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Modified cue exposure for adolescents with binge eating behaviour: study protocol of a randomised pilot trial called EXI$_{(ea)}$T

Hanna Preuss-van Viersen [iD],[1] Inken Kirschbaum-Lesch,[2] Jasmina Eskic [iD],[1] Sophie Lukes,[1] Jana Pydd,[2] Laura Derks,[2] Florian Hammerle [iD],[1] Tanja Legenbauer[2]

[1]Department of Child and Adolescent Psychiatry and Psychotherapy, University Medical Center of the Johannes Gutenberg University Mainz, Mainz, Germany
[2]LWL-University Hospital for Child and Adolescent Psychiatry, Psychotherapy and Psychosomatic Medicine, Ruhr University Bochum, Hamm, Germany

Correspondence to
Dr Hanna Preuss-van Viersen; hannamaren.preuss@unimedizin-mainz.de

ABSTRACT

Introduction Binge eating (BE) behaviour is highly prevalent in adolescents, and can result in serious metabolic derangements and overweight in the long term. Weakened functioning of the behavioural inhibition system is one potential pathway leading to BE. Food cue exposure focusing on expectancy violation (CE$_{EV}$) is a short intervention for BE that has proven effective in adults but has never been tested in adolescents. Thus, the current randomised pilot trial evaluates the feasibility of CE$_{EV}$ for adolescents and its efficacy in reducing eating in the absence of hunger (EAH) of binge food items.

Methods and analysis The trial will include N=76 female adolescents aged between 13 and 20 years with a diagnosis of bulimia nervosa, binge eating disorder (BED) or their subthreshold forms based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). Participants will be randomly assigned to two sessions of CE$_{EV}$ or behavioural analysis (BA), a classical cognitive–behavioural therapy-based intervention. The primary endpoint is the change in EAH measured according to ad libitum consumption of personally preferred binge food in a bogus taste test at post-test based on the intention-to-treat population. Key secondary endpoints are changes in EAH of standardised binge food at post-test, in EAH at 3-month follow-up (FU) and in food craving after induction of food cue reactivity at post-test and FU. To identify further valid outcome parameters, we will assess effects of CE$_{EV}$ compared with BA on global ED psychopathology, BE frequency within the last 28 days, body weight, response inhibition and emotion regulation abilities. Treatment groups will be compared using analysis of covariance with intervention as fixed factor and body mass index at baseline as covariate.

Ethics and dissemination This clinical trial has been approved by the Ethics Review Committee of the Medical Association of Rhineland-Palatinate and the Medical Faculty of the Ruhr-University Bochum. The collected data will be disseminated locally and internationally through publications in relevant peer-reviewed journals and will be presented at scientific and clinical conferences. Participants data will only be published in an anonymised form.

Trial registration number DRKS00024009.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ EXI$_{(ea)}$T is a randomised pilot trial comparing cue exposure with expectancy violation (CE$_{EV}$) to behavioural analysis of binge eating (BE) episodes, the gold standard intervention of cognitive–behavioural therapy.

⇒ CE$_{EV}$ is informed by previous evidence in adults with BE episodes and youth with obesity integrating age-appropriate material for a transdiagnostic adolescent sample.

⇒ The multimodal assessment approach uses an objective measure as the primary outcome, ad libitum food intake.

⇒ As a multicentre trial, EXI$_{(ea)}$T enables a generalisation of the proof-of-concept, and contributes to quality assurance in the cooperating centres.

⇒ Due to the short follow-up period of 3 months, no conclusions about the long-term efficacy of CE$_{EV}$ for eating disorder psychopathology and body weight can be drawn.

INTRODUCTION
Binge eating in adolescents

Binge eating (BE) behaviour refers to recurrent episodes of impulsive overeating accompanied by the feeling of loss of control over eating. About 18% of 16-year-old adolescents reported BE as a single symptom at least sometimes, 8.5% even weekly during the last year.[1 2] BE is a core feature of both bulimia nervosa (BN) and binge eating disorder (BED), which show high prevalences of 0.9% to 3% (BN) and 1.3% to 5% (BED) in youth with overweight.[3–5] However, the majority of affected youth do not seek treatment as they associate BE with shame and guilt, leading to a long illness duration (8–14 years) and to a persistence of adverse outcomes into adulthood.[5 6]

Available first-line treatments for BE-related disorders in youth are mostly based on

'enhanced' cognitive–behavioural therapy for EDs (CBT-E).[7] Behavioural analysis (BA) of BE episodes is among the gold standard interventions within CBT-E, and focuses on early symptom changes.[8] CBT-E has been shown to be effective in achieving BE abstinence in almost 50% of patients with BN, but remission rates are lower in youth than in adults, for example, 29% remitted.[9] Initial findings for CBT-E in adolescents with BED suggest that abstinence rates are comparable to those in adults, ranging between 43% and 61%.[10 11] Given the higher number of early responders in CBT-E compared with other therapy approaches, BA can be seen as at least partially responsible for the rapid therapeutic effects.[12 13]

In sum, at least 50% of youth continue to have BE episodes or certain impulsive eating behaviour patterns as residual symptoms at the end of treatment. One reason for this might be that the direct underlying mechanism—food-related inhibitory control deficits—is rarely targeted in conventional treatment programmes.

