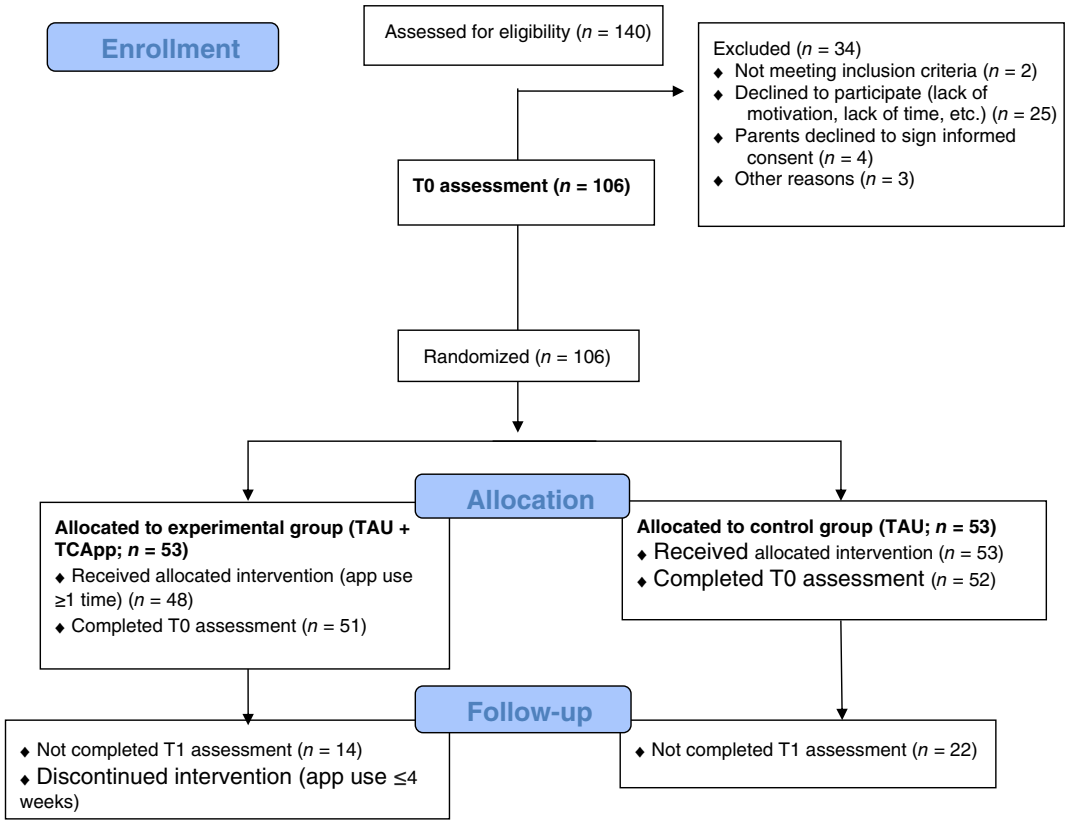

FIGURE 1 Flow of participants through each stage of the study [Color figure can be viewed at wileyonlinelibrary.com]

control group were given access to the TCApp 6 months after the start of the study.

A related point to consider is that all ED units that have been chosen to take part in the trial employed CBT as a standard treatment for EDs and that ED specialists from the seven ED units (five psychologists, one psychiatrist, and one nursing staff) had previously received a CBT-specific training during their specialization internship. In addition, ED specialists responsible for the online monitoring (experimental group) were trained on the basic principles of the application and the online platform.

2.4 | Measures

Clinical interviews (First et al., 2002; Kaufman et al., 1997) were used to assess ED diagnosis and comorbidities among participants. An additional interview was employed to assess socio-demographic and illness-related characteristics in the sample.

The primary outcome of the study concerned ED symptomatology and was assessed with the Eating Disorder Examination Questionnaire (EDE-Q) (Peláez-Fernández, Javier Labrador, & Raich, 2012), and the Short Evaluation of Eating Disorders (SEED) (Bauer, Winn, Schmidt, & Kordy, 2005). Secondary outcomes were general psychopathology and quality of life, measured using the Beck Depression Inventory (BDI-II) (Wiebe & Penley, 2005), the State-Trait Anxiety Inventory (STAI) (Spielberger, Gorsuch, & Lushene, 1982), the EuroQoL-EQ-5L (EQ-5D-5L), and the child-friendly EQ-5D version (EuroQol Group, 1990). The variable called "total number of regular visits" was also used as secondary outcome. It was assessed at T0 and T1 by way of telephone interviews with the clinician responsible for the online monitoring of each patient, and included the number of visits to ED specialists (i.e., individual therapy psychologist, group therapy psychologist, psychiatrist, nursing staff, other medical staff of various departments/specialities, nutritionist, or social worker). An additional variable that reflected the total number of emergency visits was also used as a secondary outcome. Finally, internal consistencies for all measures at pretreatment were good (see Table 2 for Cronbach's αs).

2.5 | Data analysis

Prior to the study, we estimated that a sample size of 200 participants (100 patients per study arm) would be recommended, increasing this number to 250 to allow for a 25% loss to follow-up, and assuming an α of .05 and a power of 0.80 ($\beta - 1$).

