

Relationship between Overactivity, Stress and anxiety in Anorexia Nervosa

Submission date 10/11/2010	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 04/08/2011	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 20/03/2017	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☐ 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

Primary study design

Observational

Study design

Multicentre observational non-randomised longitudinal case-controlled study

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