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Can exposure to body odors be used to enhance a mindfulness treatment for social anxiety?

Submission date
08/11/2023

Recruitment status
No longer recruiting

Registration date
18/12/2023

Overall study status
Completed

Last Edited
28/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The POTION project (Promoting Social Interaction Through Emotional Body Odors) aims to understand the nature of chemosignals and how chemistry influences human social interactions. Several studies have shown that chemosignals, which are extracted from human sweat, can be used to communicate different emotional states. For example, experiments have shown that subjects react differently to body odors/chemosignals from a person who is afraid compared to chemosignals from a person who is happy. The reaction occurs unconsciously and is often measured by facial muscles or eye movements.
Building on the existing literature on olfactory processing, previous clinical studies within the POTION project have shown that individuals with social anxiety symptoms who undergo mindfulness meditation display a steeper reduction of anxiety scores when exposed to human chemosignals compared to clean air. The team of chemists from the University of Pisa involved in the project was able to isolate and identify the chemical compounds that are deemed to be responsible for the abovementioned results. A mixture of the identified compounds was then created based on artificial apocrine sweat.
The aim of the current study is to test this solution to assess whether it can be used as a treatment enhancer for subjects with social anxiety symptoms.

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

What does the study involve?
The study will take place at the University of Padua over two consecutive days. The researcher will recruit women aged 18 to 35 years old who scored 30 or above on the Liebowitz Social Anxiety Scale (LSAS). After recruitment and collection of informed consent, the subjects will be randomly allocated to an intervention group (fear odor or clean air/control) in which they will remain for the duration of the trial.

After completing the baseline questionnaires, the participants will start a treatment intervention. The treatment consists of 25 minutes of mindfulness meditation, either exposed to

fear odor or clean air (the control condition). During the intervention, electrodermal activity and heart rate is measured. After the intervention, they will complete the questionnaires assessing anxiety symptoms once more. On the second day, they will undergo the same procedure. Finally, they will be asked to complete an online follow-up on the day after the end of the trial (day 3).

What are the possible benefits and risks of participating?
The study has the potential to offer several significant benefits for participants. First and foremost, it employs non-invasive measures such as questionnaires and physiological measurements, ensuring minimal intrusion. The study intervention may enable participants to gain valuable insights into mindfulness meditation, a practical tool that can benefit them in the future.

Whilst the study does not pose any significant risks to participants, some may find interviews and questionnaires about mental health symptoms distressing. In such instances, the study staff will remind participants that they are free to stop the study at any point, and all participants will be informed about the availability of clinical services at the SCUP (Servizi Clinici Universitari Psicologici) of the University of Padova. Similarly, if a moderate mental disorder is identified during the trial, participants will receive referrals to the local clinical services, offering them access to professional support. Therefore, they will have the opportunity to address their psychological discomfort by learning about and accessing local clinical services.

In summary, the study's benefits, including non-invasive measurements, professional referrals, mindfulness meditation, and information about access to clinical services, far outweigh any potential risks such as the detection of a psychological disorder or temporary discomfort.

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

When is the study starting and how long is it expected to run for?
June 2023 to June 2024

Who is funding the study?
Horizon 2020

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
824153

Study information

Scientific Title
Investigating the potential of synthesized body odors to enhance a mindfulness treatment for social anxiety – a single centre, double-blind randomized controlled trial

Study objectives
1. The group exposed to fear body odor in combination with mindfulness treatment will exhibit greater reductions in mean State-Trait Anxiety Inventory (STAI) scores from baseline to post-treatment compared to the control group (mindfulness and clean air).
2. The group exposed to fear body odor in combination with mindfulness treatment will exhibit lower vagally mediated heart rate variability (HRV) indices compared to the control group (mindfulness and clean air).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/07/2023, Ethical Committee for Psychological Research at the University of Padua (Via Venezia 8, Padova, 35131, Italy; +39 (0)498276587; comitato.etico.area17@unipd.it), ref: 145-a

Study design
Single-centre double-blind between-subjects randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
This procedure has already been described in the pre-registration of a preliminary study (registration number: https://www.isrctn.com/ISRCTN64408867) and a pilot study (registration number: https://www.isrctn.com/ISRCTN98675422) conducted within the same project (POTION project, serial number 824153). Given the exploratory nature and the results of the preliminary and pilot studies, the current study has been developed with a larger sample size and refined design.

