Study Protocol

Effects of coherent breathing breathwork on mental health and wellbeing: A randomised placebo-controlled study (NCT05676658)

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Background and rationale

Autonomic nervous system activity can be measured using heart rate variability (HRV); in brief, as we inhale heart rate increases and, as we exhale, heart rate decreases. HRV is essentially the gap or difference (variation in the time interval between heartbeats), hence a greater/higher HRV is more favourable in relation to health. Researchers have found breathing at 5-6 breath cycles per minute (bcpm) with equal inhalation/exhalation results in electrical rhythms of brain, heart and lungs synchronising — and that this breathwork technique (called 'coherent breathing') optimises HRV, translating into healthy autonomic responses to changes in breathing and thus a more resilient stress-response system (Brown & Gerbarg, 2012). However, despite over two decades of research, there are no well-controlled studies exploring coherent breathing's effects on mental health. We plan to complete the first robust randomised-controlled trial (RCT) comparing coherent breathing to a well-designed placebo.

The theoretical rationale for our study is identifying ways in which coherent breathing exerts its effects via a well-designed RCT within the general population. An appropriate breathwork placebo could help disentangle effects of coherent breathing (Sevoz-Couche & Laborde, 2022). The practical rationale is using the data and information collected to help develop time- and cost-effective remote interventions for lowering stress and improving well-being. This will build upon our previous work; a systematic review and meta-analysis on breathwork and mental health (Fincham et al., 2023). We found significant small-medium effects, denoting breathwork was associated with lower levels of stress, anxiety and depression, compared to non-breathwork RCTs. Using the Cochrane Collaboration's latest tool for assessing risk of bias in randomised trials, all the RCTs that were included in our meta-analysis were deemed as being at moderate or high risk of bias, hence we wish to carry out the first robust breathwork RCT with low risk of bias. We want to share our findings through publication in a reputable open-access journal to inform practice and hopefully benefit others.

Objectives and endpoints

The main question that our study attempts to address is: Does coherent breathing lead to improved mental health and wellbeing in a general population adult sample in comparison to a well-designed placebo control?

Study hypotheses

Primary hypothesis
Coherent breathing breathwork practice for ~10min/day over a 4-week period will lead to greater reduction in self-reported stress than practice of a placebo control breathwork practice at post-intervention.

Secondary Hypotheses

- Coherent breathing breathwork practice for ~10min/day over a 4-week period will lead to greater reduction in self-reported stress than practice of a placebo control breathwork practice at follow-up.

- Coherent breathing breathwork practice for ~10min/day over a 4-week period will lead to greater reduction in self-reported anxiety than practice of a placebo control breathwork practice at: a) post-intervention, b) follow-up.
- Coherent breathing breathwork practice for ~10min/day over a 4-week period will lead to greater reduction in self-reported anxiety than practice of a placebo control breathwork practice at: a) post-intervention, b) follow-up.
- Coherent breathing breathwork practice for ~10min/day over a 4-week period will lead to greater reduction in self-reported depression than practice of a placebo control breathwork practice at: a) post-intervention, b) follow-up.
- Coherent breathing breathwork practice for ~10min/day over a 4-week period will lead to greater increase in self-reported well-being than practice of a placebo control breathwork practice at: a) post-intervention, b) follow-up.
- Coherent breathing breathwork practice for ~10min/day over a 4-week period will lead to greater reduction in sleep disturbance than practice of a placebo control breathwork practice at: a) post-intervention, b) follow-up.
- There will be no significant differences between intervention and placebo groups on the: a) credibility and b) expectancy of the breathwork randomly assigned to groups.

Exploratory Hypotheses

- Additionally, we want to see if pre-post changes are correlated with a) adherence (amount of breathwork practice, i.e., is there a dose response?), and b) credibility/expectancy of the breathwork intervention given. We would expect both greater adherence(in the coherent breathwork practice arm) and credibility/expectancy to be associated with greater improvements on the outcome measures listed.

Methods

Participants

400 people (200 per group) will be recruited to account for potential attrition (Prolific has had up to 50% attrition rate before); 260 participants are needed based on a significance level, statistical power, and effect size of $p<0.05$, 0.80, and $d=0.35$, respectively. This builds upon our meta-analysis on breathwork and mental which found a significant small-medium effect ($d=0.35$), denoting breathwork was associated with lower stress. The (self-assessed) inclusion criteria are as follows: -18+ years of age (18 is the automatic minimum age on Prolific), -Able to breathe through nose, -Have access to headphones. -The following pre-screeners on Prolific will also be set so only those eligible on Prolific will see the study: Located/living in UK, Fluent in English, approval rate of 98% and at least 20 previous submissions (as recommended by Prolific to increase retention and reduce dropout rates in longitudinal and multi-part studies). The (self-assessed) exclusion criteria are as follows: -Any problems which affect one's ability to pace their breathing (i.e., active/chronic respiratory infection including blocked nose/cough/cold/fever, etc.), breathlessness, cardiovascular problems, respiratory conditions or diseases (i.e., uncontrolled symptomatic asthma, COPD, lung cancer, etc.), abnormally slow breathing (bradypnea), or abnormally fast breathing (tachypnoea), -Any other physical/mental health conditions or current life events which impair or affect one's ability to engage in activities involving breath control.

Outcome measures

All outcomes (primary, secondary, other) are mentioned below. Pre-post intervention and follow-up questionnaires will be self-completed by participants online via the survey platform Qualtrics, which will be linked to Prolific. Three short scales will be used to measure outcomes of mental health, well-being and sleep disturbance at these timepoints (baseline/pre-intervention, post-intervention, 1-month follow-up): the Depression Anxiety Stress Scale (DASS-21) (Lovibond, & Lovibond, 1995), World Health Organisation- Five Well-Being Index (WHO-5) (WHO, 1998) and PROMIS Item Bank v. 1.0 - Sleep-Related Impairment - Short Form 8a (Hanish, Lin-Dyken & Han, 2017). The primary outcome will be stress (measured using the DASS-21 stress subscale), and the primary timepoint will be post-intervention (four weeks post-randomisation). The secondary outcomes will be: anxiety and depression (from DASS-21) well-being (WHO-5) and sleep disturbance (PROMIS). Immediately after starting the breathwork, participants will be asked about the credibility/expectancy of the intervention randomly allocated to them to assess if the intervention and placebo are seen as equally credible and thus merit equal expectation of benefit. This will be measured using the 6-item Credibility/Expectancy Questionnaire (CEQ) (Devilly & Borkovec, 2000), which is another secondary outcome. The last secondary outcome, which will be measured post-intervention, is: adherence (number of times participants self-reported practicing breathwork out of the 28days assigned). Other outcomes include an open-ended question on participants overall experiences of the protocol and/or study period. Pre-intervention, simple demographics (Age, Gender and Ethnicity) will be collected and, post-intervention/follow-up, participants will be asked if anything impaired their ability to perform the breathwork, and if they can guess the study hypothesis (to tentatively see if blinding was successful—see Procedure section).

Primary Outcome Measure:

1. *Subjective stress* (DASS-21 stress subscale)

Secondary Outcome Measures:

2. Subjective anxiety (DASS-21 anxiety subscale)
3. Subjective depressive symptoms (DASS-21 depression subscale)
4. Subjective wellbeing (WHO-5)
5. Subjective sleep disturbance (PROMIS-8a)

All of above outcomes measured pre-post-follow-up.

6. Self-reported credibility and expectancy of protocol (CEQ-6) . Measured after completing first session of breathwork.
7. Self-reported adherence to breathwork protocol (number of sessions participants self-report practicing out of 28 days assigned). Measured post-intervention.

Other—Overall experience, Impairment of practice, Hypothesis guessing, Attention checks

Optional open-ended questions on participants' perspectives and overall experience of the protocol (post-intervention) / study-period (follow-up), whether anything impaired participants' ability to perform their randomly allocated breathwork (post-intervention), and if they can guess the hypothesis of the study (follow-up). Lastly, The DASS, WHO, and

PROMIS will all have one attention-check question in them to ensure participants are completing the surveys properly.

