

# Relationship between Overactivity, Stress and anxiety in Anorexia Nervosa

<b>Submission date</b> 10/11/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/03/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

**Protocol serial number**  
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

## **Study type(s)**

Screening

## **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**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**

United Kingdom

England

**Study participating centre**

**Psychology PO77**

London

United Kingdom

SE5 8AF

**Sponsor information****Organisation**

South London and Maudsley NHS Foundation Trust (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**

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

**IPD sharing plan summary**

Not provided at time of registration