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# Biofeedback and Training of Interoceptive Insight and Metacognitive Efficacy Beliefs to Improve Adaptive Interoception: A Subclinical Randomised Controlled Trial

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#### **Keywords**

Randomised controlled trial · Biofeedback · Interoception · Eating disorders · Self-efficacy · Slow breathing

#### **Abstract**

Introduction: Interoception, the sensing, awareness, and regulation of physiological states, is crucial for wellbeing and mental health. Behavioural interventions targeting interoception exist, but randomised controlled trials (RCTs) testing efficacy remain limited. The present, preregistered (ISRCTN16762367) RCT tested the novel Interoceptive iNsight and Metacognitive Efficacy beliefs (InMe) intervention. InMe uses slow breathing and cardiac biofeedback during stress to train interoceptive self-efficacy beliefs and improve selfreported interoception. *Methods:* Healthy participants aged 18–30 years with low self-reported interoception were randomly assigned (1:1) to the InMe intervention (n = 50) or an active control (guided imagery; n = 52). Participants blinded to allocation were stratified by gender and disordered eating. Assessments included baseline (T0), post-intervention (T1), and 7-8 weeks post-intervention

(T2). The primary outcome was the "adaptive interoception" factor of the Multidimensional Assessment of Interoceptive Awareness guestionnaire. **Results:** Both arms improved in the primary outcome at T1 (InMe: adjusted M difference = 5.76; 95% CI [-0.03; 11.56], p = 0.05; control: adjusted M difference = 7.90; 95% CI [1.92; 13.87], p = 0.002; marginal  $R^2 = 0.09$ ). However, only InMe sustained this improvement at T2 (InMe: adjusted M difference = 9.25, 95% CI [3.37; 15.13], p < 0.001; control: adjusted M difference = 2.94, 95% CI [-3.07; 8.96], p = 0.72), as indicated by a significant time\*arm interaction (b = 6.31; SE = 2.92, 95% CI [0.56; 12.05], p < 0.03; marginal  $R^2 =$ 0.12). Secondary outcomes showed a reduction in disordered eating scores across both arms at both time points (T1: b = -1.44, SE = 0.37, 95% CI [-2.17; -0.71], p < 0.001; T2: b = -1.05, SE = 0.37, 95% CI [-1.79; -0.32], p = 0.005). **Conclusion:** The InMe intervention selectively improved self-reported interoception at follow-up but did not outperform the control for secondary outcomes. Future research should explore its efficacy in clinical populations alongside complementary therapies.

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#### Introduction

Interoception refers to the processes of peripheral and central signalling by which we come to sense, integrate, regulate, and interpret physiological signals to form neural and mental representations of the physiological states of the body [1]. As these representations are crucial for homoeostatic regulation and thus our emotional, psychological, and physical health, research interest in interoception has burgeoned in recent decades [1]. Studies have identified interoceptive disruptions as a key transdiagnostic factor contributing to an array of mental health disorders, particularly to those at the intersection with physical health [1-3]. Consequently, there is also an increasing number of psychological [4], pharmacological [5], and stimulation-based [6] interventions aiming to target interoceptive disruptions as a way to reduce mental and physical health symptoms. Psychological interventions tend to range from those following more 'psychophysiological' traditions that target the perturbation and accurate perception, or regulation of, and/or attention to physiological signals themselves (e.g., biofeedback protocols [6-9]; to more traditional psychotherapeutic approaches that target maladaptive attention or beliefs about interoceptive signals without necessarily measuring, or visualising these signals (e.g., interoceptive exposure or mindfulness training; [4, 10–12]).

Interestingly, a recent systematic review revealed that the randomised controlled trials (RCTs) of psychological interventions that simultaneously targeted both the processing of interoceptive signals (in most cases without measurement) and higher order beliefs about these signals had a greater therapeutic impact on interoceptive abilities compared to those that targeted either aspect alone (i.e., processing of interoceptive signals or beliefs about these signals [4]). Accordingly, in the present study, we aimed to integrate insights across such intervention traditions.

We developed and tested a novel intervention that both manipulated and measured cardiac interoceptive signals and targeted explicit interoceptive self-efficacy beliefs (as described below) about one's ability to regulate cardiac interoception by visualising this regulation and externalising it for participants via peripheral biofeedback (see details below).

