Online Breathwork-Assisted Therapy for Social Anxiety

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Primary Objective: The primary objective is to assess the effectiveness of HVB-assisted therapy (HV-BAT) in reducing self-reported SA.Secondary Objectives: The secondary objective is to assess the effectiveness of HVB-assisted therapy (HV-BAT) in...

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

Summary

ID

NL-OMON57397

Source
ToetsingOnline

Brief title
Breathe hard to breathe easy

Condition

- Other condition

Synonym
Social phobia

Health condition

Social anxiety

Research involving
Human

Sponsors and support

Primary sponsor: Neuropsychologie & Psychofarmacologie
Source(s) of monetary or material Support: Tiny Blue Dot Foundation

Intervention

Keyword: altered states of consciousness, breathwork, social anxiety, therapy

Outcome measures

Primary outcome

Social anxiety - Liebowitz Social Anxiety Scale (LSAS)

Secondary outcome

Rater-assessed performance in the Getting Acquainted Task (GAT)

Heart rate variability (HRV)

Salivary Cortisol (SC)

Therapeutic alliance - Working Alliance Inventory - Self-Report (WAI-SR)

Treatment expectancy - Credibility and Expectancy Questionnaire (CEQ)

Openness to experience - Big Five Inventory (BFI)

Suggestibility - Modified Tellegen Absorption Scale (MODTAS)

ASC phenomenology - 5 Dimensions of Altered States of Consciousness (5D-ASC);

Peak Experience Scale (PES)

Empathy - Multifaceted Empathy Test (MET); Interpersonal Reactivity Index (IRI)

Well-being - World Health Organisation Well-Being Index (WHO-5);

Resilience - Resilience Scale (RS)

Cognitive Flexibility - Cognitive Flexibility Index (CFI)

Person perception - Implicit Association Task (IAT)

Mood - Positive And Negative Affect Schedule (PANAS)

Sleep - Groeningen Sleep Quality Scale (GSQS)

Anxiety - State and Trait Anxiety Inventory

Study description

Background summary

Social anxiety disorder (SAD) is diagnosed when social anxiety (SA) is so intense that it causes clinically significant suffering and impairment in an individual*s life (1). SAD is among the most prevalent mental health disorders, with an estimated lifetime prevalence of 13% (2). Starting early in adolescence, typically around the age of 13, and often persisting over time (2), SA imposes significant personal and societal burdens (2). When combined with other mental health conditions such as depression, it tends to predict a more severe trajectory, including a heightened risk of suicide (2).
Individuals experiencing high levels of SA are caught in a harmful cycle shaped by two primary factors: a profoundly negative self-image and acute awareness of their increased physiological reactions (3, 4) in social situations (1). This interaction leads to a vicious cycle they will a) anxiously anticipate the feared situation (5), b) experience intense sympathetic responses (e.g., palpitations, sweating, blushing) (3, 4), c) which will confirm their self-defeating beliefs (5), d) potentially impact their social performance, e) and strengthen their anticipatory anxiety (5), thus completing the circle.
Therefore, high SA is understandably associated with isolation (6), reduced socio-economic status, reduced quality of life, and comorbid conditions such as depression, substance-use disorders, and cardiovascular disease (7).
The current first-line treatment for clinically significant SA is cognitive-behavioral therapy, with studies estimating response rates between 50% and 65% (against 32% after placebo-treatment) (2). Considering that the condition is undertreated due to these individuals* difficulties in meeting therapists or other health professionals (8), the need for new, more accessible treatments becomes even more apparent.
Psychedelic research has given a new impulse to explore the therapeutic potential of experiencing altered states of consciousness (ASC) in therapeutic settings (9) for conditions like substance addiction (10, 11), depression (12), and anxiety linked with life-threatening illnesses (13-16). Of particular relevance for this project, results from a proof-of-concept, double-blind, placebo-controlled, randomized parallel-group trial showed a significantly greater improvement in self-perception and speech performance after one dose of ayahuasca in a sample of patients with SAD (17). Furthermore, MDMA-assisted therapy showed promise in reducing social anxiety in adult autistic individuals (18) and a protocol to investigate the effects of MDMA-assisted psychotherapy in the treatment of SAD was recently published (19).

High-ventilation breathwork (HVB) is a non-pharmacological way to induce ASC (20). It has been used therapeutically instead of psychedelics in countries where these substances are outlawed (21). HVB-induced ASC causes a similar, albeit less intense, phenomenology compared to psychedelics and can, in some cases, generate full mystical experiences (20). While research on its therapeutic potential is still in its infancy, reports suggest that HVB leads to improvements in the same areas that psychedelics are researched for, including anxiety and well-being (20). Particularly relevant for SA and potentially for the treatment of SAD, considering that one of their core features is a strong, negative self-evaluation (5), HVB has been found to promote improvements in non-judgment of thoughts, dogmatic thinking, and connection to others (20).

Study objective

Primary Objective: The primary objective is to assess the effectiveness of HVB-assisted therapy (HV-BAT) in reducing self-reported SA.

Secondary Objectives: The secondary objective is to assess the effectiveness of HVB-assisted therapy (HV-BAT) in improving social performance in a social interaction task (Getting Acquainted Task, GAT). Social performance will be assessed by raters and heart rate variability (HRV) and salivary cortisol (SC) will be used as a measure of physiological arousal in response to the task.

Additional Objectives: we will also test whether measures of therapeutic alliance, treatment expectancy, personality, and ASC phenomenology influence the potential outcomes. Finally, we will test whether the treatment will have an effect on empathy, people perception, resilience and well-being.

Primary Hypothesis: we hypothesize that participants in the HV-BAT group will show greater reductions in SA one week after the end of the study compared to participants in the slow-paced breathwork-assisted therapy (SP-BAT) group.

Secondary Hypotheses: we hypothesize that participants in the HV-BAT group will show better performance, increased HRV and decreased SC in response to the GAT compared to the SP-BAT one week after the end of the study.

Study design

The study will be conducted according to a randomized, experimental, between-groups design with two intervention options: high-ventilation breathwork-assisted therapy and slow-paced breathwork-assisted therapy, with the latter serving as an active control. The intervention will consist of a total of 6 sessions including two preparation sessions, two breathwork sessions, and two integration session.

Intervention

Following t0 assessment, participants will be assigned a therapist who will lead the preparation and integration sessions and a trained facilitator who will lead the breathwork sessions. Following that, they will take part in a first 90-minute preparation session aimed at establishing therapeutic alliance, gathering personal and family history, SA history, and providing an explanation of the treatment rationale. During this session the participant will also be introduced to their breathwork facilitator. After the first preparation session (post-p1), the LSAS, WAI-SR (for both the therapist and the breathwork facilitator), STAI and CEQ will be administered.
About one to three days later, a 60-minute preparation session will take place with the aim of discussing the participants* hypotheses concerning the cause of their SA, setting intentions and treatment objectives for each breathwork session, and establishing realistic and positive expectations. Before the session participants will fill the GSGQ and the PANAS. After the session the LSAS, PANAS and STAI will be administered.
One to three days later, a 60-minute breathwork session (bw1, either HVB or SPB) will take place. Before the session, participants will be administered the PANAS and GSQS. Once the session is complete, participants will fill out the ASC phenomenology questionnaires (5D-ASC and PES), LSAS, STAI and PANAS.
One to three days after the breathwork session, participants will take part in a 60-minute integration session aimed at processing the contents and potential insights that emerged during the breathwork session, generalising them to daily life and preparing for the next breathwork session. Before integration sessions, participants will be administered the PANAS and GSQS. After integration sessions they will be administered the LSAS, STAI and PANAS.
The second breathwork session will be held one to three days after the integration session and will be followed by a final integration session after a similar interval. All breathwork sessions will be held online in the lab and the participant will connect with the facilitator through a computer. All therapy sessions (i.e., preparation and integration) will take place online from a location of the participant*s choosing. Online therapy has received support from the scientific literature (65).

Study burden and risks

Participants will be invited to the lab twice for the administration of behavioral tasks and two more times to participate to the breathwork sessions. Each visit will last about 2 hours. The treatment will run online and includes activities for a total 6.5h. Finally, we estimate a cumulative 1 hour to fill in all questionnaires. The total maximum load per participant is therefore 11.5 hours. High-ventilation breathwork can produce an increased state of physiological arousal accompanied by elevations in heart rate and blood pressure that are considered safe in appropriately screened individuals. It also produces altered states of consciousness that may, in some cases, be

characterized by transient anxiety. Participants may also experience discomfort during the social interaction task. In case the treatment yields the expected results, a potential benefit may be the reduction of social anxiety.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Fluent in the English or Dutch language
Aged between 18 and 65
LSAS score >=50
Written informed consent

Exclusion criteria

Hypotension (diastolic < 60 mmHg; systolic > 90 mmHg) or hypertension (diastolic > 90 mmHg; systolic > 140 mmHg)
History or presence of psychotic or bipolar disorders or first-degree relatives suffering from this
History of respiratory or cardiovascular/heart problems or disease
History of fainting or syncope, epilepsy or seizures
History of panic disorder or panic attacks, cerebral aneurysm,
Having had adverse reactions with prior breathwork sessions (i.e., fainting),
Pregnancy, thinking one might be pregnant, trying to get pregnant, or breastfeeding
Any problems affecting the ability to pace breathing (i.e., active/chronic respiratory infection including blocked nose/cough/cold/fever, etc.), breathlessness, abnormally slow breathing (bradypnea), or abnormally fast breathing (tachypnoea), any other physical/mental health conditions or current life events impairing the ability to engage in activities involving breath control
Taking any regular medication other than the contraceptive pill, including medications to reduce blood pressure (i.e., Ramipril or other ACE-inhibitors) and beta-blockers (i.e., Propranolol).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	98

Type:	Anticipated

Ethics review

Approved WMO Date:	07-04-2025
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL87496.068.25