

# Can yoga improve affect regulation in response to daily life stress in people with long-term pre-existing mood or anxiety disorders?

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<b>Registration date</b> 27/09/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/08/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Patients with chronic mood and anxiety disorders experience many life stressors and are more reactive to these stressors. Mindful yoga represents an intervention that might reduce stress reactivity. However, little is known about affect regulation strategies by which yoga might reduce stress reactivity. In this study, we examined within-person temporal associations between stressful experiences, affect and four potential affect regulation strategies: rumination, fear of emotions, mindfulness and body awareness, before and after a yoga intervention. Using experience sampling methodology, 12 patients with chronic mood and anxiety disorders completed five daily assessments for 15 days before and after a 9-week mindful yoga intervention. Autoregressive moving average models were used to assess mean-level change from pre to post intervention and vector autoregressive models to assess change in the temporal associations. Most individuals experienced positive changes in affect and the proposed affect regulation strategies. There were individual differences in which pathways from stress to the strategies and from the strategies to affect changed and how they changed. In the context of daily life stress, change seems to be more difficult and complex, and it remains difficult for many individuals to preserve a better affect balance with regards to the proposed affect regulation strategies.

## Background and study aims

Patients with chronic (long-standing) mood and anxiety disorders experience many stressful situations in the life such as suicide attempts and hospitalizations, higher risk of developing physical illnesses and problems with physical, social and work functioning. Moreover, they also react more strongly to these stressors. Mindful yoga could be a technique to reduce stress reactivity. However, little is known about the processes by which mindful yoga might reduce stress reactivity. Rumination (repeatedly thinking about problems) and fear of emotions are two processes that might increase stress reactivity, and mindfulness and body awareness (understanding of the body's position and sensations) are two processes that might reduce stress reactivity. This study aims to investigate changes within people from before to after a 9-week mindful yoga course. It will examine the relationships between stressful experiences, moods and feelings, and four ways of changing moods and feelings: rumination, fear of emotions, mindfulness, and body awareness.

Who can participate?

Adults with a chronic mood or anxiety disorder who are currently in treatment at a mental health clinic.

What does the study involve?

All participants receive a 9-week mindful yoga intervention. Before and after the intervention they completed five daily assessments over 15 days. These daily assessments involved questions about the stressful events during their day, current mood/feelings, and questions on rumination, fear of emotions, mindfulness, and body awareness. Before and after the yoga treatment, and at 6 and 12 months after the end of the yoga treatment, they also completed several questionnaires to assess psychological symptoms, and quality of life.

What are the possible benefits and risks of participating?

Participants may potentially benefit from receiving the 9-week mindful yoga intervention. Mindful yoga, especially unsupervised practice, may lead to injuries. The participants were medically screened to see if they needed any adaptations of yoga postures because of certain health conditions. Also, the intervention was designed to be safe and well-supervised in order to reduce the risk of injuries for the participants.

Where is the study run from?

The Center for Integrative Psychiatry, an outpatient department of Lentis Psychiatric Institute (Netherlands)

When is the study starting and how long is it expected to run for?

May 2015 to May 2017

Who is funding the study?

The Center for Integrative Psychiatry, an outpatient department of Lentis Psychiatric Institute (Netherlands)

Who is the main contact?

Nina Vollbehr, [n.vollbehr@lentis.nl](mailto:n.vollbehr@lentis.nl)

## Contact information

**Type(s)**

Public

**Contact name**

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

2015/387

## **Study information**

### **Scientific Title**

The temporal dynamics of daily life stress, affect, and several affect regulation strategies, in patients with (chronic) mood and anxiety disorders before and after a yoga intervention

### **Study objectives**

We hypothesized that after the yoga intervention, participants would show improved affect, and changes in the proposed affect regulation strategies, including reduced rumination and fear of emotions and greater mindfulness and body awareness. We also hypothesized that the temporal associations between the variables would change in beneficial directions (e.g., weakening of the positive association between stressful experiences and rumination). Finally, we hypothesized that we would find different individual pathways of change in the relationships between stress and the proposed affect regulation strategies; and in the relationships between these affect regulation strategies and affect.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The Medical Ethical Committee of the University Medical Center Groningen judged the study protocol to be exempted from review by the Medical Research Involving Human Subjects Act (in Dutch: WMO) because it concerned a non-randomized open study (registration number 2015 /387).

