

Yoga for Generalized Anxiety Disorder

Stefan G. Hofmann

Elizabeth Hoge

Sat Bir Khalsa

Shelley Kind

Elizabeth Mundy

David Rosenfield

Naomi Simon

Supported by: The National Center for Complementary and Integrative Health
(NCCIH) 1R01AT007257-01A1 & 1R01AT007258-01A1

Principal Investigators: Stefan Hofmann, Ph.D. and Naomi Simon, M.D.

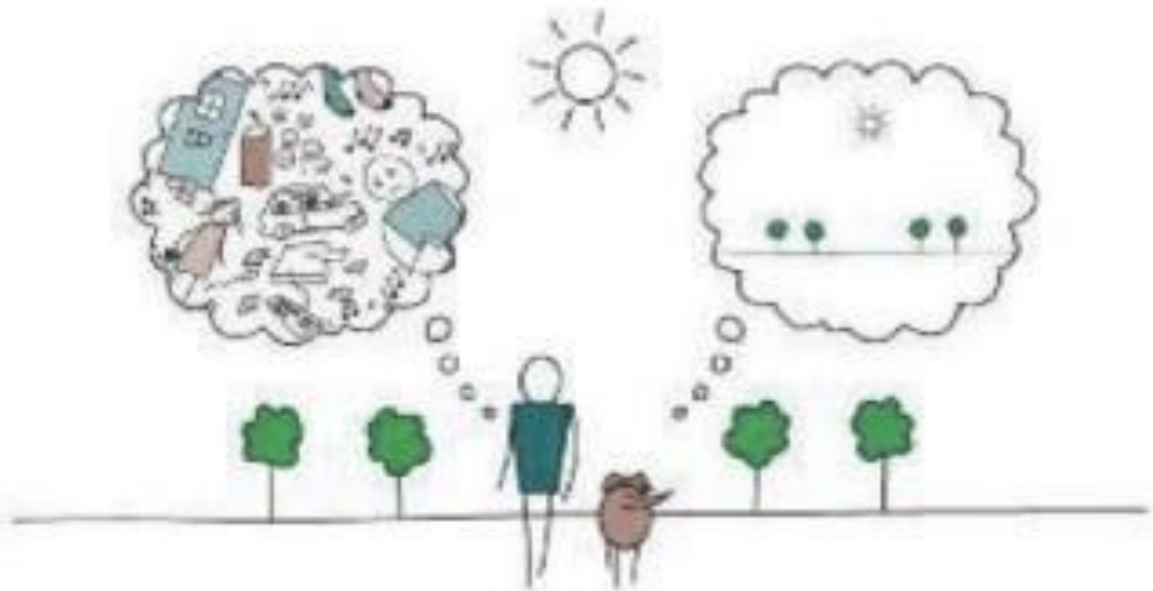
Background

- Lifetime prevalence rate of generalized anxiety disorder (GAD) is estimated to be 5.7% and is associated with high comorbidity, suffering, and burden
- Cognitive Behavioral Therapy (CBT) is the gold standard for treatment for GAD, but CBT is not widely accessible.
- Mindfulness practices also appear to be beneficial (Hofmann et al., 2010). Kundalini Yoga is a mindfulness based practice that is widely accessible to many

I DON'T ALWAYS PRACTICE MINDFULNESS AND BEING IN THE MOMENT...



BUT WHEN I DO, I IMMEDIATELY TELL FACEBOOK



Mind Full, or Mindful?

I WANT TO KNOW THE MEANING OF LIFE

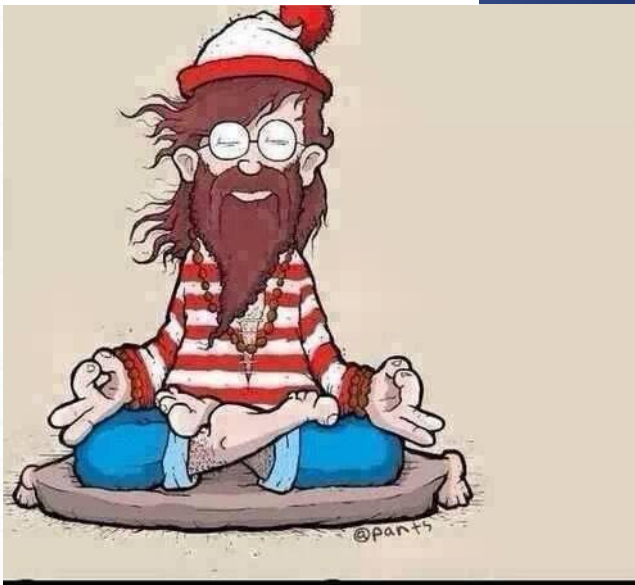
HAVE YOU TRIED GOOGLING IT?