Procedure

Participants will be recruited entirely online via the research study platform Prolific to gain a general population sample. Participants will see a title of the study, a description (describing what participants will be doing in the study), including the participant information sheet and consent form with all key information that will help them to decide if they wish to participate. It will also be specified that the study requires audio. Participants will see all this information before they choose to take part in the study, allowing them to make an informed choice as to whether they'd like to participate. Again, pre-screeners on Prolific will also be set so only those eligible on Prolific will see the study on the platform. Participants will paid to complete the surveys at the hourly rate of 9GBP/hour (1.50GBP per survey, so 4.50GBP in total) which is deemed as a good, recommended amount by Prolific. We unfortunately do not have funds to pay participants to complete the daily breathwork (classed as low effort activity by Prolific). Daily reminder messages will be sent through Prolific to practice breathwork over the 28days/4weeks and keep a record of number of times practiced. All participant data will be anonymous (only Prolific user IDs will be seen). No identifiable personal information will be collected. When the first (pre-intervention) survey is complete we will get the participant IDs of the relevant Prolific participants. We will then invite these participants to post-intervention and follow-up surveys using a custom allowlist on Prolific. As we have two conditions and want to keep these conditions consistent between surveys, a separate identical CEQ, post-intervention and follow-up survey for each condition is set up. However, only one pre-intervention survey is needed as Qualtrics supports allocation to conditions from one URL. Messages will also be sent through Prolific to complete post-intervention and follow-up questionnaires when required.

Intervention and Comparator
Both groups will also be provided with an identical ~5min introductory/welcome audio to the study which they can listen to on the first day.

Participants in intervention group will be randomised to a guided audio of coherent breathing (at ~5.5.bcpm with equal inhales/exhales of ~5.5secs each without deliberate pauses), for 28days (4weeks), pre-recorded by a trained breathwork facilitator, delivered remotely online. The average coherent breathing rate for maximising HRV is around 5.5bcpm so this cadence was chosen for the intervention group. The duration of ~10min was deemed as a manageable time for participants, and several studies (ranging from days to weeks) on meditation have shown benefit can be derived from this short length of practice.

Participants in control group will be randomised to a guided audio of placebo 'sham' coherent breathing breathwork (12bcpm with equal inhales/exhales of 2.5secs each without deliberate pauses) for ~10mins/day, for 28days (4weeks), pre-recorded by a trained breathwork facilitator, delivered remotely online. The metric of 12bcpm is in line with guidance from the British Journal of Nursing, Royal College of Physicians, and Johns Hopkins University which state that the average, healthy bcpm should range from: 12-18bcpm, 12-20bcpm, and 12-16bcpm, respectively, hence we chose the minimum for the control group.

12 bcpm is highly unlikely to be difficult or detrimental to anyone based on BJN, RCP, and JHU guidance as it is at the lower bound of bcpm for typical resting breathing for adults.

The intervention/control audios are identical (exact same sound and instruction). The placebo control is matched to the active intervention in all domains but pace of breathing.

Randomisation and blinding
The type of study is participant blinded RCT with assessor blinded data collection (that is assessor is not present for data collection which is self-completed by the participant on a survey software platform). After completing the pre-intervention survey, participants will be randomly assigned, via the online survey software Qualtrics using block randomisation (1:1), to receive either the intervention coherent breathing breathwork (5.5bcpm), or placebo coherent breathing breathwork (12bcpm). Participants will be blinded to their intervention (concealment)—the technique of breathwork will be referred to as 'rhythmic breathing' in both the active intervention and placebo control breathwork audios, in an attempt to blind participants to the intervention being used.

Safety and ethical considerations

This study has been approved by the Research Ethics Committee at the University of Sussex Sciences & Technology C-REC (reference: ER/GF221/2).

References

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