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Raising awareness of the bodily responses to stress (interoceptive awareness) with a psychological intervention

Submission date
30/06/2022

Recruitment status
No longer recruiting

Registration date
06/07/2022

Overall study status
Completed

Last Edited
06/06/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Disruptions in interoception (the sensing, perception and interpretation of one's physiological states) have emerged as a transdiagnostic pathogenic mechanism for several disorders at the mental-physical health interface, such as eating, functional or somatic symptom disorders. However, the interdisciplinary expertise required to identify and therapeutically target psychophysiological mechanisms has limited the efficacy of related therapeutic endeavors.

We aim to develop and test the efficacy and mechanisms of action of a new, interdisciplinary (psychophysiological) therapeutic module (InMe) to aid individuals with low interoception awareness.

This study will compare the InMe intervention to an active control intervention (imagery training without biofeedback). Participants will be randomly assigned (and stratified by eating disorder symptoms) to receive InMe intervention or control intervention. InMe will use cardiac biofeedback during guided respiration exercises to train individuals to down-regulate their own heart rate under different conditions of stress, while also enhancing related metacognitive beliefs.

Who can participate?
Healthy male and female adults experiencing low interoception awareness

What does the study involve?
This is a two-part study, the first part involves the completion of online questionnaires (10 minutes) and the second part comprises three in-person sessions. During the first part of the study, participants will be asked to fill out certain questionnaires about themselves their personality traits and behaviors. Some questions will include specific questions about their recent experiences including questions such as "were you bothered by symptoms during the last week such as headaches, faintness or dizziness or in relation to your eating habits" or have "you ever deliberately tried to limit the amount of food you eat". Participants completing the online part will be reimbursed, with an online voucher of £1.

Some of the participants will be invited back for the second part of the study, comprised of 3 sessions taking place at the UCL research laboratory. Each session will last for up to 90 minutes. The first two sessions will be completed within the first week of enrollment and the 3rd session will be scheduled two months post-enrollment.

Study sessions will include:
1. Questionnaires about personality traits and behaviors
2. Simple computerized response tasks. For example, to estimate heartbeat e.g. participants will be asked to answer questions about the perception of their heart rate.
3. Simple tasks designed to slightly increase the heart rate and simple breathing relaxation techniques to assist in the downregulation of the heart rate.

What are the possible benefits and risks of taking part?
Whilst there are no immediate benefits for those people participating in the study, a possible benefit is that during the second part of the study participants will be introduced to a calming technique, which can help in downregulating somatic arousal. It is hoped that this work will be a valuable contribution to research on body awareness, and mental health, which can have beneficial effects on society and health in the future.

We expect no major risks or disadvantages associated with participating in this study. However, in case of any kind of discomfort, the experimenter should be notified immediately. Any concerns and/or complaints following the intervention can be addressed by contacting the principal researcher.

Where is the study run from?
University College London (UK)

When is the study starting and how long it it expected to run for?
February 2022 to May 2023

Who is funding the study?
European Research Council (ERC) (UK)
University College London Institute of Mental Health (IoMH) small grant award (UK)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number

Study information

Scientific Title
Interoceptive iNsight and Metacognitive Efficacy beliefs (InMe): RCT protocol for a biofeedback-assisted psychological intervention for interoceptive awareness.

Acronym
InMe

Study objectives
1. Primary objectives
1. To test people with low interoceptive awareness and compare a new interoceptive intervention involving real-time biofeedback with a control intervention (imagery-based affective regulation) without biofeedback, to raise people's awareness of their bodily responses to stress and raise individuals' beliefs about their ability to control their cardiac response using breathing
Hypothesis 1. Adaptive interoception (primary outcome) will be increased in the InMe arm, versus the control arm post-intervention (T1).

2. Secondary objectives
1. Identify mechanisms of action to improve individuals' awareness of their bodily responses.
Hypothesis 2. Elevated belief updating about one's self-efficacy in interoceptive control (as compared to the first prior at baseline (T0) and quantified using different computational methods (see https://psyarxiv.com/rntsf/) will mediate the expected primary outcomes change from T0 to T1 in the InMe arm.
Hypothesis 3. Core dimensions of Obsessive-Compulsive Disorder (harm avoidance and incompleteness) and Intolerance of Uncertainty will act as moderators of the expected primary outcomes change from T0 to T1 in the InMe arm.
Specifically, individuals with high harm avoidance, incompleteness and intolerance of uncertainty will benefit more from the InMe arm, as the biofeedback can provide increased subjective certainty, agency and perceived control. Measures of cardiac physiology, such as heart rate (HR) and heart rate variability (HRV) as well as self-efficacy and alexithymia traits, will also be used as secondary exploratory moderators following preliminary analyses of their interrelations and the relation with other key variables in the design (see section 17).