Study design & procedure:
This single-centre study will employ a double-blind randomized controlled trial design, where individuals with social anxiety will be randomly allocated to receive a brief mindfulness treatment whilst exposed to human fear body odor, or a brief mindfulness treatment whilst exposed to clean air (control condition). Prospective participants will be screened using the Liebowitz Social Anxiety Scale (LSAS). If the LSAS score is equal to or above 30 they will be called to the lab and after giving informed consent, they will undergo a Structured Clinical Interview for DSM-5 to confirm the presence of social anxiety symptoms and the Sniffin Stick test to evaluate their olfactory abilities, only normosmic subjects are recruited. Only females aged 18 to 35 will be recruited.

Once eligibility is confirmed and informed consent acquired, participants will be randomly assigned to one of the two odor groups (clean air or fear body odor) and will remain in that group throughout the trial. Randomization into the two groups will be performed using the package “blockrand” in R statistical software (version 4.1.0), where individuals will be evenly randomized within blocks to ensure equal numbers in each group. To avoid potential unblinding the permuted block design will randomly apply block sizes of 4, 6, and 8. The study will be conducted over 2 consecutive days with an online follow-up on the third day.

The study procedure is as follows:
On day 1, all participants will complete a set of baseline questionnaires including a demographic questionnaire (age and education), the State-Trait Anxiety Inventory (STAI), the LSAS, the Social Odor Scale (SOS), the Patient Health Questionnaire (PHQ-9), and the Positive and Negative Affect Schedule (PANAS). Additionally, participants will be asked about their experience with mindfulness meditation.

Following the baseline assessments, participants are told that they will have to give a short presentation in front of a small audience at the end of the trial on day 2 (the beginning of the stress induction). After the stress induction, they are administered the STAI and PANAS questionnaires again, to evaluate the effectiveness of the stress induction procedures. Subsequently, participants will begin the 25-minute mindfulness meditation session while

exposed to their assigned odor. Electrodermal activity and heart rate will be continuously monitored during the session. A 3-minute recording of physiological measurements (heart rate variability and skin conductance) will be collected before and after the intervention to establish baseline and post-treatment data. The mindfulness intervention will be conducted using the "Con tatto" app, developed by the LifeSTech research team, and participants will access it from a computer located in the experimental room. After completing the mindfulness intervention, participants will undergo another assessment of the STAI and will also complete the State of Mindfulness Scale (SMS). In total, trial day 1 will last approximately 60 minutes.

On the following day (day 2), participants will complete the STAI questionnaire before the treatment. Following this, the intervention will be administered following similar procedures as on day 1. Once the mindfulness session is finished, participants will complete the STAI, the SMS, and the PANAS, and rate the intensity, pleasantness, and familiarity of the odors (both clean air and fear-related). After that, they will be told that they will not have to give a short presentation in front of the audience (end of the stress induction), and subsequently, they will be asked to complete the STAI and PANAS once more. The entire procedure on day 2 is expected to take approximately 60 minutes.

On day 3, participants will be invited to an online follow-up session, during which they will complete the STAI, the LSAS, and an additional questionnaire regarding their perception of the helpfulness and acceptability of the intervention. This session is expected to last approximately 15 minutes.

To fully explore acceptability and feasibility and to minimize response bias, 'drop-out' cases will be asked to complete the acceptability questionnaire, the perceived usefulness question, and an open-ended question to state the reason for drop-out. This will be done anonymously via an online survey platform. The data will be used to evaluate patient compliance, acceptability and perceived usability, whilst also taking reasons for study dropouts into account.

Sweat sample:
During the previous experiments conducted by our research group (ISRCTN64408867 & ISRCTN98675422), the sweat samples used to deliver the body odors were collected from healthy volunteers during 30-minute sessions of viewing a video clip inducing different emotional states: fear, happiness or relaxation. Chemical analysis of these samples has been carried out to identify and isolate the chemical compounds thought to be responsible for the emotional state communication that has been tested during the preliminary and pilot studies.

The body odor samples used during the current study will instead consist of compounds that have been identified from sweat during a fear-induced state that has been shown to significantly increase during fear elicitation, compared to a relaxed state. These compounds have been added to a reference sweat solution that was created based on artificial apocrine sweat modified with a subtractive isolation method to obtain a chemical profile comparable to the sweat samples collected during a relaxed state.

