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Randomized Controlled Trial Comparing Smartphone Assisted Versus Traditional Guided Self-Help for Adults with Binge Eating

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Abstract

Objective—Guided self-help treatments based on cognitive-behavior therapy (CBT-GSH) are efficacious for binge eating. With limited availability of CBT-GSH in the community, mobile technology offers a means to increase use of these interventions. The purpose of this study was to test the initial efficacy of Noom Monitor, a smartphone application designed to facilitate CBT-GSH (CBT-GSH+Noom), on study retention, adherence, and eating disorder symptoms compared to traditional CBT-GSH.

Method—Sixty-six men and women with DSM-5 binge eating disorder (BED) or bulimia nervosa (BN) were randomized to receive 8 sessions of CBT-GSH + Noom (n = 33) or CBT-GSH (n = 33) over 12 weeks. Primary symptom outcomes were Eating Disorder Examination objective bulimic episodes (OBEs), subjective bulimic episodes (SBEs), and compensatory behaviors. Assessments were collected at 0, 4, 8, 12, 24, and 36 weeks. Behavioral outcomes were modeled using zero-inflated negative-binomial latent growth curve models with intent-to-treat.

Results—There was a significant effect of treatment on change in OBEs ($\beta = -0.84$, 95%CI = $-1.49, -0.19$) favoring CBT-GSH + Noom. Remission rates were not statistically different between treatments for OBEs ($\beta_{\text{logit}} = -0.73$, 95%CI = $-1.86, 3.27$; CBT-GSH + Noom = 17/27, 63.0% vs. CBT-GSH 11/27, 40.7%, NNT = 4.5), but CBT-GSH + Noom participants reported greater meal and snack adherence and regular meal adherence mediated treatment effects on OBEs. The treatments did not differ at the 6-month follow-up.

Discussion—Smartphone applications for the treatment binge eating appear to have advantages for adherence, a critical component of treatment dissemination.

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Conflicts of Interest: Drs. Hildebrandt is a scientific advisory board member of Noom, Inc. and Drs Hildebrandt and Sysko have equity in Noom, Inc (non-publicly traded company). Drs. MacKinnon and Michaelides are employees of Noom, Inc. and had no role in study analyses or data collection. Drs. Greif and DeBar had no conflicts of interest to declare.

Keywords

guided self-help; technology; smartphone; bulimia nervosa; binge eating disorder

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INTRODUCTION

Specialty treatment is available to a limited number of eating disorder patients in the United States (Kazdin, Fitzsimmons-Craft, & Wilfley, 2017). To increase accessibility, investigators developed and tested a range of self-help programs for bulimia nervosa (BN) and binge eating disorder (BED) based on cognitive-behavior therapy (CBT; (Grilo & Masheb, 2005; Mitchell et al., 2001; Walsh, Fairburn, Mickley, Sysko, & Parides, 2004; Wilson, Wilfley, Agras, & Bryson, 2010). These interventions, typically provided in book format, aim to reduce binge eating and/or purging behaviors via structured application of core CBT strategies. The guided self-help (GSH) format combines the use of the self-help material with brief in-person visits designed to help patients implement the treatment intervention. Studies examining GSH forms of CBT (CBT-GSH) for BN, BED, and related variants (e.g., recurrent binge eating) have generally found this treatment to be superior to no-treatment/wait list comparisons or control interventions, with comparable outcomes to specialized interventions (e.g., CBT, interpersonal psychotherapy, family-based therapy; Hay, Bacaltchuk, Stefano, & Kashyap, 2009; Palmer, Birchall, McGrain, Sullivan, 2002; Perkins, Murphy, Schmidt, & Williams, 2006; Sysko, 2017; Wilson et al., 2010). On average, patients with BN or BED show abstinence from binge eating and/or purging of approximately 30%–50% with individual or group CBT treatment (Wilson, Grilo, & Vitousek, 2007), in comparison to about 10%–50% with CBT-GSH (Sysko & Walsh, 2008).

