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ORIGINAL ARTICLE



Economic evaluation of web-based guided self-help cognitive behavioral therapy-enhanced for binge-eating disorder compared to a waiting list: A randomized controlled trial o o

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Abstract

Introduction: The aim is to perform an economic evaluation alongside a randomized controlled trial comparing guided self-help cognitive behavioral therapy-enhanced (CBT-E) for binge-eating disorder (BED) to a waiting list control condition.

Methods: BED patients (N = 212) were randomly assigned to guided self-help CBT-E or the 3-month waiting list. Measurements took place at baseline and the end-oftreatment. The cost-effectiveness analysis was performed using the number of binge-eating episodes during the last 28 days as an outcome indicator according to the eating disorder examination. A cost-utility analysis was performed using the EuroQol-5D.

Results: The difference in societal costs over the 3 months of the intervention between both conditions was €679 (confidence interval [CI] 50-1330). The incremental costs associated with one incremental binge eating episode prevented in the guided self-help condition was approximately €18 (Cl 1-41). From a societal perspective there was a 96% likelihood that guided self-help CBT-E led to a greater number of binge-eating episodes prevented, but at higher costs. Each additional qualityadjusted life year (QALY) gained was associated with incremental costs of €34,000 (CI 2494-154,530). With a 95% likelihood guided self-help CBT-E led to greater QALY gain at higher costs compared to waiting for treatment. Based on the National Institute for Health and Clinical Excellence willingness-to-pay threshold of €35,000 per QALY, guided self-help CBT-E can be considered cost-effective with a likelihood of 95% from a societal perspective.

Discussion: Guided self-help CBT-E is likely a cost-effective treatment for BED in the short-term (3-month course of treatment). Comparison to treatment-as-usual is recommended for future research, as it enables an economic evaluation with a longer time horizon.

Public Significance: Offering treatment remotely has several benefits for patients suffering from binge-eating disorders. Guided self-help CBT-E is an efficacious and

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likely cost-effective treatment, reducing binge eating and improving quality-of-life, albeit at higher societal costs.

KEYWORDS

binge-eating disorder, cognitive behavioral therapy-enhanced, cost-effectiveness, cost-utility, economic evaluation, guided self-help, randomized controlled trial

1 | INTRODUCTION

Binge-eating disorder (BED) is characterized by recurrent episodes of binge eating accompanied by a sense of lack of control. Inadequate compensatory behavior such as self-induced vomiting and laxative misuse is absent (American Psychiatric Association [APA], 2013). BED is associated with decreased quality-of-life, increased risk of excess weight, and noncommunicable diseases. Patients with BED experience poorer psychosocial functioning and somatic health compared to individuals who merely suffer from excess weight (Melisse et al., 2020; Mond & Hay, 2007). The medical conditions associated with BED potentially result in increased healthcare utilization and other societal costs including productivity losses (Striegel et al., 2012; van Hoeken & Hoek, 2020). Efficacious treatments are important to reduce the personal and societal burden of BED (Lynch et al., 2010). However, the exact reduction in quality-of-life of BED and the costs of quality-of-life gain after treatment are unknown. When evaluating the economic impact of treatment for BED, such costs should also be considered.

Cognitive behavior therapy-enhanced (CBT-E) is an evidence-based treatment for eating disorders (Fairburn, 2008; Melisse, Dekker, et al., 2022), and a web-based guided self-help version of CBT-E (guided self-help CBT-E) is promising (Melisse et al., 2023). Guided self-help CBT-E has several benefits for patients compared with in-person CBT-E, such as the removal of geographical barriers (Abrahamsson et al., 2018). Furthermore, guided self-help CBT-E requires less therapist involvement, is briefer than in-person CBT-E, and is therefore associated with lower costs of offering treatment. Costs of offering guided self-help CBT vary between ϵ 630 and ϵ 900, whereas costs for in-person CBT-E are around ϵ 3500 (Jenkins et al., 2021; König et al., 2018). In addition, a cost-effectiveness study of guided self-help for BED estimated the willingness-to-pay per binge-free day, representing the maximum amount that society is willing to pay for an additional unit of health outcome, between ϵ 118 and ϵ 177 (Jenkins et al., 2021).

Guided self-help CBT-E has been shown to be efficacious for BED (Melisse et al., 2023; Striegel-Moore et al., 2010). To distinguish the efficiency of the various eating disorder treatments (Streatfeild et al., 2021), it is important to evaluate the cost-effectiveness of guided self-help CBT-E. There is only limited economic evidence for the effect of BED treatments (König et al., 2018). Most economic evaluations face marked limitations: they do not involve BED (Striegel-Moore et al., 2008) and predominantly focus on younger patient populations, whereas BED affects patients of all ages (Ling et al., 2017; Streatfeild et al., 2021). Furthermore, most studies neglect costs outside of the healthcare system (Streatfeild et al., 2021). Society's monetary valuation of health care

benefits are represented by a willingness-to-pay (Steigenberger et al., 2022) for one quality-adjusted life year (QALY). One QALY is defined as one extra year lived in perfect health based on mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (EuroQol-Group, 1990). One study showed that guided self-help for BED was likely to be cost-effective compared to treatment-as-usual, with an estimated willingness-to-pay per QALY gained of around €50,000 (König et al., 2018).