2. To investigate if the InMe intervention can reduce mental health symptoms, and in particular subclinical symptoms of disordered eating, somatisation and other related difficulties in emotion regulation and mood.
Hypothesis 4. Reduction in eating disorder symptoms at T1 (as compared to T0), will be observed and this effect would be greater in the InMe arm as compared to the control arm.
Hypothesis 5. We also expect a reduction in somatisation, depression and anxiety as well as in difficulties of emotion regulation measures, at T1 (as compared to T0).

3. Identify mechanisms of action to reduce mental health symptoms, and in particular symptoms of eating disorders or other related difficulties in emotion regulation, such as somatisation.
Hypothesis 6. The above-expected mediators (hypothesis 2) and moderators (hypothesis 3) would act as mechanisms of change to reduce mental health symptoms and in particular symptoms of eating disorders or other related difficulties in emotion regulation, such as somatisation.

4. Identify maintenance of the treatment effect.
Hypothesis 7. The expected improvement in “Adaptive” interoception and reduction in mental health symptoms in the InMe group versus control arm will be observed in a 2-month follow-up assessment.

5. Identify maintenance of the treatment effect in relation to mechanism of actions
Hypothesis 8. Primary and secondary mechanisms of action, that acted as moderators or mediators of the association between change in "Adaptive interoception” or mental-health symptoms from T0 to T1, will be observed after 2 month-follow up assessment.

6. Use the expected efficacy and feasibility results and comments and feedback from users participating in the trial, as well as the PPI components of the work to develop a protocol for a large, follow-up transdiagnostic randomised-controlled trial targeting key pathogenic mechanisms and feasible determinants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/02/2022, Departmental Research Ethics Committee University College London (Office of the Vice-Provost (Research), University College London, 2 Taviton St, London WC1E 6BT, United Kingdom; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: CEHP/2019/577

Study design
Two-arm pilot interventional parallel-group randomized active-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healthy individuals with low levels of interoception awareness

Interventions
We aim to recruit 120 people experiencing low interoception awareness, as measured by the Bodily Awareness Questionnaire (BAQ), who will be individually randomised to receive InMe intervention ("InMe arm") or control intervention ("Control arm") for one week (two sessions). Participants have a 50:50 chance of being allocated to receive InMe or Control arm. Data, including the primary and secondary outcomes, will be collected online or at the PI’s research lab at baseline (T0), post-intervention (T1a and T1b) and at Follow-up (T2, 2 months post the end of T1).

Participants in both arms will take part in two intervention sessions. Each intervention session is comprised of two blocks:
1. Training including psychoeducation and familiarisation
Participants will be given brief psychoeducation and task instructions and be told that they will be shown how their heart rate may fluctuate at different points in time and how heart rate changes when one breathes in and out. Participants in arm 1 will be invited to practice the breathing exercises following the Polar app (https://www.polar.com/en/smart-coaching/serene)

default practice. Participants in arm 2, will follow guided imagery (see SOP_InMe/SOP control). In both arms, the psychoeducational component (see SOP) which will teach participants about the importance and role of the autonomic nervous system (in general terms) and explain that heart rate tends to increase when one is stressed and decrease when one is relaxed. Psychoeducation will also stress that one can train oneself to better control one's heart rate, with beneficial effects on one's mood and health. Participants will also be able to ask questions prior to moving on to the main part of the intervention. Throughout the session, heart rate will be recorded using the Polar Ignite 2 watch application. Participants in arm 2 will wear the Polar watch. but will not be able to see its screen.
2. Stressors and interoception self-efficacy beliefs
During the main part of the intervention, we will use the Trier Social Stress Test, which consists of a mock job interview for a high-status managerial position or prestigious university society (order counterbalanced between participants), followed by a verbal mental math task (see details in SOP). All stressors are aimed to enhance the heartbeat and allow participants to practice their ability to use their breathing (InMe) or imagery (Control) to downregulate their heartbeat. During the pre- and post-stressor blocks, each participant will be asked to rate their pre-/post- interoception self-efficacy beliefs in their abilities to downregulate their heart rate.