Inhibitory control as an underlying mechanism

Recent studies emphasise an association of BE with self-reported impulsivity and behaviourally measured inhibitory control deficits.[14 15] Inhibitory control is conceptualised as the ability to inhibit impulsive responses in order to select a more value-based functional behaviour, for example, eating out of deliberate pleasure instead of impulsivity.[16] Response inhibition in general, and towards food stimuli might be impaired in adults with bulimic-type EDs,[17] although evidence for adolescents with BE is predominantly only available for non-clinical samples.[18 19] Moreover, a recent study revealed that adolescents with obesity and BED displayed a poorer inhibition performance compared with normal-weight adolescents,[20] although the study did not allow for any conclusions on stimulus specificity. Studies examining samples with overweight have yielded contradictory findings: While one study reported that children were less effective in food-specific response inhibition,[21] we found that adolescent psychiatric inpatients showed a rather generally impaired inhibitory control irrespective of ED pathology.[22] Analogous to adults, it can be assumed that there is a specific subgroup of youth with impulsive eating patterns and inhibitory control deficits, presumably more generalised based on their current stage of development.

In this framework, the dual-pathway model by Hofmann and colleagues[23] postulates that BE is controlled via two processes—(1) automatic, unconscious processes and (2) reflexive, conscious processes. Automatic responses to food stimuli are primarily associated with the rewarding component of impulsive behaviour. This appetitive responding may be related to reward sensitivity and food-related inhibition deficits and is based on a heightened reactivity to palatable food cues or non-food cues that signal the availability of tempting food, that is, food cue-reactivity.[24 25] In turn, top-down processes primarily involve executive functions such as emotion regulation and general inhibition abilities and are designed to counteract automatic behaviour.[26 27] A weakened reflexive system can be over-ridden by strong impulsive reactions to appetitive food stimuli, resulting in food craving and BE. Crucially, the impaired inhibitory control seems to be met with a hyper-responsive reward system due to neuro-adaptive changes in reward circuits (see maintenance model for BE).[28]

In line with the dual-process model, recent findings have highlighted the interaction between emotion regulation and inhibitory control in terms of predicting BE.[29 30] In an adult sample with self-reported ED symptoms, eating expectancies mediated the relationship between emotion regulation difficulties and BE, but only in individuals with reward-based inhibition deficits.[30] Moreover, adolescents with poor self-reported inhibition experienced more uncontrolled eating, but only in the case of a negative mood.[31]

In sum, food-related inhibitory control deficits might act as an underlying perpetuating mechanism of BE, but studies examining interventions to address these deficits are lacking. So far, research has not identified an intervention for impulsive eating behaviour that integrates food stimuli and has proven to be superior to other approaches.[10 32]

Inhibitory learning approach to exposure

One option to improve food-related inhibitory control is food cue exposure (CE), that is, exposure to typical binge food and its stimulus characteristics, such as the taste or smell of a food, while preventing food consumption. The effect of CE on BE is often measured by the intake of palatable foods in laboratory paradigms, that is, eating in the absence of hunger (EAH) in line with Birch and colleagues.[33]

Researchers have discussed two potential working mechanisms for CE in the area of BE: habituation and inhibitory learning. Initially, CE was seen as classical extinction training derived from principles of learning theory. Treatment manuals postulating habituation as a rationale recommend that patients focus on their desire to eat on a psychological and physiological level, while food stimuli (conditioned stimuli, CS) are presented in order to reduce food cue reactivity (conditioned appetitive responses, CR) via in-session habituation.[34] Since the 1980s, CE with habituation has mainly been researched for the treatment of BN, although over the years, this intervention was forgotten somewhat due to the complexity of implementing it in clinical practice.[35–38]