No study has yet provided an economic evaluation of web-based guided self-help CBT-E for BED compared to a waiting list. Guided self-help CBT-E has the potential to offer treatment at an earlier stage and with reduced therapist involvement (Crow et al., 2013) instead of waiting for treatment. The average wait time for an initial intake session is 11 weeks, and a further 20 weeks for treatment in the Netherlands (NZA, 2022). Hence, the current practice is actually very similar to our waiting list condition. Therefore, the comparison of guided self-help CBT-E to a waiting list allows us to examine the differences in costs and effects between the current practice with a waiting period before treatment can commence and the direct start of treatment through guided self-help CBT-E. Like in studies with a comparable design, costs of guided self-help CBT-E between the start and end-of-treatment are expected to be higher compared to waiting for treatment (Titov et al., 2015). These costs are expected to stem from the intervention (mainly therapist time). Patients in the experimental condition are not expected to show less absenteeism from work compared to waiting for treatment. In addition, other studies showed that during the intervention there were no differences in presenteeism and absenteeism between the experimental and waiting list control groups. However, after the intervention, the costs decreased in the intervention groups compared to the waiting list control groups (Andersson et al., 2011; Hedman et al., 2013; Ljótsson, 2011).

The aim of the present economic evaluation is to determine the cost-effectiveness (costs per binge prevented) and cost-utility (costs per QALY gain) of web-based guided self-help CBT-E for BED as compared to a waiting list control condition. This will be measured alongside a randomized controlled trial (RCT) primarily examining the efficacy of guided self-help CBT-E. The economic evaluation will be performed from a societal perspective, covering the effects and various healthcare and societal costs related to guided self-help CBT-E on the whole of society. It is expected that from a societal perspective, guided self-help CBT-E will be more effective (binge-eating episodes prevented and increase in quality-of-life) compared to waiting for treatment. This will come at higher costs, which are associated with the guided self-help CBT-E intervention.



2 | METHODS

2.1 | Design

This economic evaluation of guided self-help CBT-E was performed using data obtained from a two-arm efficacy RCT among patients with BED or other specified feeding or eating disorder (OSFED)-BED. The study protocol (van den Berg et al., 2020) and efficacy were published elsewhere (Melisse et al., 2023). Allocation was balanced (1:1) to either (i) guided self-help CBT-E (N = 106) or to (ii) a waiting list with a delayed treatment control condition (N = 106). Participants (N = 180) were recruited to take part in the efficacy study (Melisse et al., 2023). However, the first 51 participants were not administered the questionnaire on healthcare utilization and productivity losses (TiC-P; Hakkaart-van Roijen et al., 2002). Therefore, their data could not be used for the economic evaluation. Hence, an additional 83 participants were recruited (N = 212). The economic evaluation will focus on the 3-month phase before the wait-listed participants received guided self-help CBT-E. The study is registered with the Netherlands Trial Registry (NTR7994), and approved by the Medical Research Ethics Committees United (NL6958.100.19). The economic evaluation was performed and reported in line with the CHEERS (Husereau et al., 2013) and the ISPOR guidelines (Ramsey et al., 2015).

2.2 | Procedure

Eligible patients referred to the Novarum Center for eating disorders (part of Arkin Mental Healthcare) were invited to participate in the study. After the patients signed the informed consent, a baseline assessment was administered to assess for exclusion criteria, and to measure the severity of BED. Patients who met all inclusion and no exclusion criteria were randomly allocated to the guided self-help CBT-E or waiting list control condition. Randomization was performed in Castor EDC (CASTOR, n.d.) by a 4,6,8 block design, and stratified for body mass index (BMI: kg/m²) below 29.9 or above 30. Study allocation and treatment appointments were confirmed by email and those randomized to guided self-help CBT-E were informed on how to use the digital treatment environment. The time horizon was 3 months: assessments took place at baseline (Week 0) and at 3 months postrandomization by interview and self-report questionnaires. Interviews were held by phone, and self-report measures were administered on the web, both of which were processed in Castor EDC (https://www.castoredc.com), which is ISO 27001/27002/9001 and NEN7510 certified. Nonresponders were repeatedly contacted by phone. Participants received a €10 gift card after completion of the posttreatment assessments.

2.3 | Participants and recruitment

Eligible patients were >18 years old, diagnosed with BED or OSFED-BED (APA, 2013) and $19.5 \ge BMI \le 40$. They also had internet access,

a desktop or laptop computer, and sufficient proficiency in Dutch. Exclusion criteria were acute psychosis, clinical depression, and/or suicidal ideation, as assessed by the Dutch version of the semi-structured interview SCID-5-CV (First et al., 2016), eating disorders other than BED/OSFED-BED, having received eating disorder treatment in the past 6 months, pregnancy or use of medication that might influence eating behavior. The inclusion period was September 2019–December 2020.

2.4 | Intervention

All 17 therapists completed a web-based CBT-E training provided by the Centre for Research on Eating Disorders at Oxford, United Kingdom (Fairburn, 2008), before they attended a 2-day workshop provided by authors B.M. and M.d.J. Weekly 45-min supervision sessions with B.M. were offered to ensure protocol adherence. Therapists self-rated their level of adherence after each session ("O:not at all" to "5:excellent"), 94.7% of all sessions obtained the maximum score of adherence.

Guided self-help CBT-E is a 3-month program and is a translated, digitalized version of part two of the self-help book *Overcoming Binge Eating* (Fairburn, 2013). Further details regarding the intervention are described elsewhere (Melisse et al., 2023; van den Berg et al., 2020). The intervention started in the same week as the baseline assessment. Before they commenced treatment, patients were instructed to read the psychoeducational section of the Dutch version of *Overcoming Binge Eating* (Fairburn, 2013). The intervention included psychoeducation, daily assignments, and two weekly self-evaluations. Feedback on the assignments was given during 13 weekly telephone sessions of 20 min. In the sessions, completed assignments were discussed, as well as upcoming assignments and compliance with treatment. The sessions were scripted in accordance with the treatment manual as developed by E.v.d.B. and B.M. and offered by therapists.

