An experience sampling methods study of cognitive emotion regulation in younger and older adults

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Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON41188

Source
ToetsingOnline

Brief title
An ESM study of cognitive emotion regulation

Condition

- Anxiety disorders and symptoms

Synonym
anxiety, stress

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: ERC ADvanced Grant

Intervention

Keyword: anxiety, elderly, emotion regulation, experience sampling methods

Outcome measures

Primary outcome

Our main time-dependent outcome relates to self-reported negative and positive affect and continuous HRV registration. In this way on the basis of the ESM measurements the degree of subjective and physiological responding to negative daily life situations can be determined.

Secondary outcome

Our main time-dependent independent variable is the self-reported occurrence of circumscribed and complex high demand life situations and our main time-dependent mediating variable is use of cognitive emotion regulation strategies.

Study description

Background summary

This study tries to disentangle the effect of age and anxiety disorder on use and effectiveness of emotion regulation strategies in daily life. Experimental lab studies indicate that in comparison to younger adults, older adults react less to negative stimuli and ignore irrelevant negative stimuli better. We hypothesize that when the resource demands of a situation overtax individual cognitive capacities, age-related vulnerabilities will become apparent resulting in enhanced psychological and physiological responding to more negative and complex situations in daily life. As enhanced responding to negative events due to diminished cognitive control is also a defining characteristic of anxiety, it is pertinent to distinguish between age-related and anxiety-related deficits in the control of emotions.

Study objective

The first objective is to assess the effect of age and anxiety disorder on use and effectiveness of emotion regulation strategies in circumscribed vs. complex daily life situations. The second objective is to assess the effect of treatment of anxiety disorder on use and effectiveness of emotion regulation strategies in circumscribed vs. complex daily life situations in younger and older adults.

Study design

We will use experiencing sampling methods (ESM) to systematically obtain self-report and physiological data to study the temporal relations between naturally occurring variables (i.e., negative situations, emotion regulation, affect and heart rate variability (HRV)). Assessments will take place during two weeks (and for RCT participants two weeks before and two weeks after an online course of anxiety or waiting list period).

Participants will be asked to complete ESM assessments using electronic diary techniques at five random moments each day over a period of two weeks with the use of a specially developed smartphone. An Android smartphone with chest belt and MovisensXS sampling software will be used for continuous HRV assessments.

Study burden and risks

There are no anticipated risks for taking part in this study. Given the burden of the baseline assessment and instruction session and completing about 60 ESM measurements and wearing a chest strap during two periods of two weeks (+/- 5 minutes each) participants will receive 140 Euro as a financial compensation for completing ESM measurements for each period of two whole weeks.

Contacts

Public
Universiteit Leiden

Wassenaarseweg 52
Leiden 2333 AK
NL
Scientific
Universiteit Leiden

Wassenaarseweg 52
Leiden 2333 AK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

(a) presence of anxiety disorder
(b) age between 18 and 75 years

Exclusion criteria

(a) severe anxiety or depression symptomatology
(b) severe role impairments on various life domains
(c) other severe psychiatric disorder

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	400
Type:	Anticipated

Ethics review

Approved WMO Date:	02-10-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL50528.058.14