ISRCTN61942768 https://doi.org/10.1186/ISRCTN61942768

Trial to investigate the maintenance effects of yawning on salivary cortisol levels

Submission date
19/04/2012

Recruitment status
No longer recruiting

Registration date
26/04/2012

Overall study status
Completed

Last Edited
23/09/2015

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There is considerable debate among scientists over why we yawn, and the mechanism of yawning is still not fully understood. About half of adults yawn after someone else yawns due to a phenomenon called contagious yawning. The aim of this study is to test whether levels of the hormone cortisol are higher during yawning and contagious yawning, just as cortisol levels are raised during stress and fatigue.

Who can participate?
Volunteers aged 18-65 will be recruited from students at Bournemouth University.

What does the study involve?
Participants are exposed to three conditions intended to provoke yawning – photos of people yawning, boring text about yawning, and a short video of a person yawning. We collect saliva samples from participants at the start and after yawning to measure saliva cortisol levels, and record the electrical activity of their jaw muscles via surface-placed electrodes. Questionnaires about yawning, anxiety and depression, general health, and demographic and health details are also collected from each participant.

What are the possible benefits and risks of participating?
The results of this study may improve our understanding of yawning and its role in many neurological disorders, and allow us to develop a diagnostic tool for neurological disorders. There are no risks involved. All participants will have the right to withdraw at any time and will be debriefed. All data is anonymised.

Where is the study run from?
Bournemouth University (UK).

When is the study starting and how long is it expected to run for?
June 2012 to December 2012.

Who is funding the study?
Bournemouth University and Santander plc (UK).

Who is the main contact?
Dr Simon Thompson
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Contact information

Type(s)
Scientific

Contact name
Dr Simon Thompson

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Additional identifiers

Protocol serial number
BU-PS5/10/11-PS1/3/12

Study information

Scientific Title
Thompson Cortisol Hypothesis: trial to investigate the maintenance effects of Yawning on salivary Cortisol levels - an observational study

Acronym
TCH-YawnCort

Study objectives
Cortisol levels rise during the yawning episode

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bournemouth University Research & Ethics Committee, 05/10/2011, ref: BU-PS5/10/11-PS1/3/12
Amendments approved 01/03/2012

Primary study design
Observational

Study design
Observational study

Study type(s)
Other

Health condition(s) or problem(s) studied
Salivary cortisol levels

Interventions
Collection of saliva samples; collection of non-invasive surface-placed electrode data of electrical nerve impulses around jaw-line during yawning.

Observing participants' yawning, their level of saliva cortisol before and after yawning, and their electrical (nerve) activity around the jaw muscles at rest and during yawning. The duration of observation is determined by the time it takes to view the stimuli (about 20 minutes) and to yawn. If yawning occurs before all the stimuli have been viewed, then the observation period is shorter for the participant as the stimuli merely serve to elicit a yawn. We aim to conduct a longitudinal study at a later date once data has been analysed and results are known.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Salivary cortisol levels - collection of saliva deposited (spit into tube) by each participant into sample bottle at start of study then again immediately after yawning, or if no yawn elicited, at end of last stimuli presentation
2. Electrical nerve activity - non-invasive surface-placed electrodes around the jaw line receive data throughout the study (20 mins maximum), or only until yawning is elicited, whichever happens first

Key secondary outcome(s)
Demographic and descriptive details of participants age, gender, ethnicity

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. 100 male and female volunteers aged between 18-65 years will be recruited from students at Bournemouth University using the computerised recruitment system (SONA), and Facebook
2. All participants will be properly consented according to code of conduct and research guidelines

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. Chronic fatigue
2. Diabetes
3. Fibromyalgia
4. Heart condition
5. High blood pressure
6. Hormone replacement therapy
7. Multiple sclerosis
8. Stroke

Date of first enrolment
01/06/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bournemouth University
Poole
United Kingdom
BH12 5BB

Sponsor information

Organisation
Bournemouth University (UK)

ROR
https://ror.org/05wwcw481

Funder(s)

Funder type
University/education

Funder Name
Bournemouth University (UK) ref: BU-26.08.11

Alternative Name(s)
Bournemouth Municipal College, Bournemouth College of Technology, Dorset Institute of Higher Education, Bournemouth Polytechnic, BU, DIHE

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Santander plc (UK) ref: SANTANDER-30.09

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/09/2012		Yes	No