Recognising and therapeutically targeting different interoceptive levels has long been acknowledged as important in the field [1, 3, 4, 10]. While most interoceptive processes operate autonomously and without conscious awareness (e.g., circadian systems), the successful regulation of certain signals (e.g., maintaining

glucose levels) often requires conscious attention, awareness, and accurate interpretation of the signal (e.g., hunger). Additionally, it involves holding a set of counterfactual beliefs about its regulation (e.g., knowing that one can feel satiated and full after eating). The term interoceptive self-efficacy beliefs refers to such counterfactual beliefs about one's ability to perceive, interpret, or regulate interoceptive signals [13] (see also "allostatic self-efficacy" for a similar concept [14]).

Disrupted interoceptive self-efficacy can undermine an individual's confidence in their bodily signals and make these signals feel out of self-control and threatening. Previous findings suggest that interventions targeting these beliefs could potentially reduce symptoms of mental health disorders, such as eating disorders [15]. Recent studies using computational models to understand brain function and neural processes underlying human behaviour have shown that patients with anorexia nervosa hold more 'pessimistic' interoceptive self-efficacy beliefs, and update these beliefs at a slower rate than healthy controls, even when their interoceptive performance remains relatively intact [13, 16, 17].

Interestingly, slower updating learning rates about one's interoceptive signals - i.e., the adaptation of beliefs about one's abilities based on newly incoming information from internal bodily systems (see [17] for computational and Bayesian models of belief updating) - has been proposed as a transdiagnostic factor in mental health disorders. Specifically, individuals with various mental health symptoms tend to underestimate the reliability of their interoceptive bodily signals during stress compared to healthy controls [17]. Such underestimation suggests that, in some mental health disorders, bodily signals may not be perceived with sufficient precision to enable belief updating [17, 18]. Therefore, "externalising" and learning to control interoceptive signals via biofeedback, might offer an alternative way to facilitate belief updating, learning and self-regulation during stress regulation. For example, biofeedback has been successfully used in eating disorders to increase patients' ability to tolerate stress and the ability to cope with situations involving food (see [19] for a systematic review).

More specifically, biofeedback uses real-time physiological data to help individuals learn how to control and respond to information about their automatic bodily reactions. Cardiac biofeedback can be used in conjunction with slow-paced breathing (typically at six inhalation-exhalation cycles per minute) as a more effective way to self-regulate physiological activity in comparison to slow breathing and other mindfulness

exercises alone (see [20, 21]). This practice has been shown to influence respiratory sinus arrhythmia (defined as the cyclical change in heart rate occurring when the heart rate increases during inhalation and decreases during exhalation), enhance baroreflex sensitivity, and increase the vagal and parasympathetic control of the heart [20]. In turn, these physiological changes lead to reduction in stress, anxiety, and depressive symptoms, as well as eating-related symptoms in eating disorders [22] (see [7, 23] for detailed information about the neurophysiological pathways).

However, despite the potential of this kind of cardiac biofeedback and related interoceptive training interventions, there is increasing understanding that physiological changes and their accurate perception (termed interoceptive accuracy [24]) do not fully account for the observed variance in clinical outcomes [9, 13, 20]. There are therefore calls to integrate elements from other clinical traditions, such as targeting cognitive appraisals and interoceptive, self-efficacy beliefs, with biofeedback protocols (see [9, 25]). This integrative perspective, along with feedback from patients and clinicians [13, 26] (see below) informed the design and delivery of the present preregistered RCT, which aimed to combine the advantages of the neurophysiological-informed, "interoceptive biofeedback" interventions (mostly targeting signal perception and regulation) with those of psychologically-informed interventions (primarily targeting beliefs about signal perception and regulation).

Specifically, we developed a novel therapeutic intervention called Interoceptive iNsight and Metacognitive Efficacy beliefs (InMe). This intervention uses guided, slow breathing and cardiac biofeedback to train individuals to regulate their own heart rate following a controlled stress induction procedure, while also asking participants to generate and regularly update related interoceptive self-efficacy beliefs. We compared the InMe intervention to an active control intervention, which involved imagery-based, stress regulation without cardiac biofeedback. We hypothesised that by providing real-time feedback on cardiac regulation during stress and by highlighting related interoceptive self-efficacy beliefs, individuals would not only become better at noticing their somatic signals but also increase their interoceptive selfefficacy beliefs about their ability to regulate interoception in anxiety-inducing situations. We further hypothesised that this increase in interoception regulatory abilities would primarily manifest in individuals' interoceptive sensibility, as measured by our primary outcome [27]. Specifically, we expected that participants in the InMe intervention arm would show greater improvements in

interoceptive sensibility, compared to the active control arm, both immediately post-intervention (T1) and at the 7–8 weeks of follow-up (T2).