Recently, CE has been experiencing a revival in the treatment of BN and BED, with inhibitory control being used as rationale.[39–41] Research in anxiety disorders suggests that repeated exposure creates a new inhibitory association such that binge food then also signals the non-availability of the unconditioned eating response, that is, a new CS-no unconditioned stimulus (noUS) pairing.[42] To enhance inhibitory learning in CE, sessions should be designed so as to maximise the discrepancy between the expectancy of overeating and what really happens,

namely no overeating.[43] Magson and colleagues[44] even assume that habituation occurs because of inhibitory learning—if patients are exposed to food in such a way that their CS-US expectancies are not violated, no habituation processes will occur and they will be vulnerable to relapses. This assumption is also in line with observations that habituation within and between sessions, that is, desire to eat, is not beneficially related to EAH and weight loss,[39 43 45] whereas changes in expectancies were found to mediate treatment success regarding EAH.[43] Accordingly, CE should optimise the violation of idiographic beliefs about eating behaviour when confronted with the relevant binge food (eg, 'If I have milk chocolate next to me when I am sitting alone doing my homework, I have to eat the whole bar.'). In CE with expectancy violation (CE_{EV}), these beliefs are checked against what actually happens, that is, the feared BE does not occur, which may strengthen the inhibitory pathway (eg, 'If I have milk chocolate […], I am able to resist eating the whole bar.'). Moreover, there is evidence that different impulsive response domains (affective, cognitive and behavioural) exist and improvements in one domain in turn favour inhibition control in the other two domains.[46] It can be assumed that there is an improvement in self-efficacy through the implementation of positive expectations, such as being able to resist binge foods (cognitive self-control) and, with a delay, also an improvement in affective and behavioural self-control. Consequently, possible underlying mechanisms of change such as emotion regulation abilities and inhibitory control will be altered due to their interactions with BE expectancies.[29–31]

Food cue exposure with expectancy violation influencing BE

A recent review[44] included 16 studies that investigated CE in adults with BE, 3 of which focused on expectancy violation.[39 43 45] Regardless of its focus, CE significantly reduced overeating expectancies, desire to eat and EAH as measured by kcal consumption during a subsequent bogus taste test (BTT).[39] In addition, relative to a lifestyle intervention, CE_{EV} was more effective in reducing the number of BE episodes and also in reducing weight from baseline to 3-month follow-up (FU) in women with overweight ($d=0.67$ and $d=0.65$).[43] Moreover, EAH for exposed food decreased significantly in CE_{EV} ($d=0.35–0.81$),[45] but this finding did not generalise to non-exposed food.[43] The opposite findings emerged for non-personalised exposed food items.[43 45] It can be suggested that personalised food items might better capture individual learning processes and should thus be included in CE in order to achieve more profound changes in food-related inhibitory control.

With regard to mechanisms of change, both generic and idiographic BE expectancies were found to be more effectively disconfirmed in CE_{EV}, with $d=4.12$ and $d=9.50$, compared with active control interventions.[43 45] Moreover, in a recent within-group pilot study, significant improvements in expectancies about ability to tolerate distress were found after five sessions of CE_{EV} in women

with BED.[47] Interestingly, expectancy violations (idiographic CS-US and distress tolerance expectancies) were found prior to changes in BE frequency, emphasising their assumed potential for subsequent habituation processes.[44 47] To date, only one study has assessed self-reported impulsivity: Participants were randomised to an 8-session group intervention focusing on CE or a control intervention with both conditions including self-monitoring techniques.[40] No between-group differences emerged. To the best of our knowledge, however, no research has assessed the efficacy of CE for food-related inhibitory control and emotion regulation.

With respect to adolescent samples, CE has only been applied in two studies to date.[39 48] In patients with BN aged 14–19 years who had not responded well to CBT, a 12-session CE with habituation was effective in significantly decreasing BE and purging from baseline to post-treatment and at 6-month FU.[48] Schyns and colleagues[39] compared CE_{EV} with a lifestyle intervention in a clinical sample of adolescents with obesity. The main focus of the lifestyle intervention was on providing psychoeducation to increase healthier eating and physical activity. Two sessions of CE_{EV} were conducted and EAH was assessed as the primary endpoint, operationalised by the percentage of consumed kcal in a BTT relative to the personal daily energy requirement. CE_{EV} significantly reduced the ad libitum food intake of an exposed food item (chocolate mousse) and of non-exposed food items compared with the control condition ($d=0.80$ and $d=0.76$). Contrary to findings in adults, the exposure effects generalised to further highly palatable food, suggesting that adolescents might learn faster.[39] It can therefore be assumed that not all relevant food cues need to be integrated into CE_{EV} sessions. However, adherence to homework exercises was poor, suggesting the need for stronger guidance of CE_{EV} at home, especially in this young age group.

To sum up, evidence in adults and in adolescents with obesity indicates medium to large effect sizes regarding the improvement of EAH via ad libitum food intake, eating psychopathology and weight reduction after only two sessions of CE_{EV}. However, more randomised controlled trials are needed to support this inhibitory learning approach to exposure in adolescents with BE.

