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

Submission date 19/04/2012	Recruitment status No longer recruiting	[X] Prospectively registered	
		 Protocol Statistical analysis plan 	
Registration date 26/04/2012	ate Overall study status Completed	[X] Results	
Last Edited 23/09/2015	Condition category Other	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 simont@bournemouth.ac.uk

Contact information

Type(s) Scientific

Contact name Dr Simon Thompson

Contact details Bournemouth University Talbot Campus Poole House (P315) Fern Barrow Poole United Kingdom BH12 5BB

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Study design Observational study

Primary study design Observational

Secondary study design Cross sectional study

Study setting(s) Other

Study type(s) Other

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

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 measure

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

Secondary outcome measures

Demographic and descriptive details of participants age, gender, ethnicity

Overall study start date 01/06/2012

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

Age group

Adult

Lower age limit 18 Years

Upper age limit 65 Years

Sex Both

Target number of participants 100

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 England

United Kingdom

Study participating centre Bournemouth University Poole United Kingdom BH12 5BB

Sponsor information

Organisation Bournemouth University (UK)

Sponsor details

c/o Dr Simon Thompson Associate Professor Talbot Campus Poole House (P315) Fern Barrow Poole England United Kingdom TS17 6QQ

Sponsor type University/education

Website http://home.bournemouth.ac.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) BU

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

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

Study outputs

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