Attrition and adherence exert a specific impact on CBT-GSH, with extant data indicating that attrition is influenced by how self-help is provided (computer, book, internet, etc.), eating disorder diagnosis, and eating disordered symptoms (Sysko, 2017). Delivery of CBT-GSH outside of specialty settings (e.g., primary care) also shows substantially less robust effects, largely due to high rates of attrition and contextual factors that interfere with CBT-GSH delivery (Allen & Dalton, 2011; Walsh et al., 2004). Further, reduced adherence to CBT-GSH is a significant problem that limits efficacy. Self-monitoring is uniquely effective for reducing binge eating episodes in CBT-GSH (Hildebrandt & Latner, 2006; Latner & Wilson, 2002); however, traditional self-monitoring requires a significant time commitment and may be challenging to integrate into day-to-day life. Other CBT-GSH strategies (e.g., the development of regular eating) also necessitate a high degree of participant engagement outside of sessions. As CBT-GSH as it is extended into the community, adherence to these core interventions is particularly important to maintain the established efficacy of this treatment. Despite the well-documented effects of CBT-GSH, few individuals receive CBT-GSH due to a lack of availability; however, this intervention has the potential for wider adoption because it can be administered by a range of health care providers and is more cost-effective than traditional CBT because the sessions are fewer in number and shorter in length (Wilson & Zandberg, 2012).

The relatively recent advent of smartphone apps and other forms of technology to deliver or augment treatment are likely to influence the delivery of mental health services in the future (Simon & Ludman, 2009). Mobile technology offers the potential for greater accessibility to patients, and a reduced treatment burden, which could increase adherence to self-help treatments (Schlegl, Burger, Schmidt, Herbst, & Voderholzer, 2015). Tests of mobile technology to date support this hypothesis; several studies indicate greater adherence, attendance, and retention for text messaging interventions (Aguilera, Bruehlman-Senecal, Demasi, & Avila, 2017; Shapiro et al., 2010; Sims et al., 2012). However, as the availability of technology has grown, there has not been a commensurate interest in generating empirical support, and actual experimental validation of smartphone apps is extremely limited (Bakker, Kazantzis, Rickwood, & Rickard, 2016). A large proportion of these platforms have no data to support their use, very few apps are tested in randomized controlled trials, and those that are rigorously examined are often not available for use or download by typical consumers (Donker et al., 2013)

Noom Monitor is a smartphone app developed to facilitate CBT-GSH by simplifying and digitizing self-monitoring records. As CBT-GSH is a robust stand-alone treatment, the study was designed to evaluate the effect of augmenting the traditional form of this intervention with the Noom Monitor and determine whether additional improvements in adherence or out-of-session treatment engagement could be identified. Thus, our aim was to test the initial efficacy of Noom Monitor compared to traditional CBT-GSH (Fairburn, 2013) in a randomized controlled trial at the Icahn School of Medicine at Mount Sinai (ISMMS) with a sample of adult binge eaters. We hypothesized that patients receiving CBT-GSH + Noom would: (a) have significantly greater study retention, (b) show greater adherence to self-monitoring, and (c) experience a greater reduction in eating disorder symptoms, as measured by Eating Disorder Examination objective bulimic episodes (OBEs), subjective bulimic episodes (SBEs), and compensatory behaviors than in standard CBT-GSH.

METHOD

Participants

Participants contacted the clinic in response to community advertisements and referrals. Study coordinators conducted an initial telephone assessment of eligibility and described the study. Participants not excluded after the phone screen were given a complete study description, signed a written informed consent, and then completed an in-person baseline assessment (see also below). Inclusion criteria included: 1) diagnoses consistent with *DSM-5* BN or BED (*DSM-IV* BN or BED with once weekly binge eating and/or purging), 2) over the age of 18, 3) living within 50 miles of the medical center, and 4) able to speak and read English. Exclusions were: 1) significant medical illness, 2) co-occurring *DSM-IV* substance dependence, bipolar disorder, or a psychotic condition, 3) psychotropic medication initiated four weeks prior to the screening visit or a dosage change 2 weeks prior to the baseline visit.

Eligible participants were randomized to traditional CBT-GSH as delivered in prior studies (Grilo & Masheb, 2005; Striegel-Moore et al., 2010; Walsh et al., 2004; Wilson et al., 2010) or CBT-GSH + Noom and stratified by eating disorder diagnosis after completing the

informed consent process and baseline assessments. At the first treatment session, participants were informed of their treatment allocation via a sealed envelope opened at the first session by the therapist. Study assessments occurred at zero, four, eight, 12, 24, and 36 weeks, and were conducted by blind assessors not otherwise involved in this study.

Procedures

Baseline Assessments—Measures were selected to assess domains relevant to the population, and the outcomes shown to improve following CBT-GSH, including DSM-IV psychiatric diagnoses, eating disorder psychopathology, and depressive symptoms. Participants completed the SCID I (First, Spitzer, Gibbon, & Williams, November, 2002), a semi-structured interview of psychiatric symptoms that assigned DSM-IV diagnoses of psychotic, mood, eating, and substance use disorders. The Eating Disorder Examination version 16 (Fairburn, 2008), a semi-structured interview of eating disorder pathology with four subscales (restraint, eating concern, shape concern, weight concern) and a global score was also administered. Behaviors, including objective bulimic episodes (OBEs), subjective bulimic episodes (SBEs), objective overeating, and purging are also assessed by the EDE over the 28 days, three months, and six months prior to the interview. Several self-report measures were also used. Patients completed the Beck Depression Inventory II (Beck, Steer, & Brown, 1996), a 30 item measure of negative affect and symptoms of depression, and the EDE-Q 6.0 (Fairburn, 2008), a self-report version of the EDE with parallel subscales and behavioral features of eating disorders. Body mass Index (BMI) was also collected at these time-points using digital scale and stadiometer.

Within-Treatment Assessments—At weeks four, eight, and 12, participants completed the EDE-Q and portions of the EDE assessing OBEs, SBEs, and purging for the prior 28 days. *Adherence and Alliance*: Paper-and-pencil self-monitoring records were collected at every CBT-GSH visit and coded by trained staff kept blind to the purpose of the study. To assess adherence to the treatment interventions, weekly estimates of the consumption of three meals and two snacks per day were extracted from paper self-monitoring records in the CBT+GSH condition. Meals and snacks on paper records were quantified as per the instructions for self-monitoring in Fairburn (2013), or eating episodes identified in brackets by the participant. For the CBT-GSH + Noom condition, data were obtained directly from the app. The primary adherence measure was successful logging of snacks and meals after session two (where regular eating of three meals/two snacks is initiated in CBT-GSH) through the remainder of treatment (week 12) as continued use of self-monitoring is not required post-CBT-GSH, but is instead considered a learned skill that can be utilized to prevent relapse. As both of our treatment arms required self-monitoring, examining adherence to this aspect of the intervention more specifically was an important outcome of the study. To measure therapeutic alliance, participants completed the Helping Relationship Questionnaire (HRQ) and therapists utilized the HRQ-T (Luborsky, 1984) at sessions two through eight.

Follow-up Assessments—Participants completed the EDE-Q and portions of the EDE assessing OBEs, SBEs, and purging at three and six months following the completion of treatment. Weight (in lbs) was also collected at these times.

Interventions

Patients in the study were asked not to initiate other psychological treatment during the 8-sessions of the intervention. If supplemental treatment was required, participants were to be withdrawn from research.

CBT-GSH—Traditional CBT-GSH treatment involved meeting with a therapist (psychologist/graduate student), and receiving a copy of the self-help manual (Fairburn, 2013) in the first session, which lasted 60 minutes. Each subsequent session was 20–25 minutes in length with the first four sessions occurring weekly and the last four scheduled bi-weekly, which is approximately half the time required for individual CBT. In collaboration with the therapist, participants are instructed to begin reading certain specified introductory sections of *Overcoming Binge Eating*, and to work through the 6 steps described in the self-help that focus on developing regular and moderate eating using self-monitoring, problem solving, and other CBT techniques. In CBT-GSH, *Overcoming Binge Eating* is considered to be the agent of change. As a result, the primary focus of the intervention is utilizing strategies provided by the book to reduce binge eating, and the therapist role therefore differs from individual CBT where the sessions are less structured. The second edition of *Overcoming Binge Eating* also includes updated psychoeducational materials and a revised portion of the self-help program that addresses either body image problems or dietary restraint.

CBT-GSH + Noom—This condition was identical to traditional CBT-GSH with the exception that all self-monitoring activities occurred through the Noom Monitor, a customized smartphone app that recorded activities (exercise, meal/snacks, compensatory behavior, body checking, craving, and weight) and allowed for direct entry notes for each event. Participants were provided with a specialized set of instructions on how to use the monitor, and therapists checked monitoring through a therapist dashboard at the time of each therapy session. For those participants who did not own a smartphone, a phone that could only access this app, was provided for the duration of the study. The dashboard offered summary data on several levels (e.g., number of binge episodes) and was used in session via shared computer monitor or tablet.

Therapist training and monitoring—All therapists completed a 16-hour training in CBT-GSH, led by the first author, consisting of: (a) an overview of this type of treatment as provided for BN and BED, (b) the execution of skill-specific interventions (e.g., regular eating), (c) role-plays of each session, and (d) consideration of difficult clients and special issues in treatment delivery. All therapists listened to a complete course of treatment (8 sessions of CBT-GSH) selected for excellent protocol adherence. In addition, they received weekly group supervision specific to CBT-GSH, and treated at least one participant from each condition. Therapists included two clinical psychologists and eight graduate students in clinical psychology. To assess treatment integrity, 10% of all audio-recorded sessions were randomly sampled and coded for integrity by trained and blinded assessors (scale of integrity from 0–8). A standardized rating form was used to assess whether components included in each Step of the *Overcoming Binge Eating* program were included in each of the

recorded sessions (e.g., in session one, did the therapist explain step 1 of the program with reference to the book?).