Patients in the waiting list group commenced treatment with a 3-month delay. They were instructed to read the psychoeducational section of *Overcoming Binge Eating* (Fairburn, 2013), and were called once for a 10-min conversation in which questions about the recommended reading, BED, and other important areas of life were answered.

2.5 | Outcomes

2.5.1 | Effect measures

The primary outcome measure for the cost-effectiveness analysis was the number of binge-eating episodes during the last 28 days, as measured by the eating disorder examination (EDE) (Cooper & Fairburn, 1987; Jansen, 2000), a semi-structured interview, with good psychometric properties (Cooper & Fairburn, 1987; Jansen, 2000; Rosen et al., 1990).

The outcome measure for the cost-utility analysis was the number of QALYs gained between randomization and posttreatment. To calculate QALYs, quality-of-life was measured using the Dutch three-level variant of the five-dimensional EuroQol instrument (EQ-5D-3L)

(EuroQol-Group, 1990), which has good psychometric properties (Janssen et al., 2013; Rabin & de Charro, 2001). The EQ-5D-3L determines health-related quality-of-life based on five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each dimension one of three levels is chosen: "no problems," "some problems," and "extreme problems" (Dolan, 1997). The Dutch tariff (Lamers et al., 2005) was used to translate the EQ-5D-3L score to health utilities: utility weights were assigned which reflected the patient's health state between 0 (death) and 1 (perfect health). One QALY corresponds to 1 year of living in perfect health; for the calculation of QALYs gained or lost for each individual, the studies' time horizon of 3 months was taken into account.

2.5.2 | Resource use and valuation

The costs of offering the intervention were based on Dutch standard prices in Euros (Zorginsituut, 2016). The costs of delivery of guided self-help CBT-E were based on (i) direct contacts between patients and therapists, and (ii) indirect contacts, which involved consultations between therapists concerning the patients. All contacts within Arkin were derived from the patients' electronic health records from Arkin

Mental Healthcare. Other care received by the patients included all types of healthcare such as inpatient mental healthcare, outpatient mental healthcare (other than within Arkin), other healthcare such as physiotherapy and alternative medicine, and the use of medication. Healthcare contact data that could not be derived from the patients' electronic health records were collected by the first section of the Questionnaire on healthcare Consumption and productivity loss in patients with a psychiatric disorder (TiC-P) at pretreatment and posttreatment (Bouwmans et al., 2013; Hakkaart-van Roijen et al., 2002, 2011). The TiC-P has a 4-week recall period, and in line with Hakkaart-van Roijen et al. (2015), TiC-P data were extrapolated to the 3-month intervention period. All healthcare resource utilization was valued based on Dutch standard unit cost prices in Euros (Zorginsituut, 2016). The number of healthcare contacts were multiplied by Dutch standard unit costs, and medication costs were calculated by multiplying the reported drug dose with its unit cost price (Drost et al., 2014; Medicijnkosten, 2020; Zorginsituut, 2016).

Non-healthcare-related costs such as productivity losses, decreased functioning professionally, and reduced efficiency of paid and unpaid work (presenteeism) were measured by the second section of the TiC-P (Bouwmans et al., 2013; Hakkaart-van Roijen et al., 2002, 2011). The 4-week recall period was extrapolated to the

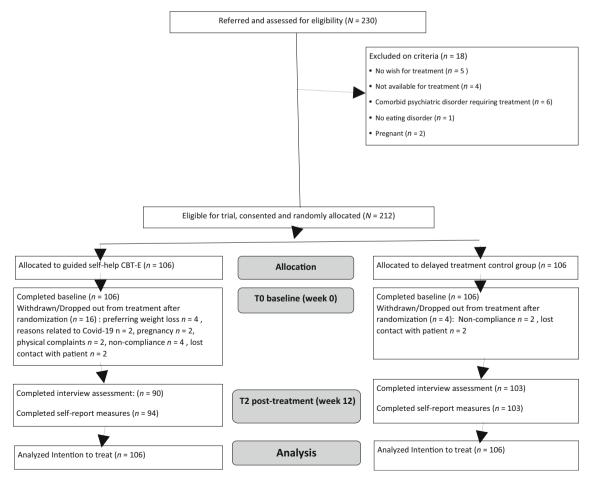


FIGURE 1 Flowchart of patients in the study. CBT-E, cognitive behavior therapy-enhanced.

TABLE 1 Patient characteristics at baseline.