Intervention Type
Behavioural

Primary outcome(s)
Adaptive interoception measured using the 25 items from the Multidimensional Assessment of Interoceptive Awareness (MAIA) questionnaire at baseline, up to 5 days before the first visit /intervention (T0), at the end of the day of the second visit/intervention, scheduled 5 to 9 days following the first visit (T1b) and at follow-up 7 to 9 weeks after T0 (T2)

Key secondary outcome(s))
1. Measures of Interoception:
1.1. Interoceptive self-efficacy beliefs updating measured using computational methods (see https://osf.io/x4ysv) at baseline (T0)
1.2. Interoception accuracy measured by the Heart Rate Discrimination (HRD) task at T0, at the end of the day of the second visit/intervention, scheduled 5 to 9 days following the first visit (T1b) and at follow-up 7 to 9 weeks after T0 (T2)
1.3. Interoceptive global Metacognitive sensitivity measured by the HRD task at T0, T1b and T2
1.4 Interoception sensibility measured using the total score of "Multidimensional Assessment of Interoceptive Awareness" (MAIA) and its specific self-regulatory subscale at T0, T1b and T2
2. Measures of mental-health-related symptoms:
2.1. Disordered eating symptoms sum score measured using EDI-3 sub-scales (drive for thinness, bulimia and body dissatisfaction) at T0, T1b and T2
2.2. Self-reported psychological symptoms measured using the General Score Index of the BSI-53 and its specific sub-scales on somatisation symptoms, anxiety and depression at T0, T1b and T2
2.3. Affective and Interpersonal problems related to eating disorders measured using interoceptive deficits scale (EDI-3) at T0, T1b and T2
2.4. Emotional regulation measured using the Difficulties in emotion regulation scale (DERS) at T0, T1b and T2
3. Measures of Potential Moderators:
3.1. Core dimensions of obsessive compulsive disorder (OCD) harm avoidance and incompleteness as measured by OC-CDQ scoring at T0

3.2. Difficulty dealing with uncertainty measured using Intolerance for Uncertainty (IUS) scoring at T0
3.3. Measures of cardiac physiology measured using heart rate variability HRV at T0, T1b and T2

Completion date
11/05/2023

Eligibility

Key inclusion criteria
1. Aged 18 to 30 years old
2. Low levels of interoception awareness with a score on the Bodily Awareness Questionnaire (BAQ) <25 percentile (Depending on recruitment rate we will need to consider less restrictive criterion of < 30/40 percentile)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
30 years

Sex
All

Total final enrolment
127

Key exclusion criteria
1. Existing substance dependency, moderate to severe cognitive impairment and severe mental health conditions (e.g., psychosis)
2. Existing severe neurological condition (e.g., epilepsy)
3. Existing diagnosis of heart-disease
4. Current use of neurological, cardiac (e.g., medications that influence blood pressure /cardiovascular functioning) or psychiatric medication (via self-report)
5. Body mass index (BMI) ≥ 30, where BMI = kg/m2
6. Low vision/hearing that cannot be corrected
7. Unable to fluently understand English speakers
8. Pregnancy

Date of first enrolment
29/06/2022

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
United Kingdom

England

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Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research council

Funder Name
H2020 European Research Council

Alternative Name(s)
H2020 Excellent Science - European Research Council, European Research Council, EXCELLENT SCIENCE - European Research Council, H2020 Ciencia Excelente - Consejo Europeo de Investigación (CEI), CIENCIA EXCELENTE - Consejo Europeo de Investigación, H2020 Wissenschaftsexzellenz - Für das Einzelziel 'Europäischer Forschungsrat (ERC)', WISSENSCHAFTSEXZELLENZ - Für das Einzelziel 'Europäischer Forschungsrat, H2020 Excellence Scientifique - Conseil européen de la recherche (CER), EXCELLENCE SCIENTIFIQUE - Conseil européen de la recherche, ECCELLENZA SCIENTIFICA - Consiglio europeo della ricerca, H2020 Eccellenza Scientifica - Consiglio europeo della ricerca (CER), ERC, CEI, CER

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
University College London

Alternative Name(s)
University College London in United Kingdom, Collegium Universitatis Londinensis, UCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/06/2025	06/06/2025	Yes	No
Protocol file	version 1.0	01/07/2022	26/07/2023	No	No
Protocol file	updates to v1.0 only version 2.0	20/07/2023	26/07/2023	No	No