Statistical analysis plan (SAP)

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

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Outcome scale measures (quantitative): Stress, anxiety, depression, well-being, sleep disturbance, credibility/expectancy of breathwork

Primary outcome of stress at post-intervention (primary timepoint) will be calculated from Depression Anxiety Stress Scale—21 items (DASS-21) stress subscale. Secondary outcomes of stress (at follow-up), anxiety and depression will be calculated from their respective DASS-21 subscales. The scores on DASS-21 subscales will be multiped by two to convert them to scores equivalent to the longer form DASS-42 score in line with scoring recommendations . Secondary outcomes of well-being and sleep disturbance will be measured by the World Health Organisation—Five Well-Being Index (WHO-5) and PROMIS Item Bank v. 1.0 - Sleep-Related Impairment—Short Form 8a, (PROMIS-8a) respectively. PROMIS-8a will be scored using a T-score transformation according to PROMIS Sleep scoring manual. Pre-intervention, post-intervention (after 28 days) and follow-up (after a further 28 days) scale score differences between groups will be analysed through mixed analysis of variance.

Self-reported credibility and expectancy of the breathwork protocol will be measured via the Credibility/Expectancy Questionnaire (CEQ-6). Descriptive statistics for all measures for all participants in each condition will be reported. Missing items within scales will be replaced using the mean for other items in the scale/subscale in cases where =<30% of items are missing for a scale/subscale. Multiple imputation will be used where >30% of data is missing from a scale/subscale or where whole scales/subscales are missing. Cronbach's alphas will be used to assess internal consistency of each scale at baseline.

Primary analysis

Intention-to-treat; using an independent t-test to see if there is a difference. Post-intervention is the primary timepoint for primary outcome stress. For both the primary outcome and secondary scale outcomes, group x time effects at the $p<.05$ level will be determined using mixed ANOVAs. Group x time effects at the $p<.05$ level will be followed up with simple contrasts (with pre-intervention as the comparator) and Bonferroni-corrected within-group t-tests. Baseline data will be controlled for depending on the outcome being tested (i.e., DASS Stress at baseline will be entered as a covariate when testing effects on DASS Stress). Data analysis will be performed in R and SPSS.

Secondary analysis

Per-protocol analysis (participants completing at least 14 sessions [50%] of the breathwork) will be conducted as secondary analysis.

Sensitivity checks

If sizeable missing data are present (greater than 5%), they will be replaced using multiple imputation, and used for sensitivity analysis. Analysis without baseline covariates will be included as sensitivity analysis. The DASS, WHO, and PROMIS all have one attention-check question in them to ensure participants are completing the surveys properly. If a participant answers more than one incorrectly at each timepoint their data will be excluded from the main analyses but included in a sensitivity analysis. The same applies to those who state that their breathwork practice was significantly impaired in response to the question on impairment of practice below.

Exploratory analysis of secondary measures (quantitative)

Adherence to breathwork protocol

Post-intervention, participants will answer how many times they completed the guided breathwork out of the assigned 28 days. This will be compared between groups via unpaired t-test, and correlated with outcome scale scores on DASS, WHO and PROMIS within each condition to see whether there are any associations between adherence and changes in these scale scores. Adherence will be looked at as a moderator.

Credibility/expectancy of breathwork protocol

Similar to adherence, CEQ scores will be correlated with the outcome scale scores above, to see whether there are relationships between CEQ and changes in these scale scores within each condition. CEQ scales will be compared between groups via unpaired t-tests. If there are significant differences between groups on credibility/expectancy, it will be used in covariance analysis.

Other complementary outcomes (qualitative)

Three simple qualitative outcomes will be explored to offer complementary findings to the main quantitative analyses above.

Overall Experience

Optional open-ended questions on participants' perspectives and overall experience of the protocol/study-period (i.e., anything positive, negative, neutral, general notes, etc.) post-intervention and follow-up. Analysis will be simple content analysis.

Impairment of Practice

Optional open-ended question on whether anything impaired participants' ability to perform their randomly allocated breathwork at post-intervention. Participants can answer yes/no and provide free text. The yes/no questions can be coded and free text analysed through simple qualitative content analysis.

Hypothesis Guessing

Optional open-ended question on whether participants can guess the hypothesis of the study at follow-up, to tentatively infer if blinding was successful. Participants can answer yes/no and provide free text. The yes/no questions will be coded and free text checked to see if guess was correct.