ISRCTN24349737 https://doi.org/10.1186/ISRCTN24349737

# How anxiety and body signals lead to binge eating in daily life

**Submission date**
06/11/2025

**Recruitment status**
No longer recruiting

**Registration date**
10/11/2025

**Overall study status**
Completed

**Last Edited**
07/11/2025

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
This study explored how anxiety and the body's physical stress signals interact to trigger binge-eating episodes in daily life. The aim was to understand, in real time, how changes in anxiety, heart rate, and stress hormones are linked to urges to binge eat. By identifying these moment-clip patterns, researchers hope to inform new ways of preventing binge-eating episodes before they occur.

Who can participate?
Adults aged 18–55 years living in Germany were invited to take part. Participants were placed into one of four groups:
1. People with both Binge-Eating Disorder (BED) and Generalized Anxiety Disorder (GAD)
2. People with BED only
3. People with GAD only
4. Healthy volunteers with no mental health diagnoses
All participants needed to have a body mass index (BMI) between 18.5 and 40 kg/m² and be fluent in German. People were excluded if they had current substance misuse, psychosis, neurological illness, active suicidal thoughts, were pregnant, or were taking medication that could affect stress hormones or heart rate.

What does the study involve?
The study was observational, meaning no experimental treatment was given. Participants first visited the laboratory for a standard stress test to measure their body's response under pressure. They then took part in a 14-day monitoring period in their everyday environment. During this time, participants:
1. Received short smartphone surveys about their feelings and urges to binge eat several times a day
2. Wore a heart rate monitor to track changes in stress and relaxation
3. Collected saliva samples four times daily to measure stress hormone (cortisol) levels
4. Allowed their smartphone to record information such as movement and screen use
This combination of data helped researchers understand how anxiety and physical stress responses interact in real-world settings.

What are the possible benefits and risks of participating?
There were no direct benefits to participants, but the findings will help improve understanding of how anxiety contributes to binge eating, which could lead to better prevention and treatment approaches in the future. Risks were minimal and mainly related to mild discomfort or stress during the laboratory test, and the time commitment required for daily surveys and sample collection.

Where is the study run from?
The study was coordinated and conducted by Freie Universität Berlin, Germany, under the ethical oversight of the Charité University Medical Center's ethics commission.

When is the study starting and how long is it expected to run for?
The study began on 15 December 2024 and was completed on 12 September 2025.

Who is funding the study?
The study was funded by the Deutschlandstipendium National Scholarship Program, a government-funded initiative.

Who is the main contact?
Dr Yixuan Liang, yliang56@jh.edu

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Dr Yixuan Liang

### Contact details
3510N Charles St
Baltimore
United States of America
21218
+1 (0)4438388609
yliang56@jh.edu

# Additional identifiers

### Protocol serial number
6734

# Study information

### Scientific Title
Physiological correlates of anxiety-driven binge eating in a naturalistic setting

### Acronym
ADBE

## Study objectives
To investigate the real-time psychophysiological mechanisms (specifically, heart rate variability and cortisol) through which anxiety triggers binge urges and episodes in the natural environment, and to determine how these mechanisms are amplified in individuals with comorbid Generalized Anxiety Disorder (GAD) and Binge-Eating Disorder (BED).

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 10/12/2024, Ethics Committee of Freie Universität Berlin (Kaiserswerther Str. 16-18, Berlin, 14195, Germany; +49 (0)17668328908; ethikkommission@charite-medizin.org), ref: 6734

## Primary study design
Observational

## Study design
Prospective observational longitudinal cohort study

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Binge-Eating Disorder (BED), Generalized Anxiety Disorder (GAD)

## Interventions
This study employed a prospective, observational longitudinal cohort design with four distinct arms: a comorbid Binge-Eating Disorder and Generalized Anxiety Disorder group (BED + GAD, n = 40), a BED-only control group (n = 20), a GAD-only control group (n = 20), and a healthy control group (n = 40). The primary purpose was etiological, aiming to understand the basic psychophysiological mechanisms of anxiety-driven binge eating. The design was non-randomized and unblinded, featuring a 14-day ecological ambulatory assessment period for real-time data collection, preceded by a laboratory-based stress reactivity assessment. The study did not involve an interventional treatment or investigational medicinal product.

All participants underwent the same assessment procedures, including: Diagnostic Clinical Interview (SCID-5), Laboratory Stress Test (Trier Social Stress Test), and a 14-day Ambulatory Monitoring Period (Ecological Momentary Assessment, continuous heart rate monitoring, passive smartphone sensing, and salivary cortisol sampling).

## Intervention Type
Other

## Primary outcome(s)
1. Momentary urge to binge (measured on a 0-100 visual analogue scale 5 times daily during the 14-day ambulatory period)
2. Binge episode occurrence (binary yes/no from event-contingent reports during the 14-day ambulatory period)

## Key secondary outcome(s)

1. Heart rate variability (Root Mean Square of Successive Differences [RMSSD] in milliseconds), measured continuously during the 14-day ambulatory period and in response to the laboratory stress test
2. Salivary cortisol level (nmol/L), measured at four fixed times daily during the 14-day period and in response to the laboratory stress test
3. Contextual/behavioral markers (location variance, screen time) derived from passive smartphone sensing during the 14-day period

### Completion date
12/09/2025

## Eligibility

### Key inclusion criteria
1. Adults aged 18–55 years
2. Body mass index (BMI) between 18.5 and 40 kg/m²
3. Sufficient fluency in German to complete study procedures
4. Meeting DSM-5 diagnostic criteria for one of the four defined groups:
4.1. Comorbid Group (GAD+BED): Co-occurring Generalized Anxiety Disorder and Binge-Eating Disorder
4.2. BED Control Group (BED-only): Binge-Eating Disorder and no lifetime anxiety disorder
4.3. Anxiety Control Group (GAD-only): Generalized Anxiety Disorder and no lifetime eating disorder
4.4. Healthy Control Group (HC): No current or lifetime psychiatric diagnosis

### Participant type(s)
Healthy volunteer, Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
55 Years

### Sex
All

### Total final enrolment
120

### Key exclusion criteria
1. Current substance use disorder, psychosis, or neurological disease
2. Active suicidality

3. Pregnancy
4. Current use of medications known to influence cardiac or endocrine function (e.g., beta-blockers, corticosteroids)

**Date of first enrolment**
15/12/2024

**Date of final enrolment**
01/09/2025

# Locations

**Countries of recruitment**
Germany

**Study participating centre**
**Freie Universität Berlin**
Kaiserswerther Str. 16-18
Berlin
Germany
14195

# Sponsor information

**Organisation**
Freie Universität Berlin

**ROR**
https://ror.org/046ak2485

# Funder(s)

**Funder type**
Government

**Funder Name**
Deutschlandstipendium National Scholarship Program

# Results and Publications

## Individual participant data (IPD) sharing plan

Yes, there is a plan to share fully anonymized and de-identified individual participant data underlying the results reported in the final publication. This data will be made available to researchers beginning 6 months after the main findings are published. Access will be granted to researchers who provide a methodologically sound proposal for use in approved research. Proposals should be directed to the corresponding author via email, and requestors will be required to sign a data sharing agreement before the data is released.

## IPD sharing plan summary

Available on request