Study aims and hypotheses

The current pilot study, called $EXI_{(ea)}T$, targets the feasibility and efficacy of CE_{EV} for adolescents with recurrent BE episodes relative to BA in a multicentre randomised trial. $EXI_{(ea)}T$ is an acronym for *EXIT* strategies as a way out of binge *ea*ting. The diagnosis of BE episodes in adolescents can be challenging for a number of reasons. First, adolescents who still live at home and are financially dependent on their parents do not have unrestricted access to food—therefore the consumption during a BE and the frequency can be externally limited. Second, there is evidence that loss of control over eating may be more important, especially in view of the large amounts of food that can be eaten due to pubertal developmental

spurts. Accordingly, it is important to also consider subthreshold BN and BED in adolescents. Marcus and Kalarchian[49] next to Tanofsky-Kraff and colleagues[50] have proposed modified criteria for BED in childhood and adolescence. For the diagnosis 'recurrent episodes of BE persisting over a period of 3 months' are required which has also found its way into the new International Classification of Diseases, 11th Revision (ICD-11) criteria. Based on our clinical ED expertise, we applied a low-threshold cut-off of only three objective BE episodes within the last 3 months although a typical clinical picture is present. Recurrent BE episodes are therefore operationalised by a diagnosis of BN, BED or Other Specified Feeding or Eating Disorder (OSFED-BN/BED). Taken together, the aims of $EXI_{(ea)}T$ are to investigate (1) the application of CE_{EV} compared with BA in a transdiagnostic adolescent sample with BE, (2) whether CE_{EV} effectively reduces EAH and food craving at post-treatment and at 3-month FU and (3) the effect of CE_{EV} on global ED pathology, number of binge episodes and weight and (4) on underlying mechanisms of change, that is, expectancy violations. We hypothesize that CE_{EV} will be superior to BA in reducing ad libitum food intake of personally preferred exposed and non-exposed binge foods beyond physiological needs at post-test. With regard to secondary endpoints, we expect CE_{EV} to lead to a stronger decrease in ad libitum intake of standardised binge food, food craving, ED psychopathology and BE frequency and to a stronger weight reduction at FU compared with BA. Moreover, we hypothesise that adolescents in the CE_{EV} condition will additionally benefit with respect to larger violations of BE expectancies. On an exploratory level, we will analyse potential moderating effects of food-related response inhibition and emotion regulation abilities.

METHODS AND ANALYSIS
Patient and public involvement
The modified CE was developed from clinical work with adolescents with EDs. To ensure appropriateness of CE_{EV} for the relevant clinical group and age range, a preliminary study on treatment expectations was conducted with a student sample aged 18–25 years who experienced stress-induced chocolate cravings. Help-seeking rates in adolescents that meet BN or BED criteria are very low with 11.6% and 22.3%[51] what underlines the significant delay from onset of symptoms to accessing eating disorder-specific treatment.[52] Consequently, for economic and ethical reasons, we included young students in the preliminary study. The results on treatment expectations were used to optimise the CE before inclusion of the first patient.

Study design
This study is a randomised (with a 4:4 allocation ratio), controlled, double-blind multicentre trial comparing CE_{EV} to BA. Recruitment, data collection, interventions and data analysis are conducted in two departments of

child and adolescent psychiatry and psychotherapy at the University Hospital Bochum and the University Medical Center Mainz.

Participants and recruitment
The following inclusion criteria are applied (1) female adolescents aged 13–20 years; (2) presence of recurrent BE episodes (at least three objective episodes within the last 3 months with loss of control and clinically significant distress/functional impairment) assessed via an expert interview (Eating Disorder Examination, EDE)[53 54]; (3) diagnosis of BN, BED or OSFED-BN/BED (BN or BED of low frequency and/or limited duration) based on DSM-5; (4) sufficient knowledge of the German language; and (5) written informed consent of the participant and the caregivers. Adolescents are excluded if they show (1) severe psychopathological comorbidities (such as severe depressive episodes, borderline personality disorder, substance use disorder, dissociative disorders, diagnosis of non-suicidal self-injury based on DSM-5), although mild-to-moderate comorbidities do not lead to exclusion as long as ED symptoms are the core symptoms; (2) anorexia nervosa; (3) immediate need for inpatient treatment due to acute suicidality or BE/purging at a high frequency; and (4) ongoing outpatient treatment with a focus on ED-specific interventions (eg, CE, mirror exposure). The participants are recruited via press releases, flyers and social media, as well as in schools, and youth centres in Hamm and Mainz and the surrounding areas. In addition, cooperations with counselling centres, child and adolescent psychiatrists and psychotherapists, and paediatricians are used for recruitment.

