An open-label efficacy trial of escitalopram for night eating syndrome

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A B S T R A C T
Objective: Night eating syndrome (NES) has become increasingly recognized as a disorder in need of effective treatments. Selective serotonin reuptake inhibitors have shown efficacy in previous trials, so we sought to expand our understanding of the efficacy of escitalopram in the current trial.

Method: Thirty-one adults with NES participated in a 12-week open-label trial of escitalopram. Outcome measures included the Night Eating Symptom Scale (NESS), percent of daily intake after the evening meal (% intake) and number of nocturnal ingestions/week (NI), weight, total awakenings/week, mood, and quality of life. Mixed-effects models were used to assess change over time.

Results: Significant reductions were observed from week 0 to week 12 for the NESS (30.2 to 15.2), % intake (46% to 17%), NI (5.8 to 1.2), weight (90.2 to 88.6 kg), awakenings (8.1 to 2.7), and BDI-II (12.1 to 7.7). Outcomes did not differ significantly by gender, age, race, or psychiatric co-morbidity status. Eighteen of 31 completed 12 weeks of treatment.

Discussion: This open-label trial of escitalopram showed significant reductions in symptoms associated with NES. Randomized controlled trials are warranted to test these findings.

Trial Registration: clinicaltrials.gov identifier: NCT01401595.

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1. Introduction

Night eating syndrome (NES) affects about 1.5% of the general population (Rand, Magregor, & Stunkard, 1997; Striegel-Moore, Franko, Thompson, Affenito, & Kraemer, 2006). The core features include a delayed circadian pattern of eating manifested by evening hyperphagia (consumption of at least 25% of daily food intake after the evening meal) and/or nocturnal ingestions (waking to eat) at least twice a week (Allison et al., 2010). Three of five additional modifiers are also required: morning anorexia, insomnia, strong cravings to eat in the evening or night, depressed mood, and the belief that one must eat to fall (back) asleep, along with distress or impairment in functioning. It is not currently included in the Diagnostic and Statistical Manual, Fourth Edition (DSM) (American Psychiatric Association, 2000), but it will likely appear in DSM 5 (American Psychiatric Association, 2012) under the category Feeding and Eating Conditions Not Elsewhere Classified. As such, more data regarding treatment efficacy are needed.

NES occurs in persons of all weights, but the prevalence seems to grow with increasing body mass. Tholm et al. (2009) showed an increased risk for obesity (2.5 times for men and 2.8 times for women) among participants in the Swedish Twin Register STAGE cohort who screened positive for night eating. In a clinical sample, psychiatric patients with NES were five times more likely to be obese than patients without NES (Lundgren et al., 2006). Night eating is also predictive of weight gain in prospective studies (Andersen, Stunkard, Sorensen, Pedersen, & Heitman, 2004; Gluck, Venti, Salbe, & Krakoff, 2008). However, some epidemiological studies have not shown a positive relationship between weight and night eating symptoms (Striegel-Moore et al., 2006).

While research on the treatment of NES is still sparse, the disorder has been successfully treated with selective serotonin reuptake inhibitors (SSRIs) in a limited number of trials. Open label trials have shown efficacy with sertraline (O’Reardon, Stunkard, & Allison, 2004; Stunkard et al., 2006), and one randomized controlled trial has illustrated the superiority of sertraline over placebo (O’Reardon et al., 2006). In this 8-week controlled trial, 71% of participants on sertraline (n = 17) were considered “responders” on the Clinical Global Impression of Improvement Scale...
participants were healthy enough to participate in a medication
metabolic panel; and an electrocardiogram to establish that the
nation; drug screen, measurement of height, weight, and blood pressure;
present for at least three months.

in functioning due to their night eating. The NES symptoms had to be
awareness of their nighttime eating, and show distress or impairment
were also required to meet at least three of the
waking up during the night to eat at least twice per week. Participants
baseline visit, participants completed a psychological assessment dur-
2.2. Procedures

This study’s protocol was reviewed and approved by the Universi-
y of Pennsylvania’s Institutional Review Board, with all participants
in completing the core features of NES significantly in this sample.

2. Material and methods

2.1. Participants

Potential participants were recruited through television and Inter-
et advertisements, along with flyers posted at the University Hospital
and around campus targeting persons who experienced overeating at
night and/or waking during the night to eat. Men and women between
the ages of 18–70 of all races and ethnicities were included. Exclusion
criteria were: pregnancy; insulin-dependent diabetes; thyroid or
other metabolic disorders; use in the past month of any psychotropic
medication, oral steroids, diuretics or hypnotics; the presence of an-
orexia nervosa or bulimia nervosa; current participation in an organized
weight reduction program or the use of weight loss medication, current
participation in psychotherapy treatment for NES or another eating dis-
order, an occupation requiring night-shifts or other unusual nighttime
requirements: severe major depressive disorder; suicidal risk; bipolar
disorder; current or past psychosis; or substance use or abuse within
the past 6 months. Weight greater than 400 lb and an allergy to shell-
fish or iodine were also exclusions, as participants were also completing
a brain imaging study.