	Total sample (N = 212)	Experimental condition ($n = 106$)	Waiting list condition ($n = 106$)
Age, mean (SD)	38.7 (13.3)	38.0 (13.4)	39.4 (13.2)
Baseline BMI, mean (SD)	33.4 (5.7)	33.4 (6.3)	33.5 (5.0)
Gender, n (%)			
Women	190 (91.1%)	95 (89.6%)	95 (89.6%)
Men	22 (9.9%)	11 (10.4%	11 (10.4%)
Highest level of education, n (%)			
Lower vocational education	4 (1.9%)	2 (1.9%)	2 (1.9%)
Lower general secondary education	16 (7.5%)	6 (5.7%)	10 (9.4%)
Senior general secondary education/university preparatory education	23 (10.8%)	13 (12.3%)	10 (9.4%)
Secondary vocational education	59 (27.8%)	28 (26.4%)	31 (29.2%)
Higher professional education	70 (33.0%)	37 (34.9%)	33 (31.1%)
University	38 (17.9%)	18 (17.0%)	20 (18.9%)
Unknown	2 (0.9%)	1 (0.9%)	1 (0.9%)
Profession, n (%)			
Student	22 (10.4%)	13 (12.3%)	9 (8.5%)
Employed	139 (65.5%)	63 (59.4%)	76 (71.7%)
Volunteer job	4 (1.9%)	3 (2.8%)	12 (0.9%)
Unemployed	15 (7.1%)	5 (4.7%)	10 (9.4%)
Other	31 (14.5%)	21 (19.8%)	10 (9.4%)
Unknown	1 (0.5%)	1 (0.9%)	0 (0.0%)
Civil status, n (%)			
Single	123 (58.0%)	59 (55.7%)	64 (60.4%)
Registered partnership	18 (8.5%)	10 (9.4%)	8 (7.5%)
Married	56 (26.4%)	30 (28.3%)	26 (24.5%)
Divorced	14 (6.6%)	6 (5.7%)	8 (7.5%)
Unknown	1 (0.5%)	1 (0.9%)	0 (0.0%)
Duration of eating disorder (years), mean (SD)	22.6 (14.6)	21.9 (14.7)	23.3 (14.6)
Eating disorder treatment in the past, n (%)			
Yes	34 (16.0%)	14 (13.2%)	20 (18.9%)
No	177 (84.0%)	91 (85.8%)	86 (81.1%)
Comorbid diagnosis, n (%)			
No	91 (42.9%)	45 (42.5%)	46 (43.4%)
I do not know	30 (14.2%)	14 (18.0%)	14 (13.2%)
Mood disorder	32 (15.01%)	14 (13.2%)	18 (17.0%)
Anxiety disorder	7 (3.3%)	4 (3.8%)	3 (2.8%)
Attention deficit (hyperactive) disorder	14 (6.6%)	7 (6.6%)	7 (6.6%)
Posttraumatic stress disorder	8 (3.8%)	4 (3.8%)	4 (3.8%)
Personality disorder	10 (4.7%)	6 (5.7%)	2 (2.5%)
Autism	7 (3.3%)	6 (7.5%)	1 (0.9%)
Obsessive compulsive disorder	1 (0.5%)	1 (0.9%)	
Other	18 (8.5%)	8 (7.5%)	10 (9.4%)
Use of psychopharmacology, n (%)			
Yes	53 (25.5%)	25 (23.6%)	28 (26.4%)
No	158 (74.5%)	80 (75.5%)	78 (73.6%)
No	158 (74.5%)	80 (75.5%)	78 (73.6%)

	Total sample $(N = 212)$	Experimental condition ($n = 106$)	Waiting list condition ($n = 106$)
Eating disorder pathology (EDE), M (SD)			
Global score	3.1 (1.0)	3.1 (0.9)	3.1 (0.9)
Objective binge episodes ^a	59.5 (51.0)	47.1 (43.7)	53.3 (47.4)
Quality of life (Equation 5D NL), M (SD)	0.7 (0.2)	0.7 (0.2)	0.7 (0.2)
Healthcare costs in Euros, M (SD)		712 (1391)	578 (808)
Societal costs, ^b M (SD)	1706 (2639)	1930 (3034)	1483 (2245)

Abbreviations: BMI, body mass index; EDE, eating disorder examination; Equation 5D NL, Dutch three-level variant of the five-dimensional EuroQol instrument.

3-month intervention period. Hours of productivity loss were multiplied by the average hourly labor costs (women: €31.60, men: €37.90 in 2014) (Hakkaart-van Roijen et al., 2002; Zwaap et al., 2015). The friction cost method estimates the indirect costs of presenteeism and absenteeism and takes the possibility to replace long-term absentees into account. The friction cost method was used to value productivity losses (Koopmanschap et al., 1995). A maximum friction cost period of 85 days was applied based on the amount of open and filled vacancies as derived by the Dutch Authority of Statistics (Hakkaart-van Roijen et al., 2015). An elasticity factor of 0.8 was applied to correct for the fact that the reduction of labor time causes less than a proportional decrease in productivity (Koopmanschap et al., 1995). Future costs after randomization were not calculated since follow-up data could not be used as both groups received the same treatment when follow-up measures were conducted. Cumulative inflation correction up until the index year 2021 was applied, and Organisation for Economic Cooperation and Development (OECD) standard purchasing power parities for the study's index year 2021 (105% for the Netherlands) were applied to all costs (OECD, 2022).

2.6 | Sample size

The sample size was based on the expected effect on the primary outcome measure (reduction of binge-eating episodes; Melisse et al., 2023). To detect an effect size of Cohen's d=0.47 (Cohen, 1977; Hilbert et al., 2019) with sufficient power ($\beta=0.8$), the required sample size was at least N=144 (n=72 per arm), and N=180 (n=90 per arm) to correct for expected dropout. The sample size was calculated using the R package "pwr" (Champely, 2020).

2.7 | Statistical analyses

Main analyses were performed according to an intention-to-treat approach, with missing observations multiple-imputed (10 times). Imputations were performed with the multiple imputations by chained equations package in *R* (van Buuren & Groothuis-Oudshoorn, 2011),

using random forests as the prediction method; 10 iterations were sufficient to achieve convergence. Results from the analyses obtained from the 10 imputed datasets were combined using Rubin's rules (Rubin, 2004). The societal perspective of this economic evaluation was considered the base case scenario, including all costs (costs of guided self-help CBT-E, medication, all other healthcare costs, and of productivity gains/losses) for each patient. This analysis was repeated from a healthcare perspective only, in which productivity costs were excluded. Units of healthcare and productivity losses were multiplied by their associated costs for all patients. Differences in costs and effects between guided self-help CBT-E and the waiting list condition were calculated as the difference in cumulative costs (in Euros) and effects over the 3 months of the intervention.