Study flow and procedure
The study flow is illustrated in figure 1. First, subjects and their caregivers are informed about the aims and procedure of the study in a telephone interview (T_0). In addition, the inclusion and exclusion criteria are checked.

At the beginning of each session, participants' most recent food intake is assessed and their current levels of hunger and desire to eat are measured on a 100 mm Visual Analogue Scale (VAS). At the baseline assessment (T_1), participants undertake two computer-based tasks (Food Challenge Task, FCT[55]; Go/NoGo Task, GNG[56 57]), before their weight, height and body fat percentage are measured by bioelectrical impedance analysis. Moreover, general psychopathology is assessed and the EDE-II and an interview on binge food (in which participants are asked to state four personally preferred binge foods) are conducted. After a short break, relevant parts of the Diagnostic Interview for Mental Disorders in Children and Adolescents (Kinder-DIPS-OA)[58] are conducted. The remaining self-rating questionnaires are completed online via Research Electronic Data Capture (REDCap).[59] The randomisation takes place after T_1 using a block-wise procedure (block sizes of four) by Sealed Envelope that run automatically in the REDCap data management. To ensure that assessors (experienced and trained
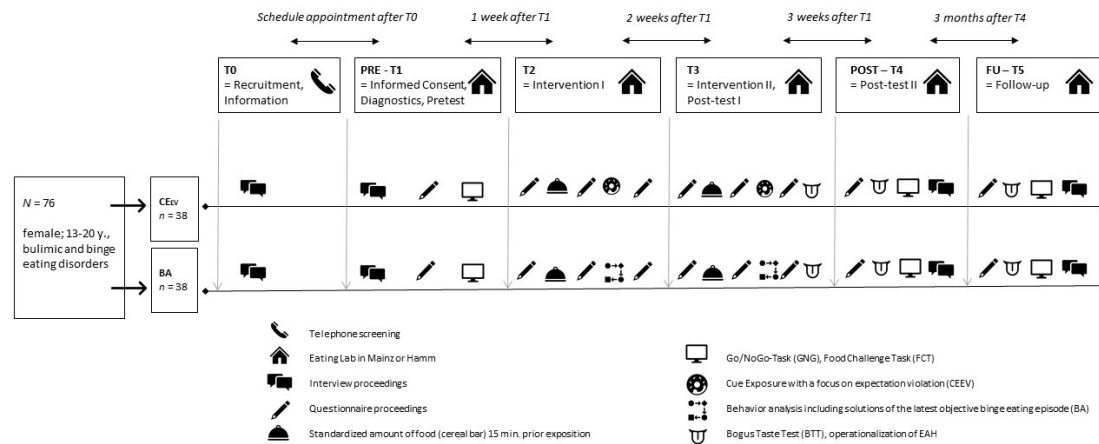
Figure 1 Study flow chart from screening (T_0) to 3-month follow-up (T_5).

psychologists) are blinded, the study leaders randomise the participants. Two sessions of CE_{EV} or BA follow at T_2 and T_3. Participants are requested to eat sufficiently prior to the appointments but not within the last 2 hours before the intervention. To avoid hunger during the interventions, participants are asked to eat a cereal bar 15 min before the intervention. After CE_{EV} and BA, current levels of hunger, desire to eat and the two relevant overeating expectancies in the CE_{EV} group are assessed again. At the end of the intervention sessions, participants are strongly encouraged to repeat the exercise at home to increase the transferability to daily life. We look for specific favourable times of day for the implementation and anticipate possible difficulties or obstacles. The participants also receive an exercise booklet with general information about the intervention as well as detailed instruction and protocol sheets. At the beginning of T_3, these home exercises, obstacles to implementation and potential solutions are discussed and participants are again encouraged to continue with the exercises at home. At the end of T_3, a BTT with all four preferred binge foods is conducted. The BTT is a valid and sensitive instrument to investigate whether experimental manipulations affect food intake with respect to EAH[60] and has been applied in obese adolescents.[39] To ensure that participants were not aware of the aims of the experimental hypotheses, they are asked to evaluate the taste of the foods on a rating sheet during a set time period of 15 min.[60] They are invited to eat as much as they need to evaluate the taste. Before and after the rating, the weight of the food is measured out of sight of the participants and the consumed calories are calculated. The dependent variable is the percentage of consumed calories in relation to the individual's daily energy demand with respect to age and gender (recommendation of the World Health Communication).

At the post-assessment (T_4), the frequency of home exercises is discussed again. Next, a BTT is performed with standardised non-exposed food items (milkshakes), and the computer-based tasks are repeated. Binge-purge behaviours are assessed. The questionnaires can be completed at home. The post-assessment is repeated at T_5 (FU) 3 months after T_4. At T_5, the BTT is conducted with three preferred and one standardised binge foods. Any outstanding questionnaires are completed on site to avoid missing data. At the end of T5, participants receive an allowance of €50.

Interventions

Both conditions include two face-to-face sessions with a maximum duration of 70 min each. Following a standardised session protocol (see online supplemental file 1), the interventions are delivered by experienced CBT therapists at each site. In the CE_{EV} group, participants are exposed to two out of four personally preferred binge food items. Two individual overeating expectancies are used during exposure, and if a subject has difficulties in formulating expectancies, standardised overeating expectancies are applied (ie, 'If I see delicious food, I won't be able to resist eating it.'). Directly before CE_{EV} and every 5 min, subjects are asked to rate their current levels of hunger, desire to eat the exposed food and the two relevant overeating expectancies on a 100 mm VAS. The exposure ends as soon as the desire to eat has decreased by 50% compared with the highest rating, but at the latest after 70 min. After the exposure, two alternative, helpful expectancies are developed together with the therapist and are written on two index cards so that the participant can carry them with her. Control group participants undergo a BA of the last BE episode based on the Stimulus-Organism-Response-Consequence (SORC) model.[61] First, situational and preceding factors as well as the cognitive, emotional, physiological and behavioural reactions of the participant are identified. In addition, consequences of the behaviour are detected. The BA ends with a solution analysis by identifying effective skills to prevent BE, but also after 70 min at the latest.

Diagnostic and outcome assessments
Patient characteristics and diagnostics

Besides sociodemographic information such as age and school type, general information such as ongoing therapy and previous treatments is gathered. In

addition, information to compute the socioeconomic status (Winkler-Index[62]) is obtained. To identify possible comorbidities, the Freiburger Screening for Mental Disorders (FSP)[63] is used as a screening instrument. The sections on depressive disorders, anxiety disorders, attention-deficit/hyperactivity disorder, conduct disorders, tic disorders, enuresis, encopresis and non-suicidal self-injury disorder are administered routinely in the Kinder-DIPS-OA; the other sections are explored in the case of relevant answers in the previously administered FSP. Eating disorder psychopathology is assessed with the well-established interview EDE which allows an accurate clinical judgement of global ED psychopathology over the last 28 days and is considered the gold standard for ED-specific diagnostics.[53 54] Other diagnostics are general psychopathology,[58] last food intake, level of hunger and desire to eat. Instruments and their psychometric characteristics are illustrated in table 1.

Primary outcome

EAH is assessed with BTT, a valid and sensitive instrument to investigate whether experimental manipulations affect food intake.[60] Participants are exposed to their personally preferred binge foods and are asked to evaluate the taste of the food on a rating sheet. They are invited to eat as much as they need to evaluate the taste. Before and after the rating, the weight of the food is measured and the consumed calories are calculated. The dependent variable is the percentage of consumed calories in relation to the individual's daily energy requirements with respect to age and gender in line with the recommendations of the United Nations University and the WHO.[64]

Secondary outcomes

EAH is measured with standardised food items in the BTT. Momentary food craving is assessed with the FCT in which a 5 min video with tasty foods is presented to induce craving.[55] After participants have watched the video, the experience of craving is measured with the Food Craving Questionnaire-State.[65] The FCT has proven to be valid for the standardised induction of food cue reactivity to measure momentary food craving.[55] Other secondary outcome measures are binge eating, eating disorder psychopathology,[66 67] weight, height, body fat and trait food craving.[68]

Moderators

To identify possible moderating effects, emotion regulation is measured with the Difficulties in Emotion Regulation Scale,[69 70] and response inhibition is assessed with a modified personalised GNG affective shifting task (high-calorie food category vs neutral category).[56 57] Neutral stimuli (flower, towel) and high-calorie foods (chocolate, pizza) are presented as Go or NoGo stimuli (depending on the block). To determine participants' personal taste preferences, prior to the GNG Task, they are asked to rate 30 high-calorie food stimuli on a 7-point Likert scale (0=not at all palatable to 6=extremely palatable). The 10

personally most palatable food stimuli are then used in the task. Participants are instructed to press a button when watching a relevant stimulus ('Go') and to not press the button when watching an irrelevant stimulus ('NoGo'). The task consists of 16 blocks with 50% of the stimuli presented as Go stimuli and 50% as NoGo stimuli in each block. Participants receive instructions at the beginning of each block. Each stimulus is presented for 500 ms with an intertrial interval of 1000 ms. Dependent variables are participants' reaction times and number of commission errors (false reactions to a NoGo instruction) and omission errors (missing reactions to a Go instruction). The GNG task is a widely used task to measure response inhibition.[22]

Additional assessments

Adherence control

Attrition rate and study dropouts are assessed in both treatment groups. Manual adherence across the different therapists is achieved through standardised treatment protocols, online trainings and fortnightly supervisions by a licensed expert in ED treatment (TL) across both participating centres.