We tested the hypothesis of a higher improvement in primary and secondary outcomes from pre- to posttreatment in participants with the TCApp plus standard face-to-face CBT compared to patients receiving standard face-to-face CBT alone, using two-level hierarchical linear models (HLMs). HLMs are considered one the best statistical techniques to examine longitudinal changes in nested data (such as in the case of individual participant data hierarchically nested within

TABLE 1 Baseline characteristics of all study participants, and separately for each group

Characteristics	Intervention (*n* = 53)	Control (*n* = 53)	Total (*n* = 106)	*p* value
Demographics				
Age (years), *M* (*SD*)	17.25 (3.54)	18.88 (7.77)	18.06 (6.04)	.557
Sex, *n* (%)				
Male	5 (9.4)	4 (7.7)	9 (8.6)	.99
Female	48 (90.6)	48 (92.3)	96 (91.4)	
Highest level of education, *n* (%)				
Primary	10 (18.9)	10 (19.2)	20 (19.0)	.806
Secondary	22 (41.5)	20 (38.5)	42 (40.0)	
Baccalaureate	7 (13.2)	8 (15.4)	15 (14.3)	
Vocational training	2 (3.8)	4 (7.7)	6 (5.7)	
University	11 (20.8)	9 (17.3)	20 (19.0)	
Employment status, *n* (%)				
Full-time job	0	1 (1.9)	1 (1.0)	.447
Part-time job	3 (5.7)	5 (9.6)	8 (7.6)	
Student	48 (90.6)	45 (86.5)	93 (88.6)	
Sick leave	2 (3.8)	0	2 (1.9)	
Retired	0	1 (1.9)	1 (1.0)	
Currently living together, *n* (%)				
Nuclear family	38 (73.1)	32 (61.5)	70 (67.3)	.411
Single parent family—mother	6 (11.5)	9 (17.3)	15 (14.4)	
Single parent family—father	2 (3.8)	0	2 (1.9)	
Single parent family—joint custody	2 (3.8)	3 (5.8)	5 (4.7)	
Grandparent family	0	1 (1.9)	1 (1.0)	
Proper family/partner	1 (1.9)	4 (7.7)	5 (4.7)	
Living alone	3 (5.8)	3 (5.8)	6 (5.7)	
Clinical data				
Evaluation center, *n* (%)				
PT	7 (13.2)	9 (17.0)	16 (15.1)	.669
BAL	6 (11.3)	3 (5.7)	9 (8.5)	
SJD	13 (24.5)	18 (34.0)	31 (29.2)	
NJ	11 (20.8)	7 (13.2)	18 (17.0)	
SC	4 (7.5)	5 (9.4)	9 (8.5)	
DEX	1 (1.9)	0	1 (0.9)	
ABB	11 (20.8)	11 (20.8)	22 (20.8)	
Diagnosis, *n* (%)				
AN-restrictive	26 (49.1)	25 (47.2)	51 (48.1)	.299
AN-purging	3 (5.7)	4 (7.5)	7 (6.6)	
BN	5 (9.4)	8 (15.1)	13 (12.3)	
BED	4 (7.5)	0	4 (3.8)	
OSFED	15 (28.3)	16 (30.2)	31 (29.2)	
BMI, *M* (*SD*)	20.54 (4.45)	20.14 (3.59)	20.34 (4.03)	.808
Comorbidity Axis I, *n* (%)				
Yes	22 (41.5)	23 (44.2)	45 (42.9)	.845
No	31 (58.5)	29 (55.8)	60 (57.1)	
Duration ED (since onset; months), *M* (*SD*)	39.62 (40.29)	47.56 (62.03)	43.59 (52.20)	.752
Duration all treatments, *M* (*SD*)	25.88 (35.16)	19.04 (20.39)	22.46 (28.81)	.772

TABLE 1 (Continued)

Characteristics	Intervention (*n* = 53)	Control (*n* = 53)	Total (*n* = 106)	*p* value
Current treatment type, *n* (%)				
Day hospital	27 (50.9)	25 (48.1)	52 (49.5)	.846
Outpatient	26 (49.1)	27 (51.9)	53 (50.5)	
Pharmacological treatment, *n* (%)				
Yes	35 (66)	28 (52.8)	63 (59.4)	.235
No	18 (34)	25 (47.2)	43 (40.6)	

Abbreviations: ABB, ABB Center; BAL, Balearic Island Health Service; NJ, Niño Jesús University Children's Hospital; PT, Parc Taulí Hospital; SC, San Carlos Clinic Hospital; SJD, Sant Joan de Déu Hospital.

treatment groups; Gallop & Tasca, 2009; Singer & Willett, 2003). Their main advantage is the flexibility in handling missing data (Gallop & Tasca, 2009), a common occurrence in longitudinal studies. We ran intent-to-treat (ITT) analyses, examining the longitudinal changes of all participants according to their assigned treatment group and regardless of actual adherence to the treatment protocol.

We first tested if data were missing at random and if having any missing data were significantly related to outcomes through a pattern mixture model (Gallop & Tasca, 2009). Because all outcomes were measured across two time-points (pre- and posttreatment), we were only able to test a linear "time" slope (see Data S1 for the multilevel model). Analyses were controlled for several individual-level covariates, namely age, the number of times the App was used, duration in months of the eating disorder, diagnosis (dummy coded), the presence of an Axis I diagnosis, and current pharmacotherapy. All covariates were grand-mean centered.

Effect sizes indicating the proportion of within-person variance accounted for by adding the linear parameter and were assessed and reported using pseudo-R^2 (Raudenbush & Bryk, 2002). Their magnitude was interpreted according to guidelines (0.01 = small, 0.06 = medium, >0.14 = large; Cohen, 1988). We additionally reported Cohen's *d* for the between-groups differences at posttreatment on all the main and secondary outcomes. Their magnitude was interpreted according to guidelines (small ≥ 0.20; medium ≥ 0.50; large ≥ 0.80; Cohen, 1988).

Analyses were conducted using SPSS version 26.0 (IBM Corp., 2013) and HLMs version 7.0.3 (Raudenbush, Bryk, Cheong, & Congdon, 2011). All statistical tests were two-tailed and maintained a 5% significance threshold.

3 | RESULTS

3.1 | Preliminary analyses

We found few outliers at the two time points (T0 and T1) for frequencies of primary and secondary outcomes, so extreme scores were brought into range (Tabachnick & Fidell, 2007). According to their skewness and kurtosis values, few variables (SEED BN severity index and BMI) were also non-normally distributed. A square-root or log10 transformation corrected the violation of this assumption, however analyses run with and without transformed variables led to similar results. Thus, we reported results with untransformed values for ease of interpretation (Tabachnick & Fidell, 2007). Because the variable "total number of visits to emergency departments" was strongly asymmetrical (i.e., less than 15% participants accessed emergency departments, and among those only 1–2 participants per group had two visits during the 3 months before), this variable was dichotomized and data were analyzed through hierarchical generalized linear models (HGLMs; see Data S1 for the multilevel model).

Finally, we tested if the data was missing at random using a pattern mixture model (Gallop & Tasca, 2009): the nonsignificant effects of the missing data pattern (dropouts vs. completers) suggested that all data were missing at random and that the estimates of effects were unbiased by the presence of dropouts.

3.2 | Patient characteristics

Of the 250 patients approached for the current study a total of 140 were enrolled, 34 of which were excluded or refused to participate. Patients not interested in participating most often reported lack of motivation or lack of time (*n* = 25). In some cases, parents declined to sign the informed consent (*n* = 4). Thus, the final study sample was of 106 patients, 53 of which were randomized to the intervention and 53 to the control group. Figure 1 displays the CONSORT diagram.

Regarding the frequency of the TCApp use by participants from the experimental group, the mean app use was *M* = 7.11 (*SD* = 4.56; range = 0–12). In specific, five users did not use the application at all, 12 users discontinued intervention (used the app for less than 4 weeks) and 35.8% of users used the app during 12 out of 12 weeks.

We compared the sociodemographic and clinical characteristics of (1) patients in the intervention and in the control group and of (2) dropouts and study completers through chi-square and Fisher exact test (for frequencies), and Mann–Whitney *U* test (for continuous variables). In both cases, no between-group differences were observed for any of the baseline variables, besides a significantly higher frequency of Axis I comorbidities among dropouts compared to study completers (*p* = .040). Of note, once the intervention began dropout rate was lower in the intervention group (30.2%) compared

TABLE 2 Means, *SD*, total *N*, effect sizes (Cohen's *d* between groups at T1) and Cronbach's αs (computed at pretreatment) for all psychological variables across the two time points, and separately for the intervention and control groups

Variable	*N*	Mean (*SD*)	*N*	Mean (*SD*)	Effect size[a]	α
		T0		T1		
EDE-Q total	91	2.70 (1.67)	70	1.93 (1.48)	0.11	.96
Intervention	47	2.83 (1.54)	39	2.01 (1.46)		
Control	44	2.55 (1.78)	31	1.84 (1.53)		
EDE-Q restriction	91	2.18 (1.80)	70	1.42 (1.43)	−0.07	.89
Intervention	47	2.22 (1.67)	39	1.38 (1.36)		
Control	44	2.14 (1.94)	31	1.48 (1.54)		
EDE-Q eating concern	91	2.20 (1.52)	70	1.51 (1.35)	0.07	.82
Intervention	47	2.27 (1.43)	39	1.56 (1.37)		
Control	44	2.13 (1.64)	31	1.46 (1.34)		
EDE-Q shape concern	91	3.30 (1.96)	70	2.44 (1.79)	0.18	.95
Intervention	47	3.53 (1.84)	39	2.58 (1.77)		
Control	44	3.05 (2.07)	31	2.27 (1.82)		
EDE-Q weight concern	92	2.74 (1.79)	70	2.04 (1.63)	0.15	.83
Intervention	47	2.83 (1.72)	39	2.16 (1.62)		
Control	45	2.64 (1.82)	31	1.91 (1.65)		
SEED AN total severity index	89	0.83 (0.48)	69	0.68 (0.50)	−0.09	–
Intervention	48	0.85 (0.47)	38	0.66 (0.48)		
Control	41	0.81 (0.50)	31	0.70 (0.53)		
SEED BN total severity index	92	0.54 (0.47)	69	0.40 (0.41)	0.09	–
Intervention	48	0.58 (0.50)	38	0.41 (0.39)		
Control	41	0.49 (0.44)	31	0.38 (0.44)		
BDI-II total	92	23.29 (14.10)	69	15.45 (13.04)	0.07	.91
Intervention	48	23.66 (13.50)	38	15.85 (13.62)		
Control	44	22.89 (14.87)	31	14.95 (12.49)		
STAI State	92	47.72 (13.80)	69	43.36 (12.84)	0.15	.95
Intervention	48	47.73 (14.36)	38	44.22 (13.65)		
Control	44	47.70 (13.32)	31	42.32 (11.90)		
EQ-5D-5L (adults)	20	0.86 (0.09)	22	0.88 (0.15)	0.88	–
Intervention	11	0.86 (0.08)	14	0.92 (0.10)		
Control	9	0.86 (0.11)	8	0.80 (0.19)		
Total visits	100	30.09 (30.38)	102	26.99 (27.87)	−0.02	–
Intervention	52	33.54 (33.59)	52	26.77 (24.27)		
Control	48	26.35 (26.30)	50	27.22 (31.42)		
Emergency visits,[b] *n* (%)	106	15 (14.1)	106	10 (9.4)	–	–
Intervention	53	8 (15.1)	53	6 (11.3)		
Control	53	7 (13.2)	53	4 (7.5)		
BMI	106	20.34 (4.03)	106	20.53 (4.05)	0.11	–
Intervention	53	20.54 (4.45)	53	20.75 (4.39)		
Control	53	20.14 (3.59)	53	20.31 (3.70)		