In addition to assessing the efficacy of the InMe intervention in improving interoceptive sensibility, we aimed to explore whether it could reduce mental health symptoms, particularly subclinical symptoms of disordered eating and somatisation. We also aimed to identify if changes in interoceptive self-efficacy beliefs could serve as a mechanism of action, mediating the anticipated improvement in interoception sensibility at T1 (see primary outcome).

Lastly, we aimed to identify individual traits that could moderate changes in interoceptive sensibility and mental health-related symptoms (see secondary outcomes). We focused on traits that might influence how individuals respond to stressful events and could therefore benefit from the biofeedback evidence provided by the InMe intervention. For example, we hypothesised that individuals with high intolerance of uncertainty, characterised by a tendency to avoid situations with ambiguous, or uncertain outcomes [28], or individuals with low General Self-Efficacy (GSE), defined as a belief in one's ability to overcome difficult or negative situations [29], might benefit from the certainty and increased sense of control and self-efficacy that biofeedback can provide about one's own cardiac regulation, even during stress.

As preregistered, we also hypothesised that core dimensions of obsessive-compulsive disorder (harm avoidance and incompleteness) will act as moderators of the expected primary outcomes change. The rationale of this analysis is that individuals with low interoceptive awareness feel uncertainty over their bodily states and their regulation and by providing them with biofeedback that allows the precise, online externalisation of interoceptive signals, we can increase such certainty and the perceived sense of control. However, this increase may be moderated by individual differences in core motivators for control [30], such as harm avoidance and incompleteness, as well as intolerance of uncertainty [31].

#### Methods

Study Design and Participants

The study is a two-arm, parallel group, RCT comparing the InMe intervention to an active control arm (guided imagery) in healthy individuals aged 18–30 years with low levels of self-reported interoceptive sensibility (i.e., scores below the 30th percentile on the Body Awareness Questionnaire (BAQ) [32, 33] – see online suppl. material for

details on this measure; for all online suppl. material, see https://doi.org/10.1159/000546298). Follow-up assessments were completed approximately 1 week and 7–8 weeks post-randomisation (see procedure), allowing for an evaluation of both immediate and sustained intervention effects. All reporting adheres to CONSORT guidelines [34] to ensure transparency and replicability in trial design, implementation, and outcome reporting (see also online suppl. Table 9S). The trial was registered on July 6, 2022, with the International Standard Randomized Controlled Trial Registry (ISRCTN16762367).

The study and protocol design (Fig. 1) and its delivery were informed by the findings of an initial audit of mindfulness practices, with and without simplified cardiac biofeedback, in an inpatient eating disorders unit [35] as well as the active involvement of our Lived Experience Advisory Panel (LEAP) and Clinical-Academic Trial Steering (CATS) (details of the LEAP and CATS involvement are fully reported elsewhere) [26]. Their continuous feedback was integrated into the RCTs standard operating procedures and protocol. This included reviewing the participant-facing documents (e.g., information sheet, consent form, and advertisements), refining the statistical plan and improving the trial preregistration. Additionally, both LEAP and CATS also provided feedback on the results interpretation, their clinical impact and future direction to utilise the InMe intervention. The goal of these contributions was to optimise the quality, integrity, and relevance of the RCT (see [26] and Methods and Discussion sections for details on how the input from these consultations informed the study).

To identify eligible individuals, we published an online screening form, advertised using the research participant system (SONA) at University College London and across several social media platforms (e.g., Facebook, X). The screening form included the following self-report criteria – inclusion: fluency in English and normal or corrected-to-normal vision and hearing; exclusion: current substance dependency, moderate to severe cognitive impairment, severe mental health conditions (e.g., psychosis), obesity (body mass index [BMI] >30 kg/m²), pregnancy, heart disease, and current use of neurological, cardiac or psychiatric medication that might influence blood pressure. These criteria were selected to minimise influences on cardiovascular functioning and our cardiac, interoceptive measures, consistent with similar RCT protocols [36].

# Randomization, Stratification, and Masking