### **Study design**

Non-randomised study

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised study

**Study setting(s)**

Other

**Study type(s)**

Treatment

**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**

Chronic mood and anxiety disorders

**Interventions**

Participants undertook a manualized 9-week mindful yoga intervention, based on traditional yogic practices and texts, which were adapted to a clinical setting for patients with mood and anxiety disorders, that was tested in a pilot study (Vollbehr, Hoenders, Bartels-Velthuis & Ostafin, 2019). The intervention consisted of weekly 90-minute sessions with yoga postures (80%), meditative practices and breathing techniques (20%). Participants received a manual with weekly registration forms and practice videos. When necessary, adaptations of postures were given (e.g., no full standing forward bend for a participant with high blood pressure). Material needed to adjust yoga postures was available for the participants.

We examined within-person temporal associations between stressful experiences, affect and four potential affect regulation strategies: rumination, fear of emotions, mindfulness and body awareness, before and after a yoga intervention, using experience sampling methodology.

Participants completed daily diary questionnaires on their smartphones. If they did not have a smartphone we gave them one including explanation of the functions to complete the questionnaires. Participants received a text message with a link to RoQua ([www.roqua.nl](http://www.roqua.nl)), a secure online survey administration program, to complete on their smartphone. After 30 minutes, the participants were sent a reminder text message to complete the questionnaire, if they had not yet done so. If participants did not complete the questionnaires within 60 min, the questionnaire became inaccessible

**Intervention Type**

Behavioural

**Primary outcome measure**

1. Affect balance assessed by deducting the positive affect items from the negative affect items in the Depression, Anxiety 2. Rumination assessed at pre- and post-intervention using one item from the Preservative Thinking Questionnaire (Ehring et al., 2011), adapted to reflect the focus on negative thoughts: "Many negative thoughts are going through my head"
2. Fear of emotions assessed at pre- and post-intervention using one item focusing on the fear of losing control of one's emotions (Williams et al., 1997): "I feel overwhelmed with my emotions", and one item focusing on the accepting, open awareness of emotions that is an aspect of mindfulness (Bishop et al., 2004): "I accept the way I am feeling"
3. Mindfulness assessed at pre- and post-intervention using items from the Mindful Attention and Awareness Scale (MAAS) with a high factor loading (Osman, Lamis, Bagge, Freedenthal & Barnes, 2016): "Over the last period I did tasks and errands automatically, without being aware"

of what I was doing" and "Over the last period I was living in the moment". We reformulated the scoring of the second item, with a higher score indicating more mindfulness.

4. Body awareness assessed at pre- and post-intervention using two items, with the first reflecting the noticing of inner sensations (Mehling et al., 2012): "Over the last period I was aware of things that were happening in my body, for example tension, emotional responses or other sensations". The other item focused on embodiment (Mehling et al., 2012): "Over the last period I felt at home in my body".

5. Temporal associations between stress, rumination, fear of emotions, mindfulness and body awareness and affect balance assessed at pre- and post-intervention

### **Secondary outcome measures**

N/A

### **Overall study start date**

01/05/2015

### **Completion date**

01/05/2017

## **Eligibility**

### **Key inclusion criteria**

1. Has a mood or anxiety disorder or post-traumatic stress disorder with an illness duration of at least 2 years
2. Receiving current treatment as usual
3. Willing to attend nine weekly sessions of a yoga intervention
4. Able to read and write Dutch
5. Aged over 18 years

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

12

### **Key exclusion criteria**

1. Acute suicidal symptoms
2. Acute psychotic symptoms
3. Substance abuse

### **Date of first enrolment**

01/10/2015

**Date of final enrolment**

01/12/2015

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

Center for Integrative Psychiatry, Lentis Psychiatric Institute

Hereweg 76

Groningen

Netherlands

9725AG

## **Sponsor information**

**Organisation**

Lentis Center for Integrated Psychiatry

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.lentis.nl>

**ROR**

<https://ror.org/00t93jm73>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Lentis

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Netherlands

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

01/01/2020

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from Nina Vollbehr, n.vollbehr@lentis.nl. Excel data files will be available from 01/10/2019 until 01/10/2029. Consent was obtained from the participants.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>		21/08/2020	21/08/2020	No	No