Health and wellbeing

Published: 15-10-2008
Last updated: 06-05-2024

To investigate the mechanisms relating psychological wellbeing to health.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON32847

Source
ToetsingOnline

Brief title
Health and wellbeing

Condition

- Other condition
- Economic and housing issues

Synonym
Heart and hormones

Health condition

autonoom zenuwstelsel en HPA-as functie, geen aandoening

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: British ESRC (overheidsinstantie)

Intervention

Keyword: Autonomic nervous system, HPA axis, Mood, Work stress

Outcome measures

Primary outcome

The main study parameter is the daily change in sympathetic/parasympathetic balance and HPA axis during a worjk versus a leisure day and the association of these changes with mood, personal circumstances and work stress in women.

Secondary outcome

None

Study description

Background summary

Psychological factors such as affect, work stress, personal circumstances have been related to health. However, the mechanisms by which these factors may influence health are yet not clear, though both the autonomic system and the hypothalamic-pituitary-adrenal (HPA) axis have been implied. Most studies have focused on work stress or negative affect while positive affect and personal circumstances have received less attention. Moreover, physiological parameters may be influenced by complex interactions between for instance work situation and personal circumstances (e.g. marital status, having children), and this may be so especially for women, who have received less attention in stress research than men.
The true nature of the interplay of these factors will not become evident in the laboratory but requires ambulatory monitoring during everyday occurring situations. The current availability of ambulatory impedance cardiography allows for the measurement of both parasympathetic and sympathetic activation throughout a normal day. The present study will increase our knowledge of the daily changes in sympathetic/parasympathetic balance and HPA axis function on a work day versus a leisure day, and how these changes relate to mood, personal circumstances and work stress. In addition, these study results will be compared with the results of similar international studies in women.

Study objective

To investigate the mechanisms relating psychological wellbeing to health.

Study design

Cross-sectional observational study.

Study burden and risks

Participants will wear the VU-AMS, a non-invasive heart action monitor during two 24-hour periods on a work day and a non-workday. The VU-AMS is small enough to be worn unobtrusively and non-restrictive in movements. Previous experiences with large groups of participants (>1000) have shown that, a few participants may report mild disturbances of sleep. Saliva sampling will occur at 7 time points during each of the measurement periods using Salivettes, which requires the participants to chew on a cotton swab for two minutes. This is a simple procedure without any discomfort. At the time of the saliva samples, participants also provide a diary entry. At the end of each measurement period, participants complete a computerized interview according to the Day Reconstruction Method. Participants are asked to recall episodes throughout the day and describe their activities and feelings for each episode. Prior to the VU-AMS measurements, participants will also complete a questionnaire booklet on their personal circumstances, work and social situation, lifestyle and their general wellbeing. This study protocol presents no or at most very limited risk for the participants. The laboratory sessions to instruct and attach the VU-AMS monitors will take at most one hour while the time participants will spent on the DRM interviews and questionnaire booklet will be approximately three hours in total. Participants will receive a report on their heart rate during the two measurement periods and the different activities and will receive 50 euro compensation for their time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy females, aged 21 to 65 years, working in a sedentary job for 32 hours or more per week

Exclusion criteria

Pregnancy, having received treatment for serious illness over the last two years, medication use other than contraceptives.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008

Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO Date:	15-10-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL24596.029.08