Primary Outcomes—Objective bulimic episodes, subjective bulimic episodes, and compensatory methods (remission and frequency) by EDE over the previous 28 days were the primary outcomes. Secondary outcomes included EDE-Q subscales and global scale, body mass index, Beck Depression Inventory, and adherence (average adherence in sessions 2–8). Adherence was the number of days where participants completed self-monitoring (paper/Noom), the number of days where three meals were recorded on the self-monitoring forms, and the number of days where two snacks were recorded on the self-monitoring forms based on the active components in the first two steps of *Overcoming Binge Eating*.

This study was reviewed and approved by the Institutional Review Board of the Icahn School of Medicine at Mount Sinai.

Statistical Analysis

We used latent growth curve models (LGCs) for within treatment (Baseline, four week, eight week, and 12 week) and post treatment (three month, six month, nine month). Because of the nonlinear change trajectories common to CBT interventions in general, and count distributions of our primary outcome with zero-inflation (i.e., a high rate of OBE remission), we fit negative binomial models with zero-inflation (ZIBN). This decision was informed by simulation studies indicating favorable statistical power using this method (Grotzinger, Hildebrandt, & Yu, 2015). Time was log-transformed for the within-treatment LGCs to account for rapid response and deceleration of change over the treatment period. Linear growth was estimated for the post-treatment LGCs (three month to nine month change) controlling for baseline effects. In the conditional models, the slope represents estimated change in symptom frequency or log odds of remission. The conditional effect of treatment indicates the mean difference in outcome at the end of treatment or follow-up. All models were estimated using robust maximum likelihood estimator and intent-to-treat assuming missing-at-random and Monte Carlo integration of random effects. We estimated 95% confidence intervals (95% CI) for all treatment effects.

To test for treatment effects on adherence, we used regression of our within-treatment measures of adherence on treatment using ZIBN regression with a maximum likelihood estimator in order to generate bias corrected bootstrapped (1,000 draws) 95% CIs consistent with Mackinnon and colleagues (Mackinnon, Lockwood, & Williams, 2004). All indirect effects controlled for baseline frequency of OBEs.

Statistical Power—Monte Carlo simulation studies were conducted using Mplus version 5.1 to determine sample size. Procedures for the Monte Carlo studies were based on recommendations by Muthén and Muthén (Muthén & Muthén, 2002) and power was calculated at 0.80 with a sample of $N = 80$ to test for moderate effect size differences in OBEs. For secondary outcomes (EDE-Q subscales), we were powered to detect moderate effect sizes with $N = 60$.

RESULTS

Baseline Characteristics

A total of 194 individuals were screened, with 66 subsequently randomized (33 per group), and 27 individuals were considered completers in each treatment (see Figure 1 for full CONSORT diagram). Table 1 summarizes baseline characteristics, including demographic variables, diagnostic group, and eating disorder symptoms by EDE for the treatment groups. Comorbid Axis I diagnosis by SCID-IV included 21% ($n = 14$) of participants with a current mood disorder, 9% ($n = 7$) of participants with an anxiety disorder, and 4.5% ($n = 3$) of participants with a current impulse control disorder. About 25% ($n = 16$) reported a lifetime history of anorexia nervosa, 15.2% ($n = 11$) reported a lifetime alcohol use disorder, and 50% ($n = 33$) reported a lifetime mood disorder. Fourteen (21.2%) patients reported stable doses of psychiatric medications.

Primary Symptom Outcomes

Figure 2 displays change in OBEs, and Table 2 reports model estimated treatment effects. At 12-weeks (end of treatment), those receiving CBT-GSH + Noom Monitor reported significantly fewer OBEs ($M = 1.96$, $SD = 3.53$; $M_{diff} = -2.31$, 95% CI -4.39 , -1.20) than those receiving CBT-GSH ($M = 4.22$, $SD = 6.99$). A similar pattern emerged for 28-day abstinence rates in favor of those receiving CBT-GSH + Noom Monitor ($n = 17/27$, 63% vs. $n = 11/27$, 41%; $NNT = 4.5$). This difference was not significant at 6 month follow-up. Post-treatment OBE frequencies in CBT-GSH were more variable, whereas remission and OBE reductions remained stable among those receiving CBT-GSH + Noom Monitor (see Figure 2). The effects of treatment on SBEs were not statistically significant. Participants receiving CBT-GSH + Noom Monitor reported less SBEs at the end of treatment ($M = 1.74$, $SD = 3.63$; $M_{diff} = -1.46$, 95% CI -3.28 , 1.61) than those receiving CBT-GSH ($M = 4.0$, $SD = 9.61$). Remission of SBEs at the end of treatment followed a similar pattern to OBEs; a greater proportion of the CBT-GSH + Noom Monitor group were remitted from SBEs (66.67%; $n = 18/27$) than those receiving CBT-GSH (52.0%; $n = 14/27$; $NNT = 6.8$). Participants receiving both treatments demonstrated significant reductions in compensatory behaviors that were maintained over follow-up. Of the 12 completers with BN in CBT-GSH, 50% ($n = 6/12$) reported 28 days free from compensatory behavior in comparison to 41.67% ($n = 5/12$) of those receiving CBT-GSH + Noom Monitor at the end of treatment.

Secondary Outcomes

The symptom subscales of the EDE-Q indicated significant reductions in eating disorder symptoms across treatment groups as a function of time (see Table 3). The effects of Noom + GSH on EDE-Q subscales were non-significant, ranging from .04 to $-.41$ within treatment to .03 to $-.20$ for follow-up. A similar pattern emerged with BDI and BMI. There were significant improvements for participants in both treatments (see Table 3), but those participants receiving CBT-GSH + Noom Monitor reported significantly fewer depressive symptoms at 6-month follow-up ($M = 9.08$, $SD = 8.95$ vs. $M = 15.33$, $SD = 8.69$, Cohen's $d = -0.71$) as evidenced by greater persistence of within-treatment reductions in depressive symptoms. Adverse events did not occur in either condition.

Adherence and Alliance

Patient and therapist-rated helping alliance scores did not differ between groups at baseline, nor did change in alliance differ between groups over the 8 sessions. Treatment integrity was high in the sampled sessions ($M = 84.52\%$, $SD = 11.32\%$) and there were no significant differences noted between treatments ($M = 2.84\%$, $95\% \text{ CI} = -7.50\%, 6.87\%$, $p = 0.76$). Therapy protocol deviations were rare (11.9%) and did not significantly differ between groups ($\chi^2 = 1.06$, $p = 0.30$). Dropout was similar in both treatments ($n = 6$ at end of treatment), suggesting equivalent acceptability in the two conditions. Specific types of self-monitoring adherence were associated with treatment differences and outcome (See Table 4). A greater proportion of the CBT-GSH + Noom Monitor group reported eating three meals and two snacks. No differences were found between the two groups in the number of days of self-monitoring completed. Across conditions, the percent of days where self-monitoring was completed was positively associated with OBEs at the end of treatment. At the end of treatment, greater reduction in binge eating among those receiving CBT-GSH + Noom was partially mediated by the percentage of days participants recorded three meals in a day. No other mediating effects were statistically significant.

DISCUSSION

The utility of CBT-GSH for the treatment of binge eating is suggested by its desirable properties for scalability, or disseminating specialized treatments more widely (Wilson & Zandberg, 2012), evidence of cost-effectiveness (Lynch et al., 2010) and efficacy among several eating disorder diagnoses (Perkins et al., 2006; Sysko, 2017; Wilson & Zandberg, 2012). Smartphone technology offers a potential means to augment scalability by increasing adherence, usability, and reducing dropout. Systematic reviews of existing apps have been negative (Juarascio, Manasse, Goldstein, Forman, & Butryn, 2015), indicating limitations with treatment relevant assessment and feedback on core symptoms (Fairburn & Rothwell, 2015), which stands in stark contrast to interest in apps from patients and providers (Juarascio, Goldstein, Manasse, Forman, & Butryn, 2015). The Noom Monitor differs from other products in specifically focusing on automated recording and feedback of self-monitoring tasks fundamental to CBT-GSH. Consistent with our hypothesis, patients receiving CBT-GSH + Noom experienced a greater reduction in objective bulimic episodes (OBEs) and purging than in standard CBT-GSH. Specifically, compared to an active CBT-GSH control, this automation produced a reduction of about 2.3 (1.2–4.3) more OBEs at the end of treatment, or a decrease of approximately 21% more in binge eating (81% vs. 60% in CBT-GSH). With traditional self-monitoring alone, a reduction of approximately 50% is noted for episodes of binge eating among patients with BN and BED (Hildebrandt & Latner, 2006). However, these treatment effects were not sustained, as remission rates and OBE count were not significantly different by six month follow-up and there were no significant effects on abstinence rates.

Participant adherence to self-help and GSH interventions is a critical component of scalability. In contrast to our hypothesis, similar rates of dropout were noted in both treatments. The rate of treatment retention in this study (78.8% in both conditions), is similar to other CBT-GSH interventions using Overcoming Binge Eating (e.g., 78% Cooper &

Fairburn, 1998; 75%, Palmer et al., 2002; 69.7%, Wilson et al., 2010). The equivalence in dropout does suggest acceptability for a self-help treatment with or without app augmentation. An increase in the number of days of self-monitoring was not observed, which was inconsistent with our hypothesis related to use of the app; however, the results of this study indicated that CBT-GSH + Noom Monitor lead to significant increases in weekly meal and snack adherence. Regular eating, and the monitoring of this pattern, are theoretically potent mechanisms of change in CBT (Wilson, Fairburn, Agras, Walsh, & Kraemer, 2002), and some preliminary evidence indicates a correlation between regular eating and better outcomes in CBT-GSH (Zendegui, West, & Zandberg, 2014). Regular meal consumption was a significant mediator of the CBT-GSH + Noom treatment effect, suggesting a potential benefit from smartphone usage that influences outcomes. Our explanation for the missing effect of Noom Monitor on monitoring frequency and dropout is that CBT-GSH is a potent treatment.

Scalable interventions and dissemination are an important priority across mental health conditions (Patel et al., 2016) and even modest effects when delivered on large scale can have meaningful impact on public health. The effect of CB-GSH + Noom Monitor on abstinences indicates for every 4.5 individuals treated, one additional patient will achieve abstinence. Within individual or small group provider networks, observable advantages in efficacy over traditional CBT-GSH would take substantially more time than implementation within large-scale provider or public health networks that may be more likely to rely on technology for service delivery. To bring a GSH intervention to scale, however, the intervention needs to be easily delivered by non-professionals and outcomes (provider and patient) need to be adequately monitored to prevent provider drift (Waller & Turner, 2016). Automated summary and feedback data captured by smartphone monitoring offers a unique opportunity to help providers limit drift by summarizing important reminders or data for supervisors or other monitoring systems (e.g., artificial intelligence) to focus efforts on cases or providers that demonstrate sub-optimal outcomes. This type of feature not only has implications for quality control when GSH interventions are utilized more widely, but also a means to improve efforts to limit dropout (Beintner, Jacobi, & Schmidt, 2014).

Strengths and Limitations

Strengths of the study include the use of an active control group, blinded assessments, and a detailed assessment of theoretically important mediator. Studies of CBT-GSH or technology interventions that do not use active control groups limit inferences about relative efficacy. There were also several important limitations to the present study. The modest sample size and short duration of follow-up prevented us from determining if smaller but meaningful effects of Noom Monitor emerge over time and to sufficiently examine moderator effects. The examination of relevant clinical (e.g. symptom severity), demographic (e.g. age, socioeconomic status), or practical (e.g., proficiency in smartphone use) moderators could be useful in determining which patient populations should be prioritized for use of CBT-GSH + Noom versus CBT-GSH given the modest effects. We note that we did not recruit the intended $N = 80$ and progressed to an ongoing phase II study with the reported evidence of initial efficacy. Longer follow-up periods and larger sample sizes are needed to determine if there are clinically meaningful changes that are durable. Secondly, both interventions were

delivered in an optimal specialty setting, and the effects cannot be generalized to community settings. It is crucially important to test the limits of the utility of this application in settings more typical of real-world mental health care treatment, by enrolling patients from larger health care delivery systems, including providers with different experience, varying the types of treatment delivery (augmenting pure self-help or telemedicine), or expanding the range of patients individuals who do not meet criteria for a DSM-5 disorder). To address this limitation, a Phase II study (R42MH096435) is currently underway to test the primary efficacy of this app in a large population of binge eaters compared to treatment as usual control condition in the Kaiser Permanente Health System, which will provide a more complete test of real-world effectiveness of the Noom Monitor. Continued adaptation of tools like Noom Monitor to self-help treatments may offer a novel way to improve accessibility of treatment while maintaining quality.

Conclusions

Smartphone apps can improve initial outcomes of CBT-GSH and may offer a useful way to improve participant adherence among those who stay engaged in treatment. Although rates of retention and self-monitoring adherence did not differentiate the interventions in this study, extant research shows CBT-GSH to be a robust treatment when delivered in a specialist setting, which may explain the failure to detect more unique effects of the app, and necessitates further study. Long-term benefits remain uncertain; however, the use of apps offer increased scalability and the potential for greater adaptability to a range of treatment contexts, including the potential for use in telemedicine or pure self-help formats.

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Figure 1.
CONSORT Flow Diagram. Data were analyzed as intent to treat, so all available data were included in the analyses.