Treatment expectation and evaluation

Treatment expectation and evaluation are assessed with the Expectation of Improvement and Suitability of Treatment Form[71] and the Patient Questionnaire on Therapy Expectation and Evaluation.[72]

Sample size calculation

The sample size calculation is based on the publication of Schyns and colleagues,[39] which reports an effect size of d=0.8 between groups for the percentage of consumed kcal during the taste test relative to the daily energy requirements (experimental group: mean 57% (n=21; SD=68%), control group: mean 146% (n=19; SD=141%)). When calculating the pooled SD (SD_{pooled}=118.5%) and assuming an effect size of 0.8, this results in an absolute difference of 75% in the mean between groups, which can be considered as relevant. When assuming a two-sided significance level, a power of 90%, an effect size of d=0.8 and a sample size of 68 patients (=2×34 patients) will be needed to detect a significant treatment difference at post-assessment when using a t-test. As the duration of treatment is very short (2 weeks only), we assume that patient loss due to non-compliance will be minimal. To account for 10% dropouts,[39] 76 patients should be randomised. The calculation was performed using SAS V.9.4.

Data analysis plan

Regarding the primary outcome EAH, treatment groups will be compared using an analysis of covariance (ANCOVA) with intervention as fixed factor and body mass index at baseline as covariate. The primary analysis is performed on the intention-to-treat population consisting of all patients randomised next to per-protocol analyses. The secondary parameters are mostly

Table 1 Assessment plan from screening (T_0) to 3-month follow-up (T_5)

Variable	Instrument	Description	Score indication	T0	T1	T2	T3	T4	T5
				Assessment moments
Diagnostics									
Eligibility screen		Inclusion and exclusion criteria		X	X				
Clinical baseline data		Eg, age, school type, treatments			X				
General psychopathology - self-report	Strengths and Difficulties Questionnaire[76][77]	25 items range from 0 to 40	Higher scores indicate more externalising and internalising problems	X					
Psychological impairment	Freiburger Screening für psychische Störungen[63]	Screening questions for 14 mental disorders with 29 items		X					
General psychopathology - clinical judgement	Diagnostic Interview for Mental Disorders in Children and Adolescents[58]	Screening for mental disorders according to the DSM-IV-TR[78] and ICD-10[79]		X					
Eating disorder psychopathology - clinical judgement	Eating Disorder Examination (EDE)[53][54]	Semi-structured interview with 22 and four subscales 'Restraint', 'Eating concerns', 'Shape concerns' and 'Weight concerns'	Higher scores indicate more eating disorder psychopathology	X					
Primary outcome									
Eating in the absence of hunger (EAH)	Bogus Taste task (BTT, preferred food items)[60]	Exposition to their personally preferred food items	Higher consumed calories indicate more EAH	X		X			
Secondary outcomes									
EAH	BTT (standardised food items)[60]	Exposition to milkshakes	Higher consumed calories indicate more EAH	X	X				
Momentary food craving	Food Challenge Task[55]	Craving is measured with the Food Craving Questionnaire-State (FCQ-S),[65] consists of 15 items range from 15 to 75	Higher scores indicate higher intensity of craving	X			X	X	
Binge eating	EDE[53][54]			X			X	X	
Eating disorder psychopathology - self-report	EDE-Questionnaire[66][67]	Self-report questionnaire with 22 items	Higher scores indicate more eating disorder psychopathology	X			X	X	
Weight, height, body fat	Bioelectrical impedance analysis, InBody770*			X			X	X	

Table 1 Continued

Variable	Instrument	Description	Score indication	Assessment moments					
				T_0	T_1	T_2	T_3	T_4	T_5
Food craving	Food Craving Questionnaire-Trait (FCQ-T-r)[68]	15 items range from 15 to 90	Higher scores indicate higher frequency and intensity of food craving	X			X	X	
Moderator variables									
Response inhibition	Go/NoGo Task[56][57]	Affective shifting task with high-caloric vs neutral food stimuli; 16 blocks with a total of 320 trials	Higher number of commission errors indicate lower inhibition skills	X			X	X	
Emotion regulation	Difficulties in Emotion Regulation Scale[69][70]	36 items range from 36 to 180	Higher scores indicate more difficulties in emotion regulation	X			X	X	
Treatment expectation and evaluation									
Treatment expectation	Expectation of Improvement and Suitability of Treatment Form[71]	Two items, rated on a 10-point Likert scale	Higher scores indicate positive treatment expectation	X			X	X	
Treatment evaluation	Patient Questionnaire on Therapy Expectation and Evaluation[72]	Eleven items, rated on a 5-point Likert scale	Higher score indicate better treatment evaluation	X			X	X	

*Body fat is only measured at the Mainz site.
T_0, telephone interview; T_1, baseline assessment; T_2, intervention session 1; T_3, intervention session 2; T_4, post-assessment; T_5, follow-up.

continuous parameters, and will be analysed using AN(C)OVAs and t-tests. Sample characteristics will be provided. A p value of <0.05 is considered as statistically significant (two-sided). Missing values will not be replaced, however an analysis of potential missing data patterns will be presented. There will be several sensitivity analyses, for example, by considering additional covariates.

Data availability
The research data generated during this study will be available on reasonable request by the corresponding authors. Anonymised data use by other researchers not involved in the study may be done with prior agreement.

ETHICS AND DISSEMINATION
Ethics and safety aspects
The trial will be conducted according to the principles of the Guideline for Good Clinical Practice (ICH-GCP) and appropriate legal regulations, and will adhere to the Declaration of Helsinki in its latest version. Participating individuals are provided with treatment as usual (which consists of BA) for EDs according to good clinical practice.[73] The study protocol including amendments has been and will be approved by the responsible ethics committees. Important protocol modifications will be reported to the German Clinical Trials Register and to the journal. Participants and caregivers must provide written informed consent before beginning the study. CE is generally well tolerated,[39][43] and risks for participants are not known or expected. Trained clinical staff will be available to monitor safety concerns and support patients during/after treatment.

Dissemination plan
The collected data will be disseminated locally and internationally through publications in relevant peer-reviewed journals and will be presented at scientific and clinical conferences. Participants data will only be published in anonymised form.

DISCUSSION
Research on effective treatment elements for BE in adolescents is still limited, leaving a gap in knowledge on interventions that might enhance outcomes for this age group. One promising way to achieve this might be to target food-related inhibitory control as an underlying perpetuating mechanism of BE. Recent results suggest a successful adaptation of CE_{EV} for pathological eating

behaviour. However, little is known about the feasibility and efficacy of CE_{EV} for adolescents with recurrent BE episodes. Thus, the findings of $EXI_{(ea)}T$ might clarify whether CE_{EV} is accepted by a transdiagnostic adolescent sample and whether it is able to reduce the ad libitum consumption of highly palatable foods when satiated as well as ED pathology. Furthermore, we will elucidate the role of CS-US expectancy violations, response inhibition and emotion regulation in CE_{EV}. The strengths of $EXI_{(ea)}T$ lie in the inclusion of a credible, active control condition, considered as the gold standard intervention of CBT-E to treat BE, and the use of an objective measure to assess changes, that is, ad libitum food intake, as the primary efficacy endpoint. Moreover, the CE_{EV} treatment protocol includes the most relevant CE strategies to maximise treatment success,[44] that is, in-vivo exposure, personally preferred food cues and non-food cues (due to imagery of trigger situations at the beginning of session), occasionally eating allowed and personal CS-US expectancies identified. Additionally, to overcome poor homework adherence, we offer a detailed exercise booklet, discuss implementation problems and debrief all exercises at the beginning of session 2. On the level of limitations, it should be noted that $EXI_{(ea)}T$ cannot evaluate the efficacy of CE_{EV} as an add-on intervention to CBT-E as a whole. BA is a very strong control intervention, which could make it difficult to identify a significant superiority of CE_{EV}. Moreover, we did not ask explicitly for 'new' expectations that might arise during the CE_{EV}. Similarly, it should be pointed out that there is no data monitoring committee to review accumulating data, which may affect the independence of the analyses. In addition, our decision to use the DSM-5 criteria and not the age-adapted criteria for BED[49 74] or modified ICD-11 criteria for bulimic disorders,[75] which emphasise the subjective loss of control (LOC), needs to be explored with respect to recruitment procedures. Indeed, we have not found prior evidence that CE_{EV} is also a valuable intervention with respect to LOC eating. However, if CE_{EV} is effective and feasible for adolescents with BE, we might conduct a confirmatory randomised trial in order to test CE_{EV} as a useful adjunct to first-line treatment.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement The research data generated during this study will be available on reasonable request by the corresponding authors. Anonymised data use by other researchers not involved in the study may be done with prior agreement.

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ORCID iDs
Hanna Preuss-van Viersen http://orcid.org/0000-0001-9537-706X
Jasmina Eskic http://orcid.org/0000-0002-5791-5688
Florian Hammerle http://orcid.org/0000-0002-2659-6266

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