Dynamic modelling of resilience: Interventional study.

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52021

Source
ToetsingOnline

Brief title
DynaMINT

Condition

- Other condition
- Anxiety disorders and symptoms

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

Health condition

stress-gerelateerde klachten

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: Ecological momentary intervention, Mental Health, Resilience, Stress

Outcome measures

Primary outcome

The main study parameter is dynamic stress resilience as measured with a

residuals-based stressors reactivity score.

Secondary outcome

Changes in resilience in relation to the given EMI are associated with

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. 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.

Study objective

The primary objective of the study is to predict the effect of a given ecological momentary intervention (either ReApp or Imager) based on acquired baseline measures. Further, the use of DBMs to generate an objective stressor reactivity score is investigated (secondary objective) and we will validate the

in-silico model that was developed in DynaMOBS.

Study design

The study follows a longitudinal design consisting of an online-prescreening; on-site appointments for baseline measures; four months of ambulatory training and assessments (including EMA, EPA, and EMI); bio-samples, and biweekly measures of stressor experience, mental health and resilience factors as well as three online follow-ups.

Intervention

Participants will be randomly allocated to receive either an EMI that boosts positive reappraisal (ReApp) or an EMI that boosts reward sensitivity (Imager).

Study burden and risks

Minimal risk is associated with this study. However, subjects may experience slight discomfort when collecting various bio- samples (blood and stool) 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)

Inclusion criteria

Participants are healthy students (18-27 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 reports the use of alcohol 24 hours before the second test baseline test battery. The participant took any psychoactive substances 4 weeks prior to the first or second baseline test battery. The participant is not eligible to wear the Chill+ or eligible for functional MRI. 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. The participant has participated in the DynaMOBS study, and/or any study including a fear conditioning and/or stress induction paradigm, and/or any study using an EMI similar to ReApp or Imager. The participant has a full beard.

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-06-2022
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO Date:	08-06-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-03-2023
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	NL78981.091.21