Figure 2.

Summary of Treatment on Binge Eating over Treatment and Follow-up. Observed means and 95% CI reported for each outcome. Remission reflects 0 OBEs over previous 4-weeks. CBT-GSH = cognitive behavior therapy-guided self-help. $N = 66$ ($n = 33$ per group).

Table 1
Sample Characteristics and Baseline Differences in Demographics and Study Outcomes by Treatment Condition

	Sample (N = 66)			CBT-GSH (n = 33)			CBT-GSH + Noom (n = 33)			<i>T or χ^2</i>	<i>M_{diff} or ϕ</i>	95% CI	
	Mean	SD (#)	Mean	SD (#)	Mean	SD (#)	Mean	SD (#)	LCL			UCL	
Age	32.11	10.82	33.88	11.97	30.33	9.39	30.33	9.39	1.34	3.55	-1.74	8.83	
BMI	27.53	5.61	26.74	5.24	28.31	5.93	28.31	5.93	-1.14	-1.57	-4.32	1.18	
Non White	37.9%	(25)	30.3%	(10)	45.5%	(15)	45.5%	(15)	1.03	-0.16			
Hispanic or Latino/a	16.7%	(11)	18.2%	(6)	15.2%	(5)	15.2%	(5)	.11	0.04			
Male	16.7%	(11)	15.2%	(5)	18.2%	(6)	18.2%	(6)	.11	0.04			
Single	71.2%	(47)	72.7%	(24)	69.7%	(23)	69.7%	(23)	.07	0.00			
At least college degree	74.2%	(49)	72.7%	(24)	75.8%	(25)	75.8%	(25)	.08	0.03			
Own smartphone	80.3%	(53)	84.8%	(28)	75.8%	(25)	75.8%	(25)	.86	-0.11			
> 50,000 USD Household Income	54.5%	(36)	54.5%	(18)	54.5%	(18)	54.5%	(18)	.00	0.00			
Diagnosis									.06	0.04			
BED	56.1%	(37)	57.6%	(19)	54.5%	(18)	54.5%	(18)					
BN	43.9%	(29)	42.4%	(14)	45.5%	(15)	45.5%	(15)					
EDE OBEs ^a	12.53	9.02	12.70	8.68	12.36	9.48	12.36	9.48	.15	0.33	-4.14	4.80	
EDE SBEs	5.61	8.72	5.55	7.74	5.67	9.73	5.67	9.73	-.06	-0.12	-4.44	4.20	
EDE Vomiting/28 days ^a	5.21	15.90	6.71	20.15	3.72	10.14	3.72	10.14	.64	2.99	-4.84	10.84	
EDE Laxatives/28 days ^a	.98	3.39	0.94	3.49	1.03	3.33	1.03	3.33	.31	-0.09	-1.76	1.59	
EDE Diuretics/28 days ^a	0.38	0.22	0.00	0.00	0.76	0.31	0.76	0.31	1.79	-0.76	-0.18	0.03	
EDE Restraint Subscale	2.81	1.42	2.79	1.46	2.83	1.39	2.83	1.39	-.12	-0.04	-0.74	0.66	
EDE Eating Concern Subscale	3.12	1.95	3.10	1.78	3.13	2.14	3.13	2.14	-.05	-0.02	-0.99	0.94	
EDE Weight Concern Subscale	3.03	1.24	3.04	1.25	3.01	1.24	3.01	1.24	.08	0.02	-0.59	0.64	
EDE Shape Concern Subscale	3.67	1.41	3.68	1.47	3.66	1.39	3.66	1.39	.07	0.02	-0.68	0.72	
Global EDE	3.16	1.21	3.16	1.25	3.16	1.20	3.16	1.20	-.02	-0.001	-0.61	0.60	

Note.

^aMann Whitney *U* reported. All secondary behavioral and symptom data derived from Eating Disorder Examination (EDE).

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BED = binge eating disorder; BMI = body mass index; kg/m²; BN = bulimia nervosa; CBT-GSH = guided self-help version of cognitive-behavior therapy; CI = confidence interval; LCL = lower confidence level; UCL = upper confidence level; OBE = objective binge/bulimic episode; SBE = subjective binge/bulimic episode; SD = standard deviation.

Zero Inflated Latent Growth Curve Model Estimates of Treatment on Primary Behavioral Outcomes

Table 2

	Within Treatment (12-Weeks)					6-Month Follow-Up					
	Slope	95% CI		CBT-GSH + Noom	β	Slope	95% CI		CBT-GSH + Noom	β	
	μ	LCL	UCL			μ	LCL	UCL			
Remission, EDE OBEs	3.28	5.58	1.53		0.73	0.48	3.27		-0.85	-5.80	4.11
OBE by EDE	-0.83	-1.23	-0.44		-0.84	0.13	-0.19		-0.04	-1.08	1.00
Remission, EDE SBEs	-1.39	-3.79	1.01		0.47	2.34	2.34		8.41	-2.74	19.55
SBE by EDE	-0.96	-1.89	-0.37		-1.06	0.42	0.42		1.39	-0.10	2.88
EDE Purging	-2.01	-3.93	-0.08		0.51	2.21	2.21		10.31	-2.77	23.39

Note. CBT-GSH= guided self-help version of cognitive-behavior therapy. CI= confidence interval. EDE=Eating Disorder Examination. OBE = objective binge/bulimic episode. SBE = subjective binge/bulimic episode. EDE Purging dichotomized (present vs. absent) to account for sparse distribution and low base rate in modeling. LCL = lower confidence level. UCL = upper confidence level. μ = mean change in outcome for CBT-GSH. β = covariate effect of CBT-GSH + Noom on outcome.

Table 3

Latent Growth Curve Model Estimates of Treatment on Secondary Outcomes

	Within Treatment (12-Weeks)						6-Month Follow-Up					
	Slope		95% CI		CBT-GSH + Noom		Slope		95% CI		CBT-GSH + Noom	
	μ	LCL	UCL	β	LCL	UCL	μ	LCL	UCL	β	LCL	UCL
EDE Shape Concern Subscale	-1.09	-1.58	-0.61	-0.41	-1.06	0.23	0.17	-0.36	0.70	-0.01	-0.74	0.72
EDE Weight Concern Subscale	-0.77	-1.20	-0.34	-0.36	-0.93	0.22	0.81	-0.11	1.73	-0.23	-0.98	0.52
EDE Eating Concern Subscale	-1.21	-1.62	-0.80	0.04	-0.46	0.55	0.35	-0.74	1.44	0.03	-0.53	0.59
EDE Restraint Subscale	-1.40	-1.90	-0.91	-0.09	-0.66	0.47	0.42	-0.14	0.96	0.01	-0.73	0.74
EDE Global Score	-1.13	-1.49	-0.77	-0.20	-0.67	0.27	0.24	-0.19	0.67	-0.05	-0.64	0.54
BDI	-8.19	-11.98	-4.40	-0.30	-5.35	4.75	5.09	2.44	7.58	-3.64	-7.15	-0.13
BMI	0.03	-0.36	0.36	0.13	-0.40	0.64	0.11	-0.70	1.36	-0.07	-1.57	0.98
HRQ	9.67	6.38	12.97	-0.28	-4.84	4.27						
HRQ-T	6.60	3.85	9.35	0.41	-3.54	4.36						

Note. BDI = Beck Depression Inventory. BMI = body mass index (kg/m^2). CBT-GSH = guided self-help version of cognitive-behavior therapy. CI = confidence interval. EDE = Eating Disorder Examination. HRQ = Helping Relationship Questionnaire/T = Therapist version. LCL = lower confidence level. UCL = upper confidence level. μ = mean change in outcome for CBT-GSH. β = covariate effect of CBT-GSH + Noom on outcome.

Table 4
Estimated Indirect Effect of Treatment on Change in Objective Binge Episodes Via Adherence

	Treatment		Mediator		Indirect effect (<i>a*b</i>)				
	<i>a</i>	95% CI	<i>B</i>	95% CI	EDE OBEs	95% CI			
	LCL	UCL	LCL	UCL	LCL	UCL			
% Self-Monitored Days	-1.93	-13.26	8.09	0.04	0.15	-0.05	-0.46	0.28	
Remission			0.02	-0.01	0.05	-0.10	-1.08	0.60	
% days with 3 Meals	45.00	31.20	57.30	2.50	-0.06	4.52	1.32	0.14	1.87
Remission			0.79	-4.15	12.38	-0.25	-2.74	5.20	
% days with 2 Snacks	-15.00	-25.40	-2.00	-1.24	-5.43	4.18	-0.11	-0.47	0.38
Remission			0.73	-2.29	3.66	0.19	-0.73	1.18	

Note. CI= confidence interval. EDE= Eating Disorder Examination. OBE=Objective Bulimic Episode. All models controlled for baseline objective binge days and 95% confidence intervals bootstrapped with 1,000 draws. *a* = treatment effect on % adherence. *b* = conditional effect of adherence on OBEs at end of treatment. *a*b* = indirect effect of treatment on OBEs via adherence. LCL = lower confidence level. UCL = upper confidence level. **Bold** = $p < .05$.