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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

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