Incremental cost-effectiveness ratio (ICER) was calculated as ICER = (costs guided self-help CBT-E - costs waiting list)/(effects guided self-help CBT-E - effects waiting list), where effects were QALYs gained or binge-eating episodes prevented. First, we applied multiple imputations to account for missing data. Next, we constructed (multilevel) regression models (with BMI as a confounder) for costs and effects separately. In these models, costs or effects were the dependent variables, a random intercept to account for the nesting of multiple (in this case, 2) measurements within participants was included in the model, as was a Time (baseline or 3 months after) × Condition (guided self-help CBT-E or waiting list) interaction term as well as the main effects for Time and Condition. For the corrected model, we also included baseline costs and effects in the model. From this regression model, we were interested in the regression coefficient for the Time \times Condition interaction term. Based on the estimate and standard deviation of this coefficient, a distribution of the incremental costs and incremental effects was created using random sampling (10,000 samples) under a normal distribution (main analysis).

As an alternative approach, 10,000 nonparametric bootstrapped samples were extracted from the imputed datasets (bootstrapped analysis). For each bootstrapped sample, incremental costs, incremental effects, and the ICER were calculated. The resulting costs, effects, and ICERs were used for further calculations and plotted on a cost-effectiveness plane to present the differences between the costs and

^aNumber of binge-eating episodes during the last 4 weeks extrapolated over the last 3 months before randomization.

^bPresenteeism and absenteeism over the last 3 months before randomization, costs in Euros.

effects of both conditions, of which the waiting list control condition is positioned in the origin of the cost-effectiveness plane. In addition, cost-effectiveness acceptability curves (CEACs) were plotted based on the distribution of the ICERs over the cost-effectiveness planes (van Hout et al., 1994) using the net benefit regression approach (base case). CEACs show the probability that the cost-effectiveness of guided self-help CBT-E is greater than a waiting list by a willingness-to-pay for each additional unit of effect (QALYs or binge-eating

episodes). Willingness-to-pay for each additional unit of effect generally ranges between $\[epsilon 20,000\]$ and $\[epsilon 80,000\]$ per QALY (Zwaap et al., 2015) in the Netherlands, and $\[epsilon 22-\[epsilon 10,000\]$ per binge-free day in the United Kingdom and the United States (Jenkins et al., 2021; Lynch et al., 2010).

In a sensitivity analysis, baseline measures of the dependent variables in the model were also included in the linear mixed models of the main costs analyses. We also conducted a healthcare perspective

TABLE 2 Costs and effects between baseline and 3 months after per cost category.

	Guided self-help CBT-E (n = 106)		Waiting list control condition ($n=106$)			
Cumulative costs in €	Mean	SD	Reported by n/106, %	Mean	SD	Reported by n/106, %
Outpatient mental healthcare within Novarum	1313.01	339.15	106, 100%	284.39	198.20	94, 88.7%
Other outpatient mental healthcare	144.38	805.19	22, 22%	81.15	221.54	211, 9.8%
Inpatient healthcare	0.14 ^a	4.441	0, 0%	42.54	214.02	6, 5.7%
Other healthcare	171.11	306.13	63, 59.4%	132.47	219.22	63, 59.4%
Medication	84.95	272.11	52, 49.1%	97.28	319.05	58, 54.7%
Overall healthcare costs ^b	1713.59	1136.97	106, 100%	637.85	541.46	106, 100%
Absenteeism	680.95	2082.27	19, 19.9%	561.32	1620.12	20, 18.7%
Presenteeism	306.43	856.83	28, 26.4%	369.69	769.34	33, 31.1%
Productivity ^c	985.02	2264.34	42, 39.6%	931.01	1757.01	45, 42.5%
Effects ^d						
Binge-eating episodes last 3 months	16.96	33.80	106, 100%	42.78	46.14	106, 100%
QALYs	0.02	0.06	106, 100%	-0.00	0.05	106, 100%

Note: Base case model, based on the imputed dataset.

Abbreviations: CBT-E cognitive behavior therapy- enhanced, QALY quality-adjusted life year.

TABLE 3 Incremental costs, effects, and ICER after 3 months of to guided self-help CBT-E (n = 106) or waiting list (n = 106).

Outcome ^a		Societal		Societal baseline corrected Mean (95% CI)	Societal complete cases Mean (95% CI)	Healthcare Mean (95% CI)
Inc	cremental costs ^a	679 (50-1330)	678 (50-1260)	679 (91-1288)	817 (190-1466)	893 (671-1123)
QALY						
QA	ALY ^b	0.02 (0.01-0.04)	0.02 (0.01-0.03)	0.01 (0.01-0.03)	0.02 (0.01-0.04)	0.01 (0.01-0.04)
ICE	ER ^c	34,463 (2494- 154,530)	33,911 (2426- 158,679)	34,404 (4461- 134,962)	34,457 (7582- 91,343)	45,206 (23,981- 186,654)
Binge-eating episodes						
	nge-eating episodes	38.2 (23.4–52.8)	38.1 (26.0-51.0)	38.2 (24.5-51.7)	42.1 (29.2-54.9)	38.2 (23.4-52.8)
ICE	ER ^c	18 (1-41)	18 (1-39)	18 (2-39)	19 (4-39)	23 (15-39)

Note: Based on the imputed dataset.

Abbreviations: CBT-E, cognitive behavior therapy-enhanced; CI, confidence interval; ICER, incremental cost-effectiveness.

^aCosts were reported by 0/106, 0% of the patients and stem from the multiple imputations.

^bOverall healthcare costs are the sum of all the healthcare costs mentioned above.

^cProductivity costs are the sum of costs stemming from absenteeism and presenteeism.

^dEffects extrapolated over the last 3 months.

^aDifferences reported in Euro's.

^bQALYs were measured by the Dutch three-level variant of the five-dimensional EuroQol instrument.

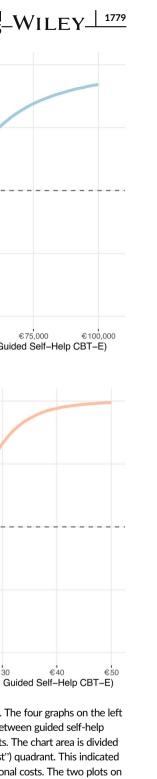
 $^{{}^{}c} Incremental \ cost-effectiveness \ ratios \ were \ calculated \ as: \ ICER = (costs \ guided \ self-help \ CBT-E-costs \ waiting \ list)/(effects \ guided \ self-help \ guided \ self-help \ list)/(effects \ guided \ self-help \ guided \ self-help \ list)/(effects \ guided \ self-help \ guided \ self-help \ list)/(effects \ guided \ self-help \ guided \ self-help \ guided \ self-help \ guided \ self-help \ list)/(effects \ guided \ self-help \ guided \ guided \ self-help \ guided \ guid$

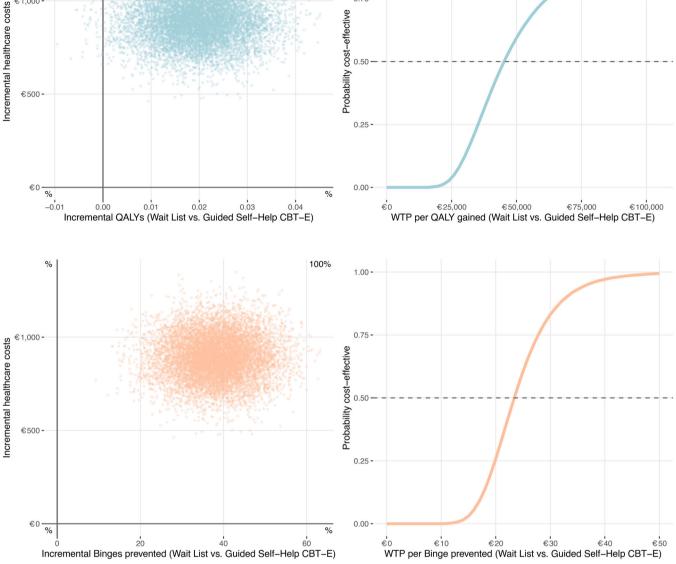
E – effects waiting list).

€1 000 -

€500**-**

0%





100%

1.00 -

0.75 -

Cost-effectiveness and cost-utility planes and acceptability curves from a societal and healthcare perspective. The four graphs on the left are cost-effectiveness planes. The horizontal axis indicated differences in binge-eating episodes prevented and QALY gains between guided self-help CBT-E and waiting for treatment over the 3 months course of treatment. The vertical axis represented the differences in costs. The chart area is divided into quadrants, each with a specific interpretation. All incremental cost-effectiveness ratios fell into the upper right ("northeast") quadrant. This indicated that guided self-help CBT-E generated a greater number of binge-eating episodes prevented and greater QALY gain at additional costs. The two plots on the right were cost-effectiveness acceptability curves. These curves show the probability that guided self-help CBT-E is cost-effective compared to waiting for treatment as a function of the willingness-to-pay for one additional unit of effect, represented as one additional binge prevented or one QALY gained. The probability of .50 on the vertical axis indicated the point of indifference. Above the point of indifference, guided self-help CBT-E has a greater likelihood to be preferred over waiting for treatment with regard to cost-effectiveness (with a likelihood equal to the probability on the vertical axis). As the exact willingness-to-pay per effect, unit is generally unknown, willingness-to-pay is presented as a series of increments on the horizontal axis. CBT-E, cognitive behavior therapy-enhanced; WTP, willingness-to-pay.

scenario analysis, in which only healthcare-related costs were taken into account. As a final sensitivity analysis, we assessed the impact of missing data on our results by performing the analyses using a dataset without imputed values (i.e., comprising only the observed data). Analysis was performed in R version 4.2.1, Ime4 package in R (Bates et al., 2015), and SPSS version 28.

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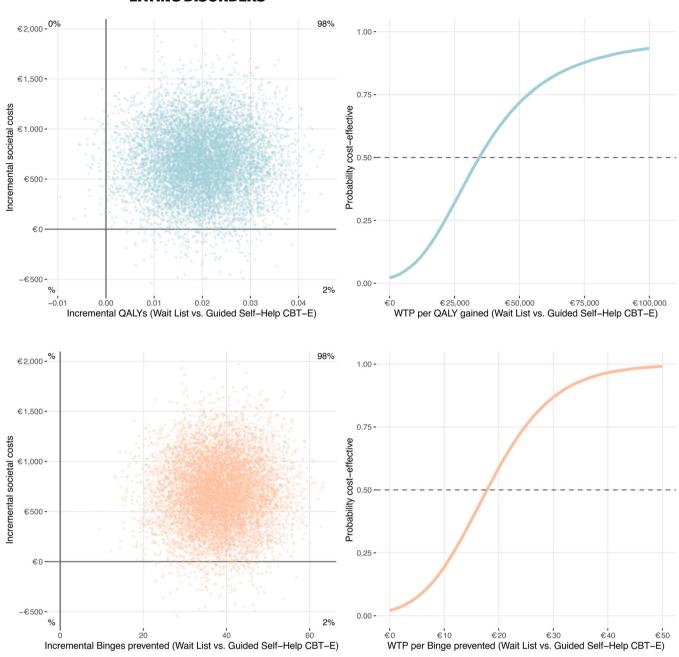


FIGURE 2 (Continued)

3 | RESULTS

3.1 | Participants

For the current study, 230 potential participants were recruited, of which 212 were randomized; n=18 did not meet in or met exclusion criteria; n=208 were diagnosed with BED, n=4 had a history of bariatric surgery, had smaller binge-eating episodes and were therefore diagnosed with OSFED-BED. Figure 1 shows participant enrollment and study flow; Table 1 summarizes participant characteristics at baseline.

 $\label{eq:constraint} \text{Dropout} \quad \text{from} \quad \text{treatment} \quad \text{(i.e., nonadherence)} \quad \text{was} \quad 15.1\%$ (n=16/106) in the guided self-help CBT-E and, 3.7% (n=4/106) in

the waiting list. Nonresponse for the measurements (i.e., nonadherence to complete the assessments) at 3 months was 15.1% (n=16/106) in the experimental condition and, 2.8% (n=3/106) in the waiting list. Therefore, the overall study's measurement nonresponse was 8.9%.

3.2 | Costs

Table 2 shows the costs and effects during the 3-month trial (from pretreatment to posttreatment). The only difference in costs between both conditions was found for outpatient mental healthcare costs (p = .009). Mean overall costs were higher in the guided self-help

CBT-E condition; the difference in societal costs (p = .095) was ϵ 679 (95% confidence interval [CI] 50–1330). The differential healthcare costs (p < .001) were ϵ 893 (CI 671–1123).

3.3 | Effects

Based on the linear mixed models in which the effect outcomes were evaluated between baseline and 3 months postbaseline, a significant Time \times Group interaction for QALYs (B=0.020, CI 0.01-0.03, p=.009) as well as for a number of binge-eating episodes (B=-38.212, CI 2.4-31.6, p<.0005) was found in the uncorrected model. In the baseline-corrected model, the Time \times Group interaction term for QALYs was also significant (B=0.020, CI 0.01-0.03, p=.006), as was the Time \times Group interaction term for the number of binge-eating episodes (B=-38.512, CI 3.5-30.5, p<.0005). See also Table 2 for descriptives of costs and effects. These effects indicated that the decline in a number of binge-eating episodes was stronger in the guided self-help CBT-E condition than in the waitlist condition, as well as the increase in the number of QALYs.

3.4 | Cost-effectiveness and cost-utility

The results of the cost-effectiveness and cost-utility analyses are presented in Table 3, Figure 2 presents the cost-effectiveness planes and the CEACs. The cost-effectiveness analysis over the 3-month trial showed that from a societal perspective, the incremental costs associated with one incremental binge prevented in the guided selfhelp CBT-E condition (ICER) was approximate €18 (CI 1-41); this was €23 (Cl 15-39) from a healthcare perspective. Figure 2 (northeast quadrant) shows that from a societal perspective, there was a 96% likelihood that guided self-help CBT-E led to a greater number of binge-eating episodes prevented at additional societal costs compared to the control condition. There was a 4% likelihood that guided self-help CBT-E led to a greater number of binge-eating episodes prevented at lower societal costs compared to the waitlist (southeast quadrant). From a healthcare perspective, there was a >99% likelihood that guided self-help led to a greater number of binge-eating episodes prevented than the control condition, at higher healthcare costs (northeast quadrant).

The cost-utility analyses from a societal perspective (Table 3, Figure 2) indicated an ICER of $\ensuremath{\in} 34,463$ (CI 2494–154,530). There was a 95% likelihood that guided self-help CBT-E led to a larger QALY gain at higher societal costs than the control condition (northeast quadrant) (Figure 2). Based on the National Institute for Health and Clinical Excellence (NICE) (2023) willingness-to-pay threshold of $\ensuremath{\in} 35,000$ per QALY, guided self-help CBT-E would be slightly preferable over the waitlist in terms of cost-effectiveness. Figure 2 (northeast quadrant) shows that from a healthcare perspective, there was a >99% likelihood that guided self-help led to a larger QALY gain at higher costs than the waitlist control condition.

3.5 | Sensitivity analyses

The robustness of the results was attested since the results of the sensitivity analyses were similar to those of the primary analyses, as can be observed from Table 3.

4 | DISCUSSION

4.1 | Main findings

This study examined the cost-effectiveness and cost-utility of guided self-help CBT-E versus a waiting list for BED over a period of 3 months using data from the initial phase of an RCT. Key findings were that guided self-help CBT-E led to greater QALY gain, and a greater number of binge-eating episodes prevented compared to waiting for treatment. There was a >96% likelihood that guided selfhelp CBT-E led to more binge-eating episodes prevented, but at higher costs. Based on the NICE willingness-to-pay threshold of €35,000 per QALY (NICE, 2023), and the Dutch willingness-to-pay threshold of €80,000 for severe diseases (Zwaap et al., 2015), guided self-help CBT-E would be preferable by the Dutch society in terms of cost-effectiveness compared to a waiting list during the first 3 months and can be seen as a reasonable investment for the Dutch healthcare system. In addition, willingness-to-pay per QALY gain was lower in the current study than in another study which found a willingness-topay of €50,000 for guided self-help CBT for BED (König et al., 2018). There were no differences in costs between the two conditions, except for outpatient mental healthcare costs (associated with the intervention provided to the experimental group). The results remained stable in the sensitivity analyses, supporting the robustness of the findings.

