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

Submission date
24/02/2021

Recruitment status
No longer recruiting

Registration date
28/04/2021

Overall study status
Completed

Last Edited
04/12/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 depression and possibly 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 depressive and social anxiety symptoms (e.g., prefrontal structures). However, more detailed research is needed on the olfactory processing in these patient groups to examine the possible diagnostic and treatment value of chemosignals. To expand this knowledge, the aim of this study is to find out whether odors extracted from people who were experiencing happy or fearful emotions can be used to increase the positive results of mindfulness meditation therapy in patients with social anxiety symptoms or depressive symptoms.

Who can participate?
Women between the ages of 18 and 35 who have been diagnosed with depressive or 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, as well as their current mood. After that, they will also do a test to determine how well they can notice odors, identify odors and distinguish different odors. Next, they will be placed at random in one of the three odor groups (happy, fearful or clear air). Then, all participants will follow the mindfulness intervention while smelling the odor through an odor-delivery system designed for this study. During the intervention, their skin conductance and heart rate are measured. When they are done with the intervention, the participants will have to answer the questionnaires about how anxious they are and what their current mood is. The experimenters will make sure that all participants feel well before they leave the study.
The next day, all participants will answer the same questionnaires as they did at the beginning of

the first day. Following this, only the participants with anxiety symptoms will be told that they will have to give a short presentation in front of a small audience (stress induction). They will be administered questionnaires about anxiety and mood again, to see if they have really become more stressed. This is not done with participants with depressive symptoms. Then, all 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. When they are done, they will have to answer the questionnaires about how anxious they are and what their current mood is one last time. Those with social anxiety symptoms are told that they do not have to make a presentation. Before the participants leave the study, the experimenters will again make sure that all participants feel well.
One week later, 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 previous two sessions, as well as an additional questionnaire about how helpful they think the 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?
A possible benefit for participating in this study includes learning how to use mindfulness meditation to lessen stressful or negative feelings. A possible side effect for the participants who are told to give a presentation, is that their stress levels might not go back to normal after the study. However, the experimenters will have the necessary knowledge and skills to help these participants before they leave.

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 December 2022

Who is funding the study?
Horizon 2020 (EU)

Who is the main contact?
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Contact information

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Scientific

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Public

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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 emotional body odors in social anxiety and depression – a pilot study on the possible effects as catalyst for treatment

Study objectives
1. The effects of a mindfulness intervention for symptoms of anxiety will be moderated by subjects' exposure to odors taken from subjects who experienced happiness or fear but not by exposure to clean air.
2. The effects of a mindfulness intervention for symptoms of depression will be moderated by subjects' exposure to odors taken from subjects who experienced happiness or fear but not by exposure to clean air.

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 patient information sheet.

Health condition(s) or problem(s) studied
Depressive symptoms and social anxiety symptoms

Interventions
Patients will be screened using the Liebowitz Social Anxiety Scale, the Patient Health Questionnaire, and the Structured Clinical Interview for DSM-5, based on which they will be allocated to either the social anxiety (Group 1) or depression group (Group 2). Only female patients will be recruited because gender influences the processing of human body odors. Moreover, depressive and social anxiety symptoms are more common among women than men and women have a greater preference for social emotional stimuli compared to men, which could result in greater effects of the body odors on the patients' depressive or social anxiety symptoms.

On the first day of the study, all patients will be asked to complete a demographic questionnaire, the Trait-State-Anxiety Inventory (STAI), the Profile of Mood States (POMS), and the State Mindfulness Scale (SMS). After completing the baseline questionnaires, the patients will be randomly allocated to an odor group (happiness, fear 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 randomised, while their electrodermal activity and heart rate is measured. Following the intervention, the STAI and POMS will be assessed once more. At the end of the session patients may watch uplifting and/or calming movie clips to restore their pre-session state.

The next day, all patients will complete the STAI and the POMS again. Next, the patients in Group 1 only will be subjected 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 and POMS will be assessed again, with the addition of manipulation checks consisting of questions measuring social anxiety, task-related anxiety and task importance. Also, electrodermal activity and heart rate will be measured in order to assess how stressful the exposure is in terms of physical arousal. The duration of these baseline measurements will be approximately 30 minutes for Group 1. Group 2 will not be subjected to

stress induction nor to the related follow-up tests. After completing the baseline questionnaires, the patients of both Group 1 and Group 2 will begin the mindfulness meditation intervention while being exposed to the same odor as they were exposed to the previous day. Their electrodermal activity and heart rate will be measured as well. After the intervention, the STAI and POMS will be assessed one last time. Finally, the patients in Group 1 will be informed that they will not have to make a presentation in front of a small audience. All patients will be debriefed and may again watch calming movie clips to restore their pre-session state.

One week later, all patients will be invited for an online follow-up session, during which they will be asked to fill out the STAI, the POMS and the Liebowitz Social Anxiety Scale, as well as an additional questionnaire regarding the perception of 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 30 minutes.

Treatment intervention
The same intervention will be administered to both groups. The 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, 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 a 216 seconds clean air. The odors are obtained from previously collected sweat samples. The patients 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
Group 1:
Anxiety symptoms measured by the Trait-State Anxiety Inventory (STAI) at baseline, at the end of day 1, at the beginning of day 2, after stress induction and at the end of day 2.

Group 2:
Mood state measured by the Profile of Mood States (POMS) at baseline, at the end of day 1, at the beginning of day 2, and at the end of day 2.

Secondary outcome measures

Group 1:
1. Anxiety symptoms measured using the Trait-State Anxiety Inventory (STAI) at 1-week follow-up
2. Mood state measured using the Profile of Mood States (POMS) at the end of the session on the second day and at 1-week follow-up
3. Social anxiety using the Liebowitz Social Anxiety Scale at baseline and at 1-week follow-up
4. Number of drop-outs in each odor group measured at the follow-up online session 1 week later

Group 2:
1. Mood state measured using the Profile of Mood States (POMS) at 1-week follow-up
2. Anxiety symptoms measured using the Trait-State Anxiety Inventory (STAI) at the end of the session on the second day and at 1-week follow-up
3. Social anxiety using the Liebowitz Social Anxiety Scale at baseline and at 1-week follow-up
4. Number of drop-outs in each odor group measured at the follow-up online session 1 week later

Overall study start date
01/01/2019

Completion date
31/12/2022

Eligibility

Key inclusion criteria
The inclusion criteria for participants with social anxiety symptoms are:
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 previous diagnosis of COVID-19
7. No pregnancy
8. Non-smokers

The inclusion criteria for participants with depressive symptoms are:
1. Aged between 18 and 35 years
2. Female gender
3. A score over 5 on the Patient Health Questionnaire (PHQ-9)
4. A confirmation of the disorder during a face-to-face interview
5. Normosmic as screened with Sniffin' Stick test
6. No previous diagnosis of COVID-19
7. No pregnancy
8. Non-smokers

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
30 participants diagnosed with depression, and 30 participants diagnosed with social anxiety disorder

Total final enrolment
84

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
01/05/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Italy

Study participating centre
University of Padua
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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/nasp/start

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

Publication of the results of the study is planned in high-impact peer-reviewed journals. There are no other public documents available for the study.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available for two reasons: 1) lack of ethical approval for a data sharing policy; 2) the registered studies are interim studies in the context of a broader project. The results will be used to generate a research hypothesis that will be tested in a randomized controlled trial the following year and used to perform the required power analyses.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results			04/12/2023	No	No