LYNCH



"Okay, your posture's very good. Now relax, concentrate, and slowly let go of your cell phone."



Plot twist. Waldo finds himself.

Preliminary Evidence for Yoga for Treating Anxiety

Reductions in anxiety have been reported after yoga in:

- Normals (Agte & Chiplonker, 2008; Kjellgren et al., 2007),
- Students under exam stress (Malathi & Damodaran 1999),
- Stressed caregivers (Waelde et al., 2004),
- Subjects with self-reported chronic distress (Michalsen et al. 2005; Smith et al., 2007),
- Anxiety in musicians (2009, 2006) and police cadet trainees (2013).

Generalized Anxiety Treatment Evaluation (GATE)

- Funded by NIH/NCCIH (formerly NCCAM)
- Large 5-year linked 2-site 2-PI R01
(R01AT007257 & R01AT007258)

Study Team

PI's



Naomi Simon
MGH



Stefan G. Hofmann
BU

Co-
PI's



Elizabeth Hoge
MGH



David Rosenfield
Southern
Methodist Univer.



Sat Bir Khalsa
Brigham and
Women

Aims

Our primary aim is to examine the short-term and long-term treatment efficacy of yoga (physical exercises/postures, meditation/mindfulness, and breathing exercises) for treating Generalized Anxiety Disorder (GAD) as compared to conventional CBT for GAD and to a stress education (SE) control condition. This study would provide the first RCT data for the comparative efficacy and acceptability of a standardized yoga group for the treatment of GAD compared to an active control, as well as gold standard CBT for GAD, and would generate a strong evidence base to support clinical use and future research.

Specific Aim 1: Short-term Efficacy of Yoga: Our primary objective is to examine the short-term treatment efficacy of yoga on GAD symptoms. We expect that, at post-treatment, a significantly greater proportion of individuals randomized to receive yoga will be classified as “responders” to treatment ($CGI-I \leq 2$) than for individuals who receive SE (Hypothesis 1.1). We further expect that a greater proportion of individuals receiving CBT for GAD will be classified as “responders” than for those receiving SE (Hypothesis 1.2). Moreover, we predict that the rate of “responders” in individuals receiving yoga will be comparable to those receiving CBT at post-treatment (Hypothesis 1.3).

Specific Aim 2: Long-term Efficacy of Yoga: Our secondary aim is to examine the long-term treatment efficacy of yoga on GAD symptoms. We hypothesize that yoga and CBT will be equally effective at the 6-month follow-up (i.e., the “responder” rate for yoga will not be inferior to that for CBT), and that yoga and CBT will each have higher “responder” rates than SE (Hypothesis 2.1-2.3).

Specific Aim 3: Mediation Analyses. Our tertiary aim is to examine and compare the mechanism of treatment changes in yoga and traditional CBT for GAD. We predict that treatment changes in responder rates during yoga treatment will be mediated via changes in mindfulness and changes in vagal tone (Hypothesis 3.1), whereas changes in CBT will be mediated via changes in maladaptive cognitions (Hypothesis 3.2.). Moderators of “responder rates” will also be examined.

Methods

- Randomized Control Trial of 230 patients with a primary diagnosis of GAD recruited from Boston University and Massachusetts General Hospital
- Kundalini Yoga (N = 95) will be compared to SE (N = 40) and CBT for GAD (N = 95)
- All interventions will be conducted in a two hour group format over 12 weeks with 4-6 patients per group and therapists/instructors

