

# Relationship between Overactivity, Stress and anxiety in Anorexia Nervosa

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 20/03/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
8909

# Study information

## Scientific Title

An investigation of the relationship between over activity (hyperactivity), anxiety, stress responsiveness and clinical outcomes in patients with anorexia nervosa (AN): a process outcome study in search for a phase advanced clinical marker

## Acronym

ROSANA

## Study objectives

The ROSANA study is a longitudinal observational investigation which runs over the course of 8 weeks, with follow ups at 12 weeks and 24 weeks. We are investigating anxiety, mood, stress responsiveness and physical activity levels as potential key moderators and/or mediators in anorexia nervosa (AN).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

ref: 09/H0807/4

## Study design

Multicentre observational non-randomised longitudinal case-controlled study

## Primary study design

Observational

## Secondary study design

Case-control study

## Study setting(s)

Hospital

## Study type(s)

Screening

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Anxiety, Eating disorders

## Interventions

Actiwatch:

A non-invasive well-tolerated device that measures activity levels over a continuous 24-hour period. The device contains an accelerometer to measure the frequency of wrist movements every 1 minute.

**Blood sample (AN group only):**

An extra vial of blood is collected alongside routine blood for hormonal (leptin, oestrogen, thyrotropin-releasing hormone [TRH], thyroid-stimulating hormone [TSH], R3) and epigenetic (leptin, fat mass and obesity associated gene [FTO], brain-derived neurotrophic factor [BDNF]) analysis.

**Body composition and body mass index (BMI):**

A 10-minute pain-free procedure in which electrodes are placed on the hands and feet of the patient whilst in a sitting position. A small electrical impulse is sent through the limbs and an analysis of water, fat, muscle and mineral content is made.

**Questionnaires:**

1. Measured at baseline, week 12 and 24:

1.1. Eating Disorders Examination Questionnaire (EDE-Q)

1.2. Depression Anxiety Stress scale (DASS21)

1.3. Obligatory Exercise Questionnaire (OEQ)

1.4. Reasons for Exercise Inventory (REI)

1.5. Exercise Addiction Inventory (EAI)

1.6. Commitment to Exercise Inventory (CEI)

1.7. Short Evaluation of Eating Disorders (SEED)

2. Weeks 1 - 8:

2.1. International Physical Activity Questionnaire (IPAQ)

2.2. Visual Analogue Scales for Anxiety and Internal Restlessness

2.3. DASS21

**Salivary cortisol:**

Morning salivary cortisol samples are collected weekly, within 10 minutes of waking. Salivettes are used to collect the sample - it is a non-invasive efficient method of collection. Samples are stored at -20° prior to analysis.

**Sleep diary:**

A sleep diary is kept over the course of each week, for the first 8 weeks of the study. It details sleep/wake times, quality of sleep and any daytime naps.

## **Intervention Type**

Other

## **Phase**

Phase I/II

## **Primary outcome measure**

BMI, measured weekly and at follow ups (after 6 months)

## **Secondary outcome measures**

1. Actiwatch data, measured weekly for 8 weeks, at 12 weeks and 24 weeks

2. Body composition, measured at baseline, week 12 and 24

3. Questionnaire data, measured at baseline, week 12 and 24

4. Salivary cortisol, measured weekly for 8 weeks, and at follow ups

## **Overall study start date**

25/02/2010

**Completion date**

31/08/2011

## Eligibility

**Key inclusion criteria**

1. Diagnosis of anorexia nervosa (AN) or generalised anxiety disorder (GAD)
2. Females aged 18 years or older, up to 65 years
3. English speaking

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

Planned sample size: 120

**Key exclusion criteria**

1. Male
2. Other psychiatric diagnoses
3. Presence of physical illness
4. Learning disability

**Date of first enrolment**

25/02/2010

**Date of final enrolment**

31/08/2011

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Psychology PO77**

London

United Kingdom

SE5 8AF

## Sponsor information

**Organisation**

South London and Maudsley NHS Foundation Trust (UK)

**Sponsor details**

Michael Rutter Centre for Children

Maudsley Hospital

De Crespigny Park

London

England

United Kingdom

SE5 8AZ

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.slam.nhs.uk/>

**ROR**

<https://ror.org/015803449>

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR), ref: RP-PG-0606-1043

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration