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Stress reduction in healthy adults: combining physical activity and relaxation

Submission date
04/05/2015

Recruitment status
No longer recruiting

Registration date
29/05/2015

Overall study status
Completed

Last Edited
18/01/2019

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Stress is a general term to describe the feeling of being under too much pressure. Feelings of stress may be triggered by the demands of daily life, such as being very busy at work or struggling with money worries. Stress may also arise as a result of important life events. Common symptoms of stress include sleeping problems, loss of appetite and difficulty concentrating. A number of techniques have been shown to help people manage their stress levels more effectively, including learning relaxation techniques and participating in exercise. The aim of this study is to compare different strategies for stress reduction and see how well they work to reduce feelings of stress in healthy adults. This study will test whether combining physical activity with relaxation techniques works better to relieve stress than carrying out relaxation techniques alone.

Who can participate?
Healthy adults currently employed.

What does the study involve?
Participants visit a thermal spa on 4 study days for approximately 2 hours at a time. All participants complete 4 different stress-relieving treatments in random order. Treatment 1 involves 30 minutes gentle walking combined with 20 minutes resting. Treatment 2 involves 30 minutes gentle walking combined with 20 minutes balneotherapy (bathing therapy). Treatment 3 involves combined relaxation (30 minutes resting and 20 minutes balneotherapy). Treatment 4 involves 60 minutes of resting only. All treatments are carried out in small groups of approximately 10 people and last for one hour. Before and after each treatment participants are asked to give a saliva sample. Participants are also asked to complete a short questionnaire and have their blood pressure taken. On one occasion participants are asked to take their own saliva sample in the morning. On the first study day participants are asked to complete a 30 minute general questionnaire.

What are the possible benefits and risks of participating?
Participants will benefit from experiencing several ways to reduce stress that can be used in daily life. Participants will learn about their own personal study results and which treatments worked best for them. On all four study days participants may stay at the thermal bath for free.

In addition, participants will receive a voucher for two more visits once the study ends. The results of this study will help provide information important to the field of stress reduction and health. There are no risks associated with participating in this study.

Where is the study run from?
Medical University of Graz (Austria)

When is the study starting and how long is it expected to run for?
January 2012 to May 2013

Who is funding the study?
Regional Tourism Association Styrian Thermal Region (Tourismusregionalverband Steirisches Thermenland (Thermenland Styria)) (Austria)

Who is the main contact?
1. Dr F Matzer (scientific)
franziska.matzer@medunigraz.at
2. Dr E Nagele (scientific)
eva.nagele@medunigraz.at

Contact information

Type(s)
Scientific

Contact name
Dr Franziska Matzer

Contact details
Auenbruggerplatz 2/8
Graz
Austria
8036
+43 316 385 83039
franziska.matzer@medunigraz.at

Type(s)
Scientific

Contact name
Dr Eva Nagele

Contact details
Medical University of Graz
Department of Obstetrics and Gynaecology
Auenbruggerplatz 14
Graz
Austria
8036
+43 316 3803306
eva.nagele@medunigraz.at

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
One hour time for stress reduction: combining physical activity and relaxation - a randomised controlled trial in healthy adults

Study objectives
1. Is combining physical activity and relaxation a beneficial strategy for stress reduction in comparison to relaxation only?
2. Do participants with a high versus low stress level benefit from these strategies in a different manner?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical University of Graz, 15/06/2012, ref: IRB00002556.

Study design
A single-centred interventional study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Stress in healthy adults.

Interventions
Participants complete four different stress-relieving interventions lasting one hour each in random sequence:
1. 30 min moderate physical activity (supervised walking across a fixed, flat route at approx. 5-6 km/h) combined with 20 min resting (in a deckchair)
2. 30 min moderate physical activity combined with 20 min balneotherapy (bathing therapy in 36° C water)
3. combined relaxation (30 min resting and 20 min balneotherapy)
4. 60 min resting only
All methods for stress reduction will be conducted in groups averaging 10 persons. Participants will be instructed and supervised by the study personnel (medical doctors and clinical psychologists).

Intervention Type
Mixed

Primary outcome measure
1. Salivary cortisol: saliva samples will be collected before intervention, then again one hour later on each study day
2. Blood pressure: measurements will be taken before and after intervention on each study day
3. State of mood: will be measured before and after intervention on each study day using the Multidimensional Mood State Questionnaire (MDBF), a validated multidimensional measurement for mood. Three bipolar dimensions are measured: (1) good mood - bad mood, (2) alertness – tiredness and (3) calmness – restlessness
4. Subjective relaxation: participants' actual level of subjective relaxation will be measured before and after intervention on each study day using a rating scale (1-10) with 1 indicating no relaxation and 10 indicating high relaxation

Secondary outcome measures
1. Individual stress levels and bodily complaints will be measured using three validated questionnaires at study entry: Hamburger Burnout Inventory (HBI), the Trier Inventory for the Assessment of Chronic Stress (TICS), and the health complaints list (BL)
2. Cortisol awakening response measurement: participants will collect saliva samples directly after waking up in the morning on the second study day

Overall study start date
02/01/2012

Completion date
31/05/2013

Eligibility

Key inclusion criteria
1. German-speaking
2. Healthy men and women
3. Currently employed
4. Aged 30-60

Participant type(s)
Healthy volunteer

Age group
Other

Sex
Both

Target number of participants
81

Key exclusion criteria
1. Participants diagnosed with any diseases
2. Participants currently taking medication that influences blood pressure and/or cortisol levels (e.g. rheumatic or cardiovascular diseases, Morbus Cushing, hypertensive medication)
3. Pregnancy or lactation period

Date of first enrolment
15/08/2012

Date of final enrolment
06/11/2012

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Graz
Department of Medical Psychology and Psychotherapy
Auenbruggerplatz 2/8
Graz
Austria
8036

Sponsor information

Organisation
Medical University of Graz

Sponsor details
Department of Medical Psychology and Psychotherapy
Auenbruggerplatz 2/8

Graz
Austria
8036

Sponsor type
University/education

ROR
https://ror.org/02n0bts35

Funder(s)

Funder type
Government

Funder Name
Regional Tourism Association Styrian Thermal Region (Tourismusregionalverband Steirisches Thermenland (Thermenland Styria)) (Austria)

Results and Publications

Publication and dissemination plan
We intend to publish main results in a peer-reviewed research journal. Data will be presented at scientific congresses.

Intention to publish date
30/06/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018	18/01/2019	Yes	No