Odor delivery system:
An odor delivery system (the POTION delivery system: PDS) based on Liquid Mass Flow Controller technology has been specifically developed for the synthetic solutions requirements. The system allows switching between the liquid sample (fear odor) and a neutral sample (for example, water) both mixed with clean air. More specifically the PDS process is as follows: the liquids are fed via a liquid mass flow controller to a heated vaporizer where a dilution gas (clean air) is also introduced. The mixing of the liquid sample and dilution gas in the vaporizer allows the chemosignals to move in the gas phase. The vaporizer outlet is connected to a vent or mixing

chamber where the gas generated in the vaporizer can be mixed with clean air to generate dilution. The odor is delivered to the subjects via a heated transfer line. The dedicated electronics and software control the PDS imposing a good combination of flows for liquid and gases to produce the desired composition of volatile organic compounds. Settings of this control module will be modified based on the POTION control module (PCM).

Intervention Type
Mixed

Primary outcome(s)
Anxiety symptoms measured using the State-Trait Anxiety Inventory (STAI) at baseline, pre-treatment (after the beginning of the stress induction) and post-treatment of day 1, at pre-treatment, post-treatment and after the end of the stress induction of day 2, and during day 3

Key secondary outcome(s))
1. Heart rate variability measured using ECG at baseline (3 min), during treatment and post-treatment (3 min) of day 1; at baseline (3 min), during treatment and post-treatment (3 min) of day 2
2. Skin conductance measured using electrodermal activity (EDA) at baseline (3 min), during treatment and post-treatment (3 min) of day 1; at baseline (3 min), during treatment and post-treatment (3 min) of day 2
3. Awareness of social odors measured using the Social Odor Scale (SOS) at baseline during day 1
4. Presence and level of social anxiety symptoms are measured using recruitment and baseline of day 1
5. Presence of depressive symptoms measured using the Patient Health Questionnaire (PHQ-9) at baseline during day 1
6. 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 using baseline during day 1
7. State mindfulness measured using the State Mindfulness Scale (SMS) post-treatment on day 1 and post-treatment on day 2
8. Overall changes in mood during the trial measured using the short form of the Positive and Negative Affect Schedule (PANAS) at baseline and pre-treatment of day 1 and post-treatment and after the end of the stress induction of day 2
9. Intensity, pleasantness and familiarity of the odor (each one on a scale from 1 to 10 from “not at all” to “very much”) on post-treatment on day 2
10. Perceived helpfulness of the intervention (0 to 10 rating scale from “not useful at all” to “very useful”) on day 3 or in case of drop-out
11. Acceptability questionnaire consisting of 10 questions asking to rate the levels of stress during different parts of the trial, the likelihood of repeating the intervention during the second day, the likelihood of recommending the intervention to others, how much the participants have valued the intervention and if they found it invasive (each one on a scale from 1 to 9 from “not at all” to “very much”) at post-treatment on day 3 or in case of drop-out
12. The reason for drop-outs measured using open-ended questions in case of drop-outs during the trial

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Aged between 18 and 35 years old
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 (SCID 5-CV)
5. Normosmic as screened with Sniffin' Stick test
6. No pregnancy
7. Non-smokers

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
Female

Total final enrolment
133

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,
7. Presence of severe psychotic symptoms (i.e., hallucinations and/or delusions)
8. Presence of suicidal thoughts
9. Incapability to understand and to give an informed consent for the experiment

Date of first enrolment
01/10/2023

Date of final enrolment
15/06/2024

Locations

Countries of recruitment
Italy

Study participating centre
University of Padua
Department of General Psychology
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Sponsor information

Organisation
Karolinska Institutet

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Government

Funder Name
Horizon 2020 Framework Programme

Alternative Name(s)
EU Framework Programme for Research and Innovation H2020, Horizon 2020, Horizon 2020 Framework Programme (H2020), Rahmenprogramm Horizont 2020, Horizont 2020, Programa Marco Horizonte 2020, Horizonte 2020, Programme-cadre Horizon 2020, Orizzonte 2020, Programma quadro Orizzonte 2020, H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to a 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes