Effect of verbal suggestions on the cortisol response to stress

Gepubliceerd: 13-09-2017 Laatst bijgewerkt: 13-12-2022

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21541

Bron
NTR

Aandoening

Cortisol

Stress

Expectations / Verwachtingen

Placebo effects / Placebo effecten

Nocebo effects / Nocebo effecten

Ondersteuning

Primaire sponsor: Health, Medical and Neuropsychology unit of Leiden University
Overige ondersteuning: ERC-2013-CoG-617700_EXPECT HEAL-TH, granted to Prof. Dr. A.W.M Evers

Health, Medical and Neuropsychology unit of Leiden University

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Salivary cortisol (area under the curve from ground) based on four measurements (baseline, directly after stressor and 15 and 30 minutes after stressor)

Toelichting onderzoek

Achtergrond van het onderzoek

Placebo and nocebo effects are known to affect a wide variety of psychological and physiological health parameters, although it is currently unknown whether different placebo/nocebo mechanisms (i.e., verbal suggestions versus conditioning) are able to affect both psychological and physiological parameters. The current study aims to examine whether placebo and nocebo effects on the psychophysiological response to stress can be induced by verbal suggestions. A randomized single-blind experiment is conducted in healthy volunteers. After receiving either a positive, negative or no verbal suggestion about their stress responsiveness, which is suggested to be based on questionnaire scores and baseline autonomous measures, participants are exposed to a validated short-term psychosocial stress paradigm. Subjective self-report, autonomous and HPA-axis parameters are measured at baseline and after stress. An emotional Stroop task is administered to investigate effects on implicit cognitive processing after stress. Knowledge on the potential effects of verbal suggestions on subjective and physiological stress responses is not only of conceptual relevance in investigating placebo and nocebo effects, but also of clinical relevance as they provide insight in the development and treatment of stress-related disorders.

Doel van het onderzoek

Placebo and nocebo effects affect physiological as well as psychological outcomes through expectancies that can be elicited by, for example, conditioning and verbal suggestions. It has been argued that placebo and nocebo effects induced by conditioning mainly affect physiological outcomes such as hormones and immune parameters, while placebo and nocebo effects induced by verbal suggestions mainly affect subjective outcomes such as pain. However, research shows that verbal suggestions regarding the expected physiological reactions to stress can induce placebo and nocebo effects on autonomic nervous system responses. It is currently unclear whether such effects would also hold for other relevant physiological parameters, such as cortisol, a key stress-regulatory parameter that has a major impact on human functioning. The primary research question of the current study is whether cortisol responses to a psychosocial stress task can be affected by verbal suggestions. As secondary outcomes, the impact of verbal suggestions on ANS and affective

responses will be investigated. Additionally, to explore possible mechanisms by which verbal suggestions may affect cortisol and ANS and affective responses, implicit processes will be assessed by an emotional Stroop-task. It is hypothesized that the placebo suggestion will lead to a reduced cortisol and ANS reactivity and less pronounced negative affective response to this task (placebo effect), while the nocebo suggestion will lead to a higher cortisol and ANS reactivity and a more pronounced negative affective response to the same task (nocebo effect). When effects of verbal suggestions would be found on affective and ANS responses, but not on cortisol responses, this would support the notion that subjective and autonomic, but not hormonal outcomes, can be affected by verbal suggestion. However, when verbal suggestions would be found to affect the cortisol, ANS and affective response to stress, this study would be the first to show that verbal suggestions can be sufficient to affect hormonal outcomes. Exploring whether positive and negative verbal suggestions affect implicit processes in response to stress, could provide insight into possible mechanisms by which verbal suggestions affect hormonal, ANS and affective responses to stress.

Onderzoeksopzet

Cortisol and alpha amylase are assessed at baseline, immediately after stress and at 15 and 30 minutes after stress.

Heart rate, heart rate variability and skin conductance are assessed at baseline, during stress, immediately after stress and 30 minutes after stress

Affect and self-reported stress are assessed at baseline, immediately after stress and 30 minutes after stress

Cognitive bias will be assessed after stress.

Onderzoeksproduct en/of interventie

For this study, participants will be allocated randomly to one of three conditions (placebo, nocebo, control). Conditions differ only with respect to a verbal suggestion that participants will receive with regard to their expected (psychophysiological) stress response to the Trier Social Stress Test, which all participants will be exposed to after receiving the verbal suggestion.

Participants in the placebo condition will be told that, based on questionnaires they filled in before the start of the experiments and baseline physiological measures, they are expected to respond in a beneficial way to the subsequent task, and therefore will experience more positive physiological and affective consequences of being stressed. Participants in the nocebo group are told that, based on questionnaires they filled in before the start of the experiments and baseline physiological measures, they are expected to respond in a detrimental way to the subsequent task, and therefore will experience more negative physiological and affective consequences of being stressed. Participants in the control group will receive no suggestion regarding their stress responsiveness.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Female and male healthy volunteers

Between 18 and 35 years of age

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Prior experiences with psychiatric or chronic somatic conditions affecting HPA-axis functioning

Colorblindness

Inability to speak Dutch

Pregnancy

Pacemaker

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	29-05-2017
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-09-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6513
NTR-old	NTR6702
Ander register	Commissie Ethiek Psychologie Leiden University : CEP17-0511/200

Resultaten

Samenvatting resultaten
Not applicable