Abbreviations: α, Cronbach's α at pretreatment; AN, anorexia nervosa; BDI-II, Beck Depression Inventory II; BMI, body mass index; BN, bulimia nervosa; EDE-Q, Eating Disorder Examination Questionnaire; EQ-5D-5L, 5 level EQ-5D version; SEED, Short Evaluation of Eating Disorders Questionnaire; STAI State, State-Trait Anxiety Inventory.

[a]Cohen's *d* (between groups, at T1).

[b]Due to the extremely low occurrence, participants with more than one emergency visit during the past 3 months were considered as cases, and only one frequency was counted.

TABLE 3 Results from the hierarchical linear models indicating the growth parameter (β_{10}) for each variable, and the effects of the interaction between study condition (i.e., intervention and control groups) and the growth parameter (β_{11}) for each variable

Variable	*β*	*SE*	95% CIs	*t* values	*df*	*p*	Pseudo R^2
EDE-Q total							
Time parameter β_{10}	−0.84	0.16	−1.15, −0.53	−5.40	83	<.001	.38
Time × condition parameter β_{11}	−0.73	0.46	−1.63, 0.17	−1.56	83	.122	
EDE-Q restriction							
Time parameter β_{10}	−0.82	0.18	−1.17, −0.47	−4.51	83	<.001	.34
Time × condition parameter β_{11}	−1.06	0.54	−2.12, −0.002	−1.96	83	.054	
EDE-Q eating concern							
Time parameter β_{10}	−0.72	0.15	−1.01, −0.43	−4.83	83	<.001	.35
Time × condition parameter β_{11}	−0.33	0.45	−1.21, 0.55	−0.74	83	.463	
EDE-Q shape concern							
Time parameter β_{10}	−0.99	0.17	−1.32, −0.66	−5.79	83	<.001	.40
Time × condition parameter β_{11}	−0.82	0.52	−1.84, 0.20	−1.59	83	.115	
EDE-Q weight concern							
Time parameter β_{10}	−0.72	0.18	−1.07, −0.37	−4.09	83	<.001	.28
Time × condition parameter β_{11}	−0.62	0.53	−1.66, 0.42	−1.19	83	.237	
SEED AN total severity index							
Time parameter β_{10}	−0.18	0.05	−0.28, −0.08	−3.58	82	<.001	.25
Time × condition parameter β_{11}	−0.28	0.15	−0.57, 0.01	1.88	82	.064	
SEED BN total severity index							
Time parameter β_{10}	−0.13	0.05	−0.23, −0.03	−2.66	82	.009	.21
Time × condition parameter β_{11}	−0.10	0.15	−0.39, 0.19	0.66	82	.510	
BDI-II total							
Time parameter β_{10}	−8.86	1.61	−12.02, −5.70	−5.50	83	<.001	.41
Time × condition parameter β_{11}	−3.34	4.76	−12.67, 5.99	−0.70	83	.485	
STAI state							
Time parameter β_{10}	−5.28	1.66	−5.58, −4.98	−3.18	83	.002	.22
Time × condition parameter β_{11}	−0.67	4.92	2.29, −3.63	−0.14	83	.891	
EQ-5D-5L (adults)							
Time parameter β_{10}	0.01	0.08	−0.15, 0.17	0.08	16	.940	.62
Time × condition parameter β_{11}	0.07	0.12	−0.17, 0.31	−0.58	16	.568	
Total visits							
Time parameter β_{10}	−3.55	2.64	−8.72, 1.62	1.34	93	.184	.13
Time × condition parameter β_{11}	−18.29	7.57	−33.13, −3.45	2.42	93	.017	
Emergency visits							
Time parameter β_{10}	−0.90	0.55	−2.31, 0.51	−1.62	97	.110	–
Time × condition parameter β_{11}	−1.43	1.47	−1.92, −0.94	−0.97	97	.333	
BMI							
Time parameter β_{10}	0.20	0.10	0.004, 0.4	1.94	93	.056	.17
Time × condition parameter β_{11}	0.11	0.30	−0.48, 0.70	−0.39	93	.700	

Note: β_{10} indicates the person-level effect of the time parameter. β_{11} indicates the interaction between condition (i.e., intervention and control groups) and the time parameter. Pseudo R^2 refers to the amount of within-person variance accounted for by adding the time parameter to level 1 of the completely unconditional multilevel model. R^2 cannot be computed for dichotomous outcomes (i.e., frequency of emergency visits during the past 3 months).
Abbreviations: *β*, unstandardized regression weight; AN, anorexia nervosa; BDI-II, Beck Depression Questionnaire II; BMI, body mass index; BN, bulimia nervosa; *df*, degrees of freedom (*df* are less than expected due to few missing values at level 2); EDE-Q, Eating Disorder Examination Questionnaire; EQ-5D-5L, 5 level EQ-5D version; SEED, Evaluation of Eating Disorders Questionnaire; STAI State, State-Trait Anxiety Inventory.

to the control group (43.4%). However, this difference was not statistically significant (p = .227).

Sociodemographic and clinical characteristics for the total sample and separately for the two study groups are provided in Table 1, while means and standard deviations for psychological dimensions at the two time points (pre and posttreatment) are reported in Table 2.

3.3 | Effect of the intervention on primary outcomes

To test our first study hypothesis, we compared the effectiveness of the two interventions designed to reduce patients' ED-related symptoms using two-levels HLMs, controlling results for several covariates.

Results showed that there was no significant difference between the two groups on the longitudinal changes in the EDE-Q total and subscale scores, and in the AN and BN total severity index of the SEED (Table 3). Of note, the slope parameter β_{10} was always significant, suggesting that CBT led to medium-to-large reductions in all ED-related symptoms (R^2 range: 0.21–0.40), regardless the group. At posttreatment, the between-groups difference in all outcomes was trivial (Cohen's d range: −0.09–0.18; see Table 2).

3.4 | Effect of the intervention on secondary outcomes

To test our secondary hypotheses, we evaluated between-group treatment effects on the secondary outcomes using HLMs, controlling results for several covariates.

Results showed that there was no statistically significant difference between the two groups on the longitudinal changes in the BDI-II, STAIState, and EQ-5D-5L total scores, in the frequency of "total number of emergency visits" during the past 3 months as well as in the BMI values. Interestingly, we found a significant effect of the Intervention on the longitudinal changes in the variable "total number of regular visits", suggesting that the total number of visits of the experimental group was significantly lower after treatment compared to the control group (Table 3).

The slope parameter β_{10} of the variables BDI-II and STAI State was significant, suggesting that CBT led to large reductions in depressive and anxious symptoms (R^2 range: 0.22–0.41), regardless the group. At posttreatment, the between-groups difference in all outcomes was trivial to large (Cohen's d range: −0.02, 0.88; see Table 2). The effect size of 0.88 was attributable to EQ-5D-5L total score, suggesting that patients in the intervention group reported a higher Quality of Life at posttreatment than those in the control group.

All regression coefficients, SEs, t and p values for β_{10} (i.e., the unstandardized regression coefficient for the average rate of growth from pre- to posttreatment) and β_{11} (i.e., the interaction between treatment condition and the time parameter) slope parameters are reported in Table 3, while all Cohen's d are reported in Table 2.

4 | DISCUSSION

The current multicenter RCT assessed the clinical efficacy of a combined intervention for EDs that included standard face-to-face CBT plus the TCApp application when compared to standard face-to-face CBT treatment. It was expected that patients in the experimental group would show more positive effects of treatment compared to those in the active control group. In contrast to our hypotheses, results showed significant reductions in primary outcomes (eating disorder symptomatology) as well as secondary outcomes (anxiety, depression, and quality of life) for participants in both groups, with moderate effects and no differences between experimental and control group. Results also suggested that the frequency with which patients attended their referral mental health institution after the intervention was lower for patients in the experimental group than for those in the control group. This finding might prove promising in the light of reducing future direct and indirect costs associated with ED treatment (Kordy, 2005).

These findings are in line with previous research which indicates that mHealth interventions for patients with EDs focusing on self-monitoring show limited additional effectiveness compared to active control groups (Mazzeo et al., 2016). In a different study that used a mobile application based on CBT principles for binge eating, however, the effectiveness of the intervention in reducing ED symptoms was indeed underscored (Hildebrandt et al., 2017). Similarly, Ruwaard et al. (2013) found encouraging effects of online CBT for BN. Comparing our findings with those in other studies should be done with caution, however, given the differences between study samples and implemented treatments. In addition, methodological issues surrounding studies examining the efficacy and effectiveness of mHealth interventions do not make it any easier to compare such studies and draw firm conclusions (Lui et al., 2017).

