

Emotional Dysregulation in Adult ADHD. (EMO-TDA)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT03494478

Recruitment Status : Not yet recruiting

First Posted : April 11, 2018

Last Update Posted : April 11, 2018

See **Contacts and Locations**

Sponsor:

University Hospital, Strasbourg, France

Information provided by (Responsible Party):

University Hospital, Strasbourg, France

• Study Details

- [Tabular View](#)
- [No Results Posted](#)

- [Disclaimer](#)
- [How to Read a Study Record](#)

Study Description

Go to ▼

Brief Summary:

Attention deficit disorder in adults with or without hyperactivity (ADHD) is a common disorder, affecting around 3% of the population. ADHD increases the risk of psychiatric disorders (mood disorders, sleep disorders, personality disorders, addictive behavior), risky behaviors, and vocational difficulties. Emotional dysregulation (ED) constitute a major hindrance in the daily life of subjects, with a great impact on the general functioning and the quality of life of the patients.

The investigators want to determine the characteristics of patients with each type of ED (impulsivity, exacerbated emotional intensity, cyclothymia, borderline personality traits), and study the stability of these traits over time. Since circadian rhythms influence mood and circadian rhythms frequently occur in patients with ADHD, the investigators want to determine if there is a link between ED and instability in circadian rhythms. Finally, they would like to observe whether the ED evolves and according to whether or not treatment is taken

Condition or disease	Intervention/treatment
Adult ADHD	Other: Neuropsychological testingOther: ActimetryOther: Self-questionnaires on emotional

Study Design

Go to ▼

Study Type : Interventional (Clinical Trial)

Estimated Enrollment : 120 participants

Intervention Model: Single Group Assignment

Masking: None (Open Label)

Primary Purpose: Other

Official Title: Emotional Dysregulation and Cyclothymia in Adult Patients With ADHD: Cohort Follow-up of Patients in Two Referral Centers

Anticipated Study Start Date : May 2018

Estimated Primary Completion Date : August 2022

Estimated Study Completion Date : August 2022

Arms and Interventions

Go to ▼

Arm	Intervention/treatment
Experimental: Cohort group All participants will have evaluations at inclusion and 12 months. Neuropsychological testing Actimetry Selfquestionnaires on emotional topics	Other: Neuropsychological testing The assessment will be done at the time of the initial evaluation (undiagnosed / untreated patients), then at one year of follow-up Other Names: <ul style="list-style-type: none">attentionworking memoryexecutive functions Other: Actimetry The assessment will be done at the time of the initial evaluation (undiagnosed / untreated patients), then at one year of follow-up. Other Name: Selfquestionnaires on emotional topics Other: Self-questionnaires on emotional topics The assessment will be done at the time of the initial evaluation (undiagnosed / untreated patients), then at one year of follow-up.

Outcome Measures

Go to ▼

Primary Outcome Measures :

1. Characterization of emotional dysregulation (descriptive analysis of different scales assessing emotional dysregulation) [Time Frame: Change in measure between inclusion and 12 months after inclusion]

Score of cyclothymia (TEMPS-A scale)
2. Characterization of emotional dysregulation (descriptive analysis of different scales assessing emotional dysregulation) [Time Frame: Change in measure between inclusion and 12 months after inclusion]

Score of emotional lability (ALS scale)
3. Characterization of emotional dysregulation (descriptive analysis of different scales assessing emotional dysregulation) [Time Frame: Change in measure between inclusion and 12 months after inclusion]

Score of emotional dysregulation (WRAADDS scale)

4. Characterization of emotional dysregulation (descriptive analysis of different scales assessing emotional dysregulation) [Time Frame: Change in measure between inclusion and 12 months after inclusion]

Score of borderline personality symptoms (BSL scale)

Secondary Outcome Measures :

1. Association between emotional dysregulation, cognitive deficits and circadian instability
[Time Frame: Change en measure between inclusion and 12 months after inclusion]

Correlation between emotional dysregulation and executive and attentional dysfunction measured with the TAP test.

2. Association between emotional dysregulation, cognitive deficits and circadian instability
[Time Frame: Change en measure between inclusion and 12 months after inclusion]

Correlation between emotional dysregulation and instability index of circadian rhythms measured by actimetry.

Eligibility Criteria

Go to ▼

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion criteria:

- Male or female aged ≥ 18 years
- diagnosis of adult ADHD prior to inclusion
- Affiliated to a social health insurance
- Subject having dated and signed informed consent
- Subject having been informed of the results of the prior medical examination

Exclusion criteria:

- Mobility project preventing follow-up for 1 year (planned move)
- impossibility to give the subject information enlightened (subject in emergency situation, difficulties in understanding the subject, mental retardation, illiteracy or insufficient command of the French language ...)

- Subject under the protection of justice
- Subject under guardianship or curatorship
- Pregnancy
- Breastfeeding

Contacts and Locations

Go to ▼

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT03494478**

Contacts

Contact: Madoé JULIANS, CRA 03 88 11 61 86 ext +33 madoe.julians@chru-strasbourg.fr

Contact: Hélène SOAVELO, PC 03 88 11 65 59 ext +33 helene.soavelo@chru-strasbourg.fr

Locations

France

Centre Hospitalier Spécialisé de Rouffach - Secteur 8 **Not yet recruiting**
Rouffach, France, 68250

Contact: Fabrice DUVAL, MD 03 89 78 70 18 ext +33 f.duval@ch-rouffach.fr

Contact: Alexis ERB, MD 03 89 78 70 18 ext +33 a.erb@ch-rouffach.fr

Hôpitaux Universitaires de Strasbourg - Service de Psychiatrie 2/PPSAM **Not yet recruiting**
Strasbourg, France, 67091

Contact: Sébastien WEIBEL, MD 03 88 11 51 57 ext +33 sebastien.weibel@chru-strasbourg.fr

Contact: Gilles BERTSCHY, MD 03 88 11 65 48 ext +33 gilles.bertschy@chru-strasbourg.fr

Sub-Investigator: Charlotte KRAEMER, MD

Sponsors and Collaborators

University Hospital, Strasbourg, France

Investigators

Principal Investigator: Sébastien WEIBEL, MD Hôpitaux Universitaires de Strasbourg

More Information

Go to ▼

Responsible Party: University Hospital, Strasbourg, France

ClinicalTrials.gov Identifier: [NCT03494478](#) [History of Changes](#)

Other Study ID Numbers: 6795

First Posted: April 11, 2018 [Key Record Dates](#)

Last Update Posted: April 11, 2018

Last Verified: March 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by University Hospital, Strasbourg, France:

Cohort study

Emotion dysregulation

Questionnaires

Actimetry

Neuropsychology