Eligible
N = 460

Consented
N = 250

Randomized
N = 230

Yoga
N = 95

Post-Treatment

6-Month Follow-Up

CBT
N = 95

Post-Treatment

6-Month Follow-Up

SE
N = 40

Post-Treatment

6-Month Follow-Up

Table 4.2

Study Weeks	Pre-Treatment	Mid-Treatment	Post-Treatment	6-month Follow-up
Interview-based measures				
CGI-S/CGI-I	✗	✗	✗	✗
SCID-IV	✗			
SIGH-A	✗	✗	✗	✗
Self-report measures of outcome				
STAI	✗	✗	✗	✗
BDI-II and BAI	✗	✗	✗	✗
PSS	✗	✗	✗	✗
SCL-90	✗	✗	✗	✗
QOLI	✗	✗	✗	✗
MCQ	✗	✗	✗	✗
FFMQ	✗	✗	✗	✗
PSWQ	✗	✗	✗	✗
Psychophysiological/Biological measures of stress				
PEP, Cortisol	✗	✗	✗	✗
Measure of treatment moderator				
Credibility/Expectancy	✗			
Measures of Study Integrity and Safety (see text)				
Adverse Events		✗	✗	✗
Homework Compliance		✗	✗	
Working Alliance	✗	✗	✗	
Physical fitness	✗			
MoCA	✗			

Methods

Treatment Response Outcome Measures

- Clinician Global Impression-Severity Scale (CGI-S) and Improvement Scale (CGI-I) will be used in determining remission and response criteria
- Treatment response is defined as a CGI-I of 1 (very much improved) or 2 (much improved)
- Remission is defined as CGI-S of 1 (not at all ill) or 2 (borderline ill)

Methods

Psychophysiology Assessment

- ECG (RSA)
- Salivette Sample (i.e., cortisol)
- Affect Grid
- Vital Signs

Other Measures

- Credibility / Expectancy
- Homework compliance
- Adverse Events Log
- Concomitant Medications/Therapy Log

Inclusion/Exclusion

<i>Inclusion Criteria</i>	<i>Rationale</i>
Male or female outpatients 18 years of age or older with a primary psychiatric diagnosis of generalized anxiety disorder	Population under study
CGI-severity score of 4 or higher	Adequate pre-treatment severity
Off concurrent psychotropic medication for at least 2 weeks prior to initiation of randomized treatment, OR stable on current medication for a minimum of 6 weeks and willing to maintain a stable dose	Treatment confound
Willingness and ability to perform the yoga intervention and to comply with the requirements of the study protocol.	Human subjects concerns
<i>Exclusion Criteria</i>	
Patients unable to understand study procedures and participate in the informed consent process.	Human subjects concern
<i>For women of childbearing age:</i> Pregnant (based on urine pregnancy test), planning to become pregnant, or lack the use of approved methods of birth control	Human Subjects Safety
Serious medical illness or instability for which hospitalization may be likely within the next year	Feasibility, subject safety
Significant current suicidal ideation or suicidal behaviors within the past 6 months (assessed with the BDI-II)	Subject safety
History of head trauma causing loss of consciousness, or seizure disorder resulting in ongoing cognitive impairment	Treatment confound, subject safety
Posttraumatic stress disorder, substance use disorder, eating disorder, or organic mental disorder within the past 6 months	Treatment confound
Lifetime history of psychotic disorder, bipolar disorder, or developmental disorder	Treatment confound
Significant personality dysfunction likely to interfere with study participation (assessed during the clinical interview)	Treatment confound
Prior experience with (more than 5 Yoga classes or CBT sessions within the last 3 years) and/or current practice of mind-body techniques (e.g., yoga, meditation, Tai-Chi, etc) or CBT	Treatment confound
Concomitant psychotherapy for GAD (any psychotherapy)	Treatment confound
Physical conditions that might cause injury from yoga (pregnancy, physical injuries and musculoskeletal problems)	Human subjects concern and subject safety
Cognitive impairment (MOCA \leq 21)	Human subjects concern and safety

CBT

Modules

- Psychoeducation
- Relaxation
- Cognitive Restructuring
- Targeting Metacognitions
- Exposure and Behavioral Change
- Relapse Prevention

Yoga

- Kundalini Yoga practices as taught by Yogi Bhajan
- It incorporates all of the traditional components of yoga including physical postures and exercises, breathing techniques, relaxation exercises and meditation practices.

Stress Education

To control for therapist attention, expectancy effects, and group support effects

Content areas

- definitions of stress and the stress response (e.g., fight or flight response)
- physiological and psychological effects of stress
- stress and performance
- the negative stress cycle
- stress and health/illness, immunity
- stress buffers and hardiness
- stress and heart disease
- the role of genes and environment in health
- the contribution of lifestyle behaviors such as caffeine and alcohol intake and cigarette smoking
- the importance of regular exercise and proper diet
- No specific instructions for exercise or dietary changes will be given

Results

Sorry, no results yet.

Come back to ADAA in 2018!