It should also be noted that, while there were no significant differences between the two treatment conditions with regard to ED symptomatology and general wellbeing, we found significant differences, although with a small effect size, in the total number of times patients attended their referral mental health institution to ask for help from different health professionals. This included individual or group therapy psychologists, psychiatrists, nursing staff, other medical staff of various medical specialities, nutritionists, and social workers. Findings suggest that the new component offered by the TCApp as complementary to the face-to-face CBT intervention does not appear to be promising from a purely therapeutic perspective but perhaps as a cost-effective tool, an important outcome of the treatment condition that should also be taken into account and judged on its own merit. An explanation of this finding may be that the group of patients who were using the TCApp may have perceived increased autonomy and self-confidence during their treatment process, which can be considered as an indicator of better adherence to their treatment (Crow et al., 2013). In addition, integrating self-management through the app in patients' daily life may be associated with reduced stigma and/or shame associated with seeking in-person treatment and sharing ED-related behaviors with the referral professional (Juarascio, Goldstein,

et al., 2015; Juarascio, Manasse, et al., 2015) as well as with barriers related to transportation and its costs and time barriers (Ali et al., 2016; Juarascio, Goldstein, et al., 2015; Juarascio, Manasse, et al., 2015). Another possibility is that the different outcome variables that we have used for clinical assessment were less sensitive to detect adherence to the CBT treatment. Such an alternative explanation might also take into account the short period of post-assessment compared to a more direct and changing variable such as the patients' total number of visits to a health professional.

Remarkably, overall adherence of the experimental group with the TCApp presented some problems, taking into account that only one third of the users (35.8%) of users used the app during the whole duration of the intervention. At this point, it is worth mentioning results from a previous qualitative study by Anastasiadou et al. (2019), which examined TCApp's adoption levels by users. Results showed that the app was deemed easy to use and acceptable by both patients and clinicians as a complementary tool to regular treatment, although concerns were expressed about the degree of personalization and the overwhelming quantification of symptoms through the app, which may have led some users to discontinue the online intervention.

The current study has several strengths and limitations. First, one of its strengths is the inclusion of an active control group and a rigorous assessment of our sample: through face-to-face diagnostic semi-structured interviews, self-report questionnaires, as well as telephone interviews. In addition, we recruited a heterogeneous sample with different ED diagnoses and illness durations, from a variety of private and public health care institutions, and with the aim to reflect the situation of daily clinical practice in Spain as much as possible.

One of the limitations of the current study is the small sample size, and the fact that some of our analyses are underpowered. For example, the large effect sizes for EQ-5D-5L scores at posttreatment suggest that the longitudinal between-group differences in this variable could have been significant with a larger sample size. We should mention here the difficulty we experienced in recruiting patients and the high dropout rate, which makes generalizability of our results decidedly more difficult. Taking into account the characteristics of our sample (treatment-resistant disorders, as well as dealing with minors under intensive treatment whose caregivers were not always willing to collaborate due to the risks associated with the exposure of their sons/daughters to app-based treatment), this is a common problem in this area of research. As a result, the modest sample size and short duration of post-assessment prevented us from determining if the clinically meaningful effects of the TCApp may attain greater significance over time—something that would have been facilitated with a greater sample size. In addition, the small sample size did not allow us to conduct specific analyses of subgroups of patients according to their specific ED diagnosis, referral institution (public vs. private sector) or age (minors vs. adults). For future research, we also suggest carrying out follow-up assessments at different time intervals, in order to identify long-term predictors of good outcome or dropout.

In conclusion, based on our results and those of previous findings (Anastasiadou, Folkvord, & Lupiañez-Villanueva, 2018; Fairburn & Rothwell, 2015), CBT using either online monitoring through the TCApp or paper-and-pen records may both be considered valuable interventions for the treatment of patients with EDs. In addition, patients' self-monitoring through the TCApp may be capable of increasing patients' sense of autonomy, thus reducing the number of weekly visits to a health institution. This comes on top of the fact that it requires only a minimal online involvement for health professionals. Nevertheless, a more detailed evaluation of treatment adherence should be carried out (Loeb et al., 2005). In addition, the examination of relevant clinical (ED diagnosis, symptom severity, psychiatric comorbidity, treatment type or duration, referral health institution), demographic (sex, age, economic status), and technical covariables (a.o. smartphone literacy) at different follow-up periods and with a larger sample should be taken into account. Finally, direct and indirect costs relating to the use of the TCApp treatment should be examined to provide evidence for its cost-effectiveness.

ACKNOWLEDGEMENTS

The current study is part of a broader project titled “mHealth: Challenges and opportunities for health systems” which receives funding from RecerCaixa of “La Caixa” Foundation.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ORCID

Dimitra Anastasiadou https://orcid.org/0000-0001-7544-523X
Eduardo SerranoTroncoso https://orcid.org/0000-0002-4935-7348

REFERENCES

Ali, K., Farrer, L., Fassnacht, D. B., Gulliver, A., Bauer, S., & Griffiths, K. M. (2016). Perceived barriers and facilitators towards help-seeking for eating disorders: A systematic review. *International Journal of Eating Disorders*, *50*(1), 9–21. https://doi.org/10.1002/eat.22598

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

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. *JMIR mHealth and uHealth*, *7*(6), e12920. https://doi.org/10.2196/12920

Anastasiadou, D., Lupiañez-Villanueva, F., Faulí, C., Arcal Cunillera, J., & Serrano-Troncoso, E. (2018). Cost-effectiveness of the mobile application TCApp combined with face-to-face CBT treatment compared to face-to-face CBT treatment alone for patients with an eating disorder: Study protocol of a multi-centre randomised controlled trial. *BMC Psychiatry*, *18*(1), 118. https://doi.org/10.1186/s12888-018-1664-4

Arcelus, J. (2011). Mortality rates in patients with anorexia nervosa and other eating disorders. *Archives of General Psychiatry*, *68*(7), 724–731. https://doi.org/10.1001/archgenpsychiatry.2011.74

Bauer, S., Percevic, R., Okon, E., Meermann, R., & Kordy, H. (2003). Use of text messaging in the aftercare of patients with bulimia nervosa. *European Eating Disorders Review*, *11*(3), 279–290. https://doi.org/10.1002/erv.521

Bauer, S., Winn, S., Schmidt, U., & Kordy, H. (2005). Construction, scoring and validation of the short evaluation of eating disorders (SEED). *European Eating Disorders Review*, *13*(3), 191–200. https://doi.org/10.1002/erv.637

Casasnovas, C., Fernández-Aranda, F., Granero, R., Krug, I., Jiménez-Murcia, S., Bulik, C. M., & Vallejo-Ruiloba, J. (2007). Motivation to change in eating disorders: Clinical and therapeutic implications. *European Eating Disorders Review*, *15*(6), 449–456. https://doi.org/10.1002/erv.780

Cohen, J. (1988). *Statistical Power Analysis for the Behavioral Sciences* (2nd ed.). Hillsdale, NJ: Lawrence Erlbaum Associates.

Cooper, Z., & Bailey-Straebler, S. (2015). Disseminating evidence-based psychological treatments for eating disorders. *Current Psychiatry Reports*, *17*(3), 12. https://doi.org/10.1007/s11920-015-0551-7

Crow, S. J., Agras, W. S., Halmi, K. A., Fairburn, C. G., Mitchell, J. E., & Nyman, J. A. (2013). A cost effectiveness analysis of stepped care treatment for bulimia nervosa. *International Journal of Eating Disorders*, *46*(4), 302–307. https://doi.org/10.1002/eat.22087

Darcy, A. M., Adler, S., Miner, A., & Lock, J. (2014). How smartphone applications may be implemented in the treatment of eating disorders: Case reports and case series data. *Advances in Eating Disorders*, *2*(3), 217–232. https://doi.org/10.1080/21662630.2014.938089

EuroQol Group. (1990). EuroQol–a new facility for the measurement of health-related quality of life. *Health Policy (Amsterdam, Netherlands)*, *16*(3), 199–208.

Fairburn, C. G. (2008). *Cognitive behavior therapy and eating disorders*. New York: Guilford Press.

Fairburn, C. G., & Patel, V. (2017). The impact of digital technology on psychological treatments and their dissemination. *Behaviour Research and Therapy*, *88*, 19–25. https://doi.org/10.1016/j.brat.2016.08.012

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

First, M., Spitzer, R., Gibbon, M., & Williams, J. (2002). *Structured clinical interview for DSM-IV-TR Axis I disorders, research version, patient edition (SCID-I/P)*. New York, NY: Biometrics Research, New York State Psychiatric Institute.

Gallop, R., & Tasca, G. A. (2009). Multilevel modeling of longitudinal data for psychotherapy researchers: II. The complexities. *Psychotherapy Research*, *19*(4–5), 438–452. https://doi.org/10.1080/10503300902849475

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

Holmes, E. A., Ghaderi, A., Harmer, C. J., Ramchandani, P. G., Cuijpers, P., Morrison, A. P., … Craske, M. G. (2018). The lancet psychiatry commission on psychological treatments research in tomorrow's science. *The Lancet Psychiatry*, *5*(3), 237–286. https://doi.org/10.1016/S2215-0366(17)30513-8

IBM Corp. (2013). *IBM SPSS statistics for windows, version 26.0*. Armonk, NY: IBM Corp.

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

Juarascio, A. S., Parker, M. N., Lagacey, M. A., & Godfrey, K. M. (2018). Just-in-time adaptive interventions: A novel approach for enhancing skill utilization and acquisition in cognitive behavioral therapy for eating disorders. *International Journal of Eating Disorders*, *51*(8), 826–830. https://doi.org/10.1002/eat.22924

Kass, A. E., Kolko, R. P., & Wilfley, D. E. (2013). Psychological treatments for eating disorders. *Current Opinion in Psychiatry*, *26*(6), 549–555. https://doi.org/10.1097/YCO.0b013e328365a30e

Kaufman, J., Birmaher, B., Brent, D., Rao, U., Flunn, C., Moreci, P., … Ryan, N. (1997). Schedule for affective disorders and schizophrenia for school-age children-present and lifetime version (K-SADS-PL): Initial reliability and validity data. *Journal of the American Academy of Child & Adolescent Psychiatry*, *36*(7), 980–988. https://doi.org/10.1097/00004583-199707000-00021

Kazdin, A. E., & Blase, S. L. (2011). Rebooting psychotherapy research and practice to reduce the burden of mental illness. *Perspectives on Psychological Science*, *6*(1), 21–37. https://doi.org/10.1177/1745691610393527

Kazdin, A. E., Fitzsimmons-Craft, E. E., & Wilfley, D. E. (2017). Addressing critical gaps in the treatment of eating disorders. *International Journal of Eating Disorders*, *50*(3), 170–189. https://doi.org/10.1002/eat.22670

Keski-Rahkonen, A., & Mustelin, L. (2016). Epidemiology of eating disorders in Europe. *Current Opinion in Psychiatry*, *29*(6), 340–345. https://doi.org/10.1097/YCO.0000000000000278

Klump, K. L., Bulik, C. M., Kaye, W. H., Treasure, J., & Tyson, E. (2009). Academy for eating disorders position paper: Eating disorders are serious mental illnesses. *International Journal of Eating Disorders*, *42*(2), 97–103. https://doi.org/10.1002/eat.20589

Kordy, H. (2005). Counting the COST: A European collaboration on the efficiency of psychotherapeutic treatment of patients with eating disorders. *European Eating Disorders Review*, *13*(3), 153–158. https://doi.org/10.1002/erv.634

Lara, E., Garin, N., Ferrari, A. J., Tyrovolas, S., Olaya, B., Sànchez-Riera, L., … Haro, J. M. (2015). The Spanish burden of disease 2010: Neurological, mental and substance use disorders. *Revista de Psiquiatría y Salud Mental (English Edition)*, *8*(4), 207–217. https://doi.org/10.1016/j.rpsmen.2015.10.003

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. *JMIR mHealth and uHealth*, *6*(6), e10253. https://doi.org/10.2196/10253

Lock, J. (2005). Adjusting cognitive behavior therapy for adolescents with bulimia nervosa: Results of case series. *American Journal of Psychotherapy*, *59*(3), 267–281.

Loeb, K. L., Wilson, G. T., Labouvie, E., Pratt, E. M., Hayaki, J., Walsh, B. T., … Fairburn, C. G. (2005). Therapeutic alliance and treatment adherence in two interventions for bulimia nervosa: A study of process and outcome. *Journal of Consulting and Clinical Psychology*, *73*(6), 1097–1106. https://doi.org/10.1037/0022-006X.73.6.1097

Lui, J. H. L., Marcus, D. K., & Barry, C. T. (2017). Evidence-based apps? A review of mental health mobile applications in a psychotherapy context. *Professional Psychology: Research and Practice*, *48*(3), 199–210. https://doi.org/10.1037/pro0000122

Luxton, D. D., McCann, R. A., Bush, N. E., Mishkind, M. C., & Reger, G. M. (2011). mHealth for mental health: Integrating smartphone technology in behavioral healthcare. *Professional Psychology: Research and Practice*, *42*(6), 505–512. https://doi.org/10.1037/a0024485

Mazzeo, S. E., Lydecker, J., Harney, M., Palmberg, A. A., Kelly, N. R., Gow, R. W., … Stern, M. (2016). Development and preliminary effectiveness of an innovative treatment for binge eating in racially diverse

adolescent girls. *Eating Behaviors*, *22*, 199–205. https://doi.org/10.1016/j.eatbeh.2016.06.014

National Institute for Health and Care Excellence. (2017). *Eating disorders: Recognition and treatment*.

Peláez-Fernández, M. A., Javier Labrador, F., & Raich, R. M. (2012). Validation of eating disorder examination questionnaire (EDE-Q)–Spanish version–for screening eating disorders. *The Spanish Journal of Psychology*, *15*(2), 817–824. https://doi.org/10.5209/rev_sjop.2012.v15.n2.38893

Raudenbush, S. W., & Bryk, A. S. (2002). *Hierarchical Linear Models: Applications and data analysis methods*. (2nd ed.). Thousand Oaks, CA: Sage Publications, Inc.

Raudenbush, S. W., Bryk, A. S., Cheong, Y. F. & Congdon, R. (2011). HLM 7 for Windows [Computer software]. Lincolnwood, IL: Scientific Software International, Inc.

Ruwaard, J., Lange, A., Broeksteeg, J., Renteria-Agirre, A., Schrieken, B., Dolan, C. V., & Emmelkamp, P. (2013). Online cognitive-Behavioural treatment of bulimic symptoms: A randomized controlled trial. *Clinical Psychology & Psychotherapy*, *20*(4), 308–318. https://doi.org/10.1002/cpp.1767

Simon, G. E., & Ludman, E. J. (2009). It's time for disruptive innovation in psychotherapy. *The Lancet*, *374*(9690), 594–595 https://doi.org/10.1016/S0140-6736(09)61415-X

Singer, J. D., & Willett, J. B. (2003). *Applied longitudinal data analysis: Modeling change and event occurrence*. Oxford, UK: Oxford University Press. https://doi.org/10.1093/acprof:oso/9780195152968.001.0001

Smink, F. R. E., van Hoeken, D., & Hoek, H. W. (2013). Epidemiology, course, and outcome of eating disorders. *Current Opinion in Psychiatry*, *26*(6), 543–548. https://doi.org/10.1097/YCO.0b013e328365a24f

Spielberger, C., Gorsuch, R., & Lushene, R. (1982). STAI. In *Cuestionario de Ansiedad Estado/Rasgo*. Madrid: Tecnicos Especialistas Asociados (TEA).

Tabachnick, B. G., & Fidell, L. S. (2007). *Using multivariate statistics* (5th ed.). New York, NY: Allyn and Bacon.

Wiebe, J. S., & Penley, J. A. (2005). A psychometric comparison of the beck depression inventory-II in English and Spanish. *Psychological Assessment*, *17*(4), 481–485. https://doi.org/10.1037/1040-3590.17.4.481

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: Anastasiadou D, Folkvord F, Brugnera A, et al. An mHealth intervention for the treatment of patients with an eating disorder: A multicenter randomized controlled trial. *Int J Eat Disord*. 2020;53:1120–1131. https://doi.org/10.1002/eat.23286