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Relationship between Overactivity, Stress and anxiety in Anorexia Nervosa

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes