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Does exposure to body odors increase the effect of mindfulness treatment in patients with social anxiety symptoms?

Submission date
06/10/2022

Recruitment status
No longer recruiting

Registration date
16/11/2022

Overall study status
Completed

Last Edited
28/07/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
It is important to understand how chemistry influences human social interactions because of its many implications for science and society. For example, previous research showed a link between the sense of smell (olfaction) and affective psychiatric disorders. Olfactory processing may be impaired in social anxiety disorders. People with social anxiety disorder have also been found to be more sensitive to social odors. A possible explanation is that parts of the brain areas involved in olfactory processing are also those that are affected by social anxiety symptoms (e. g., prefrontal structures). However, more detailed research is needed on olfactory processing in this patient group to examine the possible treatment value of human chemosignals. To expand this knowledge, the aim of this study is to find out whether odors extracted from people who were experiencing happy, fearful or neutral emotions can be used to increase the positive results of mindfulness meditation therapy in subjects with social anxiety symptoms.

Who can participate?
Women between the ages of 18 and 35 years who display social anxiety symptoms

What does the study involve?
On the first day of the study, all participants will answer several questionnaires that measure how anxious, stressed, and mindfully aware they are. Next, they will be placed at random in one of the four odor groups (happy, fearful, neutral or clear air). Then, all participants will follow the mindfulness intervention while smelling the odor through an odor-delivery system designed for this study. Their skin conductance and heart rate are measured during the intervention, for 3 minutes before and for 3 minutes after the intervention. When they are done with the intervention, the participants will have to answer the questionnaires about how anxious they are. The next day, all participants will answer the same questionnaire as the first day, assessing their level of anxiety. Then, participants will follow the mindfulness intervention while smelling the same type of odor as they did the previous day, with their skin conductance and heart rate being measured again as the previous day. When they are done, they will have to answer the questionnaires about how anxious they are one more time. Participants will be then told that they will have to give a short presentation in front of a small audience (stress induction), and

they will be administered questionnaires about anxiety one last time. At the end, participants are told that they do not have to make a presentation.
The day after, all patients will be invited for an online follow-up session. They will fill out the same questionnaires as they did at the beginning of the trial, as well as an additional questionnaire about how helpful they think mindfulness meditation will be for them in the future. This session will also show if fewer participants of one odor group show up for the experiment than another.

What are the possible benefits and risks of participating?
The questionnaires and the physiological measurements are non-invasive measures. The study involves a stress induction procedure which may increase symptoms of anxiety. However, the participants will not have to undergo a presentation, which is likely to reduce their stress response substantially by the end of the session.
If a moderate mental disorder is detected the participants will be referred to the local clinical services. In addition, if some participants in the study show severe psychological symptoms, such as severe depressive symptoms, suicidal ideation, or psychotic symptoms, colleagues with specific psychotherapeutic skills will be contacted for further examination and, if necessary, appropriate treatment or support. Finally, all participants will be reminded of the presence of clinical services at the SCUP (Servizi Clinici Universitari Psicologici) of the University of Padova.
Overall, the potential risks for the participants (diagnosis of a psychological disorder, being subjected to smells, and possible temporary discomfort due to the stress induction) are outweighed by the benefits and scientific value of the studies.
Participants are taught a useful tool (mindfulness meditation) which may aid them in the future and have the opportunity to address their psychological discomfort through being informed about the local clinical services, which decreases the burden of the disorder.

Where is the study run from?
University of Pisa (Italy)

When is the study starting and how long is it expected to run for?
January 2019 to June 2023

Who is funding the study?
Horizon 2020

Who is the main contact?
Prof. Claudio Gentili, c.gentili@unipd.it

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
824153

Study information

Scientific Title
Affective and physiological responses to human body odors in social anxiety – a pilot study on the possible effects as a catalyst for treatment

Study objectives
1. The groups exposed to body odor (neutral, fear and happiness) in combination with mindfulness treatment exhibit lower mean State-Trait Anxiety Inventory (STAI) scores post-treatment compared to the control group (clean air).
2. The group exposed to happiness body odors will show stronger effects in increasing vagally-mediated heart rate variability (HRV) indices compared to neutral and fear body odors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/07/2019, the Ethical Committee for Psychological Research at the University of Padua (Via Venezia 8, 35131, Padova, Italy; +39 (0)498276587; comitato.etico.area17@unipd.it), ref: 3113

Study design
Single-centre single-blind between-subjects randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Social anxiety symptoms

Interventions
This procedure was already described in the pre-registration of a preliminary study (registration number: ISRCTN64408867) conducted within the same project (POTION project, serial number 824153). Given the exploratory nature and the results of the preliminary study, the current study has been developed with a larger sample size and refined design.

Study design:
Patients will be screened using the Liebowitz Social Anxiety Scale, the Patient Health Questionnaire, and the Structured Clinical Interview for DSM-5. Only female patients will be recruited.

On the first day of the study, all patients will be asked to complete a demographic questionnaire, the State-Trait Anxiety Inventory (STAI) and one question to assess if the participant has experience with mindfulness meditation.

After completing the baseline questionnaires, the participants will be randomly allocated to an odor group (happiness, fear, neutral or clean air) and start a treatment intervention consisting of mindfulness meditation (more details below). The odors are previously collected from healthy volunteers (see section below). During the intervention, they will be exposed to the odor corresponding to the group to which they have been randomized, while their electrodermal activity and heart rate is measured. Following the intervention, the STAI will be assessed once more. In total, the trial day 1 should last approximately 60 minutes.

The next day, all subjects will perform the same trial as day one: first completing the STAI questionnaire at baseline, then the mindfulness meditation intervention while being exposed to the same odor as they were exposed to the previous day, then completing the STAI questionnaire one more time. After the latter step, the participant will be exposed to stress induction, during which they are told that they will have to give a short presentation at the end

of the study session about a prespecified topic in front of a small audience. Following this, the STAI will be assessed again. The participant will also be asked to complete the State Mindfulness Scale (SMS). Manipulation checks consisting of questions measuring social anxiety, task-related anxiety and task importance will be assessed. Also, electrodermal activity and heart rate will be measured throughout the trial, in order to assess how stressful the exposure is in terms of physical arousal.

Finally, the participants will be informed that they will not have to make a presentation in front of a small audience. The intensity, pleasantness and familiarity of the odor will be assessed at the end of the trial for each participant. In total, the trial day 2 should last approximately 75 minutes.

The day after (day 3), participants will be invited for an online follow-up session, during which they will be asked to fill out the STAI and the Liebowitz Social Anxiety Scale, as well as an additional questionnaire regarding the perception of the helpfulness of the intervention for the future. The second session will show whether there is a lower 'drop-out' rate for an odor group, which will indicate patients' compliance. This session will last for approximately 15 minutes.

Treatment intervention:
The mindfulness intervention will be done using the APP "Con tatto" (developer LifeSTech research team). Participants will be asked to install the app on their mobile phones one week before the first meeting and to practice with the different proposed mindfulness practices. During the two interventions participants will complete two practices for a total time of about 30 minutes. During these practices, happiness body odor, fear body odor, neutral body odor or clean air will be presented to the participants.

Odor delivery system:
The odor delivery system consists of an olfactometer, which will deliver the odor in 72-second-long pulses separated by 216 seconds of clean air. The odors are obtained from previously collected sweat samples. The participants will be exposed to the odor for the entire duration (30 minutes) of the intervention.

Collection of sweat samples:
Sweat samples were previously obtained during two sessions, separated by one week. Before each session, absorbent pads (10 cm x 10 cm) were attached to each armpit of donors, after which donors watched one of two types of state-inducing film clips: fear-inducing or happiness-inducing. The donors in the fear condition sat alone while watching the film clips, while those in the happiness condition sat in groups of three participants. Afterwards, they were asked to rate how angry, fearful, sad, happy, disgusted, neutral, surprised, calm and amused they felt on 7-point Likert scales, which were used to indicate low/high arousal and positive/negative affect.