Previously, only two studies evaluated the cost-effectiveness of guided self-help interventions for binge eating (König et al., 2018; Lynch et al., 2010) with smaller sample sizes ($N \le 150$) than the present study. However, the strength of these studies was that they represented a longer timeline than the current study as guided selfhelp was compared to treatment-as-usual. One study analyzed the cost-effectiveness of a guided self-help intervention based on the book Overcoming binge eating accompanied by eight in-person sessions among patients with subsyndromal BED. Treatment-as-usual consisted of advising patients on other treatment options. The intervention appeared cost-effective, however, that study used a nonstandardized measure to examine quality-of-life (Lynch et al., 2010). Another study compared CBT to guided self-help CBT among patients with BED and subsyndromal BED. The results of this study were inconclusive since guided self-help CBT led to greater QALY gain, whereas CBT led to a greater reduction in binge eating at end-oftreatment (König et al., 2018). However, the findings of the current study are in line with the few studies available which indicated that guided self-help interventions for binge eating are reasonable investments compared to in-person CBT or no treatment (König et al., 2018; Lynch et al., 2010).



4.2 Limitations and strengths

The most significant limitation is the time horizon of 3 months. Since patients randomized to the waiting list also received guided self-help CBT-E during follow-up, a comparison of cost-effectiveness and costutility was not possible after 3 months. This precluded an evaluation of the long-term effectiveness as well as the costs of guided self-help CBT-E as compared to no treatment. A different study design, with a comparison to a treatment-as-usual control condition (e.g., in-person CBT-E), would have enabled an economic evaluation with a longer time horizon, which is recommended for future research. In addition, a comparison to treatment-as-usual or another active comparator instead of a waiting list would better reflect what normally would happen in the absence of guided self-help CBT-E (Richards et al., 2020). Furthermore, the sample size was based on the efficacy analysis, and not on the cost-effectiveness analysis, as is often the case for economic evaluations performed alongside economic trials.

Therapists' protocol adherence was only measured by self-report, whereas adherence assessment by an independent rater would yield more valid information (Lopez-Alcalde et al., 2022). An alternative could be the adherence checklist for CBT-E which has recently become available (Bailey-Straebler et al., 2022). Last, although patient's electronic files were used to establish all mental healthcare costs of patients within the Arkin Foundation, other cost data were based on patients' self-report over the last 3 months which may have been affected by recall bias. However, to reduce the potential impact of recall bias, healthcare utilization and a number of binge-eating episodes were measured over the month before the assessment and extrapolated over 3 months between the assessments. Furthermore, recall bias probably led to an underestimation of the number of binge-eating episodes (Berg, Peterson, et al., 2012), therefore extrapolation might also have affected the measurement of binge-eating episodes.

This study has several strengths. This is the first study to perform an economic evaluation selectively including patients with full syndrome BED. Furthermore, the sample size was larger than in previously conducted studies, providing adequate statistical power to find differences between the two compared groups of patients. Study dropout of <10% was low and multiple imputation was performed to handle missing data. Patients were an accurate representation of BED patients in the Netherlands. The EDE interview (Cooper & Fairburn, 1987; Jansen, 2000), is considered the gold standard to measure binge-eating episodes, as especially patients with BED show a marked discrepancy between the self-reported and investigator-based number of binge-eating episodes (Berg, Stiles-Shields, et al., 2012; Melisse, van Furth, et al., 2022).

CONCLUSIONS 5

Guided self-help is an internationally recommend treatment for BED, but was previously not available in the Netherlands. The current study findings may stimulate consideration of alternatives to the traditional mode of in-person delivery of CBT-E. Future studies should compare the efficacy and cost-effectiveness of guided self-help CBT-E to in-person CBT-E. This will enable

comparisons over a longer timeline and further enhance decisionmaking on where the scarce resources should be allocated, and where they offer the best value for money (Konnopka et al., 2009; Stuhldreher et al., 2012). In conclusion, guided self-help CBT-E appeared the preferred treatment in terms of cost-effectiveness compared to a waiting list for patients with BED. However, longterm data are necessary to establish the long-term efficiency and cost-effectiveness of this treatment mode.

AUTHOR CONTRIBUTIONS

Bernou Melisse: Conceptualization; data curation; formal analysis; investigation; methodology; project administration; resources; software; supervision; writing - original draft. Matthijs Blankers: Conceptualization; formal analysis; writing - review and editing. Elske van den Berg: Funding acquisition; project administration. Margo de Jonge: Conceptualization; writing - review and editing. Nick Lommerse: Data curation; writing - review and editing. Eric F. van Furth: Writing - review and editing, Jack Dekker: Conceptualization: writing - review and editing, Edwin de Beurs: Supervision; writing - review and editing.

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FUNDING INFORMATION

Not applicable.

CONFLICT OF INTEREST STATEMENT

There are no conflicting interests.

OPEN RESEARCH BADGES





This article has earned Open Data, Open Materials and Preregistered Research Design badges. Data, materials and the preregistered design and analysis plan are available at [[insert provided URL(s) on the Open Research Disclosure Form]].

DATA AVAILABILITY STATEMENT

Upon reasonable request with Bernou Melisse.

ETHICS STATEMENT

Study approval was given in August 2019 by the Medical Research Ethics Committees United (MEC-U) (reference number NL 6958.100.19) in Nieuwegein, the Netherlands. All patients were informed about the

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