This study’s protocol was reviewed and approved by the Universi-
y of Pennsylvania’s Institutional Review Board, with all participants
providing informed consent.

2.2. Procedures

Participants were screened by phone for inclusion and exclusion
criteria before being scheduled for their baseline assessment. At the
baseline visit, participants completed a psychological assessment dur-
which the diagnosis of NES was confirmed through questionnaires,
clinical interviews, and, subsequently, a 10-day food and sleep log. Study personnel analyzed data from the logs with the Food Processor®
program (ESHA research, Salem, OR). All participants included in the
study met the full research criteria for NES (Allison et al., 2010). Using
the available data, the authors confirmed that participants consumed
at least 25% of their caloric intake after their evening meal and/or after
waking up during the night to eat at least twice per week. Participants
were also required to meet at least three of the five modifiers, have
awareness of their nighttime eating, and show distress or impairment
in functioning due to their night eating. The NES symptoms had to be
present for at least three months.

The baseline assessment also included a history and physical exami-
nation; drug screen, measurement of height, weight, and blood pressure;
metabolic panel; and an electrocardiogram to establish that the
participants were healthy enough to participate in a medication
trial. After completing the assessment, participants with confirmed
NES were eligible for a brain imaging study (to be described else-
where) and treatment. Participants were paid for completing the comprehensive assessment and brain imaging portion of the
study. Treatment was subsequently provided at no charge.

A total of 342 individuals responded to ads to participate in the current
study. Of the 342 whom we contacted, 75 individuals provided consent
to enroll in the study as night eating participants. Of the 75 who
provided consent, 21 were found to be ineligible during their baseline
screening appointment for the following reasons (some participants
met more than one exclusion): 3 had uncontrolled or undiagnosed dia-
abetes, 3 used illicit drugs, 4 met criteria for severe depression or suicidal
ideation, 2 had anemia, 2 had abnormally high blood pressure, 2 had ab-
normal ECG, 4 had other medical issues deemed unstable or needing fur-
ther medical care, 1 met criteria for bipolar disorder and 1 for purging
disorder, 2 used other psychotropic/sleep medications, and 1 weighed
greater than 400 lb. Additionally, 22 did not continue after the baseline
assessment: 9 were found to be eligible, but never returned their screen-
ning materials (i.e., food/sleep log and survey packet), 3 had scheduling
difficulties, 3 did not meet full NES criteria after assessment, 3 declined
the study/lost to follow-up after baseline, and 4 did not keep their base-
line (week 0) treatment appointments. The remaining 32 entered treat-
ment. Of the 32 who entered treatment, 1 did not return after the initial
treatment week and was not included in analysis (as she did not have more than one datapoint).

2.2.1. Treatment

Treatment visits occurred at week 0 (start of treatment) and weeks
1, 2, 4, 6, 8, 10, and 12. Dosing of escitalopram began at 10 mg. If partic-
ients experienced significant side effects, dose was cut to 5 mg. At
week 4, if participants’ symptoms were still present, the dose was in-
creased to 20 mg. Likewise, if significant side effects were experienced
at 20 mg, dose was cut to 15 mg.

2.3. Measures

2.3.1. Baseline

In addition to collecting demographic information, several measures
were used at baseline to characterize the sample and to assess for exclu-
sion criteria. The Night Eating Questionnaire (NEQ) (Allison et al., 2008)
was completed at baseline. This is a 14-item questionnaire that assesses
behavioral and psychological symptoms of NES. Total scores range from
0 to 52. The Beck Depression Inventory-II (BDI-II; Beck, 1996) was also
administered; it is a widely used 21-item questionnaire that measures
symptoms of depression present during the past week. Total scores
range from 0 to 63; the BDI-II has high internal consistency, test–retest
reliability and convergent and discriminant validity. The Night Eating Syndrome History and Inventory (NESHI) (Lundgren, Allison, Vinai P,
Gluck) was used to confirm a diagnosis of NES. The NEQ is embedded
in the NESHI, and additional items describe typical meal and snack pat-
terns, level of distress, and severity and course of NES symptoms. The
diagnostic criteria for NES are assessed with the NESHI.

Eating disorder psychopathology was assessed with the Eating Dis-
order Examination, 16th edition (Fairburn, Cooper, & O’Connor, 2008).
This measure has been found reliable and valid for assessment of eating
pathology (Fairburn, Cooper, & O’Connor, 2001; Gilo, Masheb, Lozano-
Blanco, & Barry, 2004). The EDE includes assessment of binge eating
and overeating episodes, four subscales (Restrain, Eating Concern,
Shape Concern, and Weight Concern), and a global disordered eating
score. The Eating Inventory was used to characterize common psycho-
logical factors related to eating, including cognitive restraint, disinhibi-
tion, and hunger (Stunkard & Messick, 1985). Axis I psychopathology
was broadly assessed with the Structured Clinical Interview for
DSM-IV Axis I Disorders (SCID-I/P) (First, Spitzer, Gibbon, Williams, &
Benjamin, 1996).
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