Dynamic modelling of resilience: Observational multicenter study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Observational invasive

Summary

ID

NL-OMON49554

Source
ToetsingOnline

Brief title
DynaMOBS

Condition

- Anxiety disorders and symptoms

Synonym
Stress-related mental health problems; Stress-related psychopathy

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Europese Commissie;Horizon 2020

Intervention

Keyword: Mental Health, Neuroscience, Resilience, Stress

Outcome measures

Primary outcome

The main study parameter is dynamic stress resilience (i.e. mental health maintenance despite stressor exposure), as measured with a residuals-based stressors reactivity score.

Secondary outcome

Several parameters are studied to unravel the time-varying, individually variable and interactive engagement of the biological, psychological and social resilience factors, including: biological parameters, psychological questionnaires, neuroimaging, and ecological momentary & physiological assessments.

Study description

Background summary

Stress-related disorders pose a significant burden on individuals, the economy, and society in general. Each year, more than half a billion people around the globe suffer from a mental disorder such as anxiety, post-traumatic stress disorder, depression, or addiction that can to some extent be traced back to the influence of exogenous or endogenous stressors (traumatic events, challenging life circumstances or life transitions, or physical illness. Despite huge efforts spent on investigating the pathophysiology of these disorders and despite the big strides that have been made in developing effective treatments, the extraordinarily high incidence of stress-related disorders has not decreased over the past decades.

DynaMORE (Dynamic MOdelling of REsilience) aims to improve the prevention of stress-related mental health problems by developing a dynamic in-silico model of resilience. Resilience is maintenance and/or quick recovery of mental health

and well-being during and after times of adversity, such as trauma, difficult life circumstances, challenging life transitions, or physical illness.

There is now ample evidence that individuals change while they successfully cope with stressors, whether this manifests at the level of altered perspectives on life , as emergence of new strengths or competences, as partial immunization against the effects of future stressors , or also as epigenetic alterations and modified gene expression patterns. Furthermore, neurobiological studies indicate that such organismic adjustments are causal for the preservation of mental health. Hence, resilience is not simply inertia, or insensitivity to stressors, or merely a passive response to adversity. In the same vein, resilience can no longer be understood simply as a stable, fixed personality trait or predisposition (the *resilient personality*) that guarantees long-term mental health and well-being whatever stressor the organism is exposed to.

This contemporary view of resilience has the important consequence that resilience cannot be measured through any one-time (cross-sectional) assessment (e.g., a questionnaire, a brain scan, genotyping etc.) performed before adversity occurs, as the outdated trait-like conceptualization of resilience implies. Instead, we must closely follow the nature and time course of the stressors an individual is exposed to as well as the changes in mental health that these stressors may or may not induce.

As a prospective resilience study, DynaMOBS consists of a baseline assessment of mental health, followed by mental health assessments during and after stressor exposure. Stressor exposure is measured and quantified, such that changes in mental health can be considered in relation to the adversity an individual has encountered.

Study objective

The primary objective of the study is to identify both modality-specific and modality-spanning predictors of stressor reactivity, thereby guiding the development of an in-silico model of resilience (secondary objective).

Study design

The study follows a longitudinal design consisting of an online-prescreening; two on-site appointments for baseline measures; six months of ambulatory monitoring (including six days of ecological momentary & physiological assessments and biweekly measures of stressor experience and mental health) and three online follow-ups.

Study burden and risks

Minimal risk is associated with this study. However, subjects may experience slight discomfort when collecting various bio-samples (blood, saliva, and stool), when participating in particular behavioral paradigms (inducing fear or stress) and when filling out several psychological questionnaires. Moreover, the MRI scanner may cause discomfort to some participants due to its noise and confined space. There is no considerable residual risk in wearing the Chill+. However, irritation at the site of the patch, is an undesirable side-effect that does happen in a small percentage of the users.

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

Participants are healthy students (18-25 years old) who have experienced at least three life events which were each evaluated as burdening. Participants

have a total GHQ (i.e. general health questionnaire) score * 20. Volunteers are proficient in the Dutch language.

Exclusion criteria

The participant currently meets criteria of a relevant psychiatric disorder except for a mild depressive episode (ICD F32.1), tobacco dependence (ICD F12) and substance abuse as established using the Mini-International Neuropsychiatric interview. The participant has met criteria for a relevant psychiatric disorder except for a mild depressive episode (ICD F32.1), tobacco dependence (ICD F12), and a substance abuse in the past 9 months. The participant has ever been diagnosed with a severe mental or organic disorder that affects neurodevelopment due to its pathological mechanism or treatment. The subject*s body mass index is lower than 18 or higher than 27. The participant is not eligible for functional magnetic resonance imaging. The participant took any psychoactive substances 4 weeks prior to Baseline Day 1 and the MRI appointment. The participant is not eligible to wear the Chill+. The participant is not free of COVID-19 related symptoms.The participant is currently in psychiatric treatment. The participant receives hormonal treatment other than oral contraceptives and/or takes steroids.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-10-2020
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	23-04-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-09-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-10-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-11-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-05-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL70983.091.19

Study results

Date completed:	15-04-2022
Actual enrolment:	57