Intervention Type
Other

Primary outcome measure
Anxiety symptoms measured by the State-Trait Anxiety Inventory (STAI) at baseline, at the end of day 1, at the beginning of day 2, after mindfulness intervention at day 2, after stress induction and during day 3

Secondary outcome measures

1. Awareness of social odors measured using the Social Odor Scale (SOS) at baseline during day 1
2. Heart rate variability measured using ECG at baseline, during treatment and post-treatment of day 1; at baseline, during treatment, post-treatment and post-stress induction of day 2.
3. Skin conductance measured using electrodermal activity (EDA) at baseline, during treatment and post-treatment of day 1; at baseline, during treatment, post-treatment and post-stress induction of day 2
4. Previous experience with mindfulness meditation (answering the question “Do you practice or have you ever practiced mindfulness meditation?”, if yes there is a follow-up question “how often do you practice?” with possible answers “not currently”, “practice less than one time a week”, “less than three times a week”, “practice three times a week or more”, “practice every day”) measured at baseline during day 1
5. State mindfulness assessed with the State Mindfulness Scale (SMS) at post-treatment during day 2
6. Manipulation check of anxiety induction (after stress induction): Social anxiety; Task-related anxiety; Task importance. Done after the stress induction during day 2
7. Perceived helpfulness of the intervention (0 to 10 rating scale from “not useful at all” to “very useful”) measured after the stress induction on day 2
8. Intensity, pleasantness and familiarity of the odor (each one on a scale from 1 to 10 from “not at all” to “very much”) measured after the stress induction on day 2
9. Number of drop-outs in each odor group measured at the follow-up online session during day 3

Overall study start date
01/01/2019

Completion date
30/06/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/12/2022:
1. Aged between 18 and 35 years
2. Female gender
3. A score over 30 on the Liebowitz Social Anxiety Scale in its self-report formulation (LSAS-SR)
4. A confirmation of the disorder during a face-to-face interview
5. Normosmic as screened with Sniffin’ Stick test
6. No pregnancy
7. Non-smokers

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Previous inclusion criteria:
1. Aged between 18 and 35 years
2. Female gender
3. A score over 50 on the Liebowitz Social Anxiety Scale in its self-report formulation (LSAS-SR)
4. A confirmation of the disorder during a face-to-face interview
5. Normosmic as screened with Sniffin’ Stick test
6. No pregnancy
7. Non-smokers

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Female

Target number of participants
96

Total final enrolment
100

Key exclusion criteria
1. Chronic rhinitis or other conditions that may affect the ability to perceive odors
2. Breastfeeding
3. Presence of other mental disorders (including substance abuse disorders) apart from major depression, chronic depression, minor depression, or dysphoria and social anxiety disorder
4. Presence of any severe somatic or neurological conditions
5. Use of psychotropic drugs at the moment of the recruitment (including antidepressants, antipsychotics, anxiolytics and mood stabilizers)
6. Presently undergoing psychological therapy, presence of severe psychotic symptoms (i.e. hallucinations and/or delusions)
7. Presence of suicidal thoughts
8. Incapability to understand and to give an informed consent for the experiment

Date of first enrolment
17/10/2022

Date of final enrolment
30/05/2023

Locations

Countries of recruitment
Italy

Study participating centre
University of Padua
Department of General Psychology
Via Venezia 8

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Sponsor information

Organisation
Karolinska Institute

Sponsor details
National Centre for Suicide Research and Prevention
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Sponsor type
University/education

Website
https://ki.se/en/nasp/national-centre-for-suicide-research-and-prevention

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-reviewed journal.

Intention to publish date
30/11/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are not expected to be made available due to lack of ethical approval for a data sharing policy.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	24/02/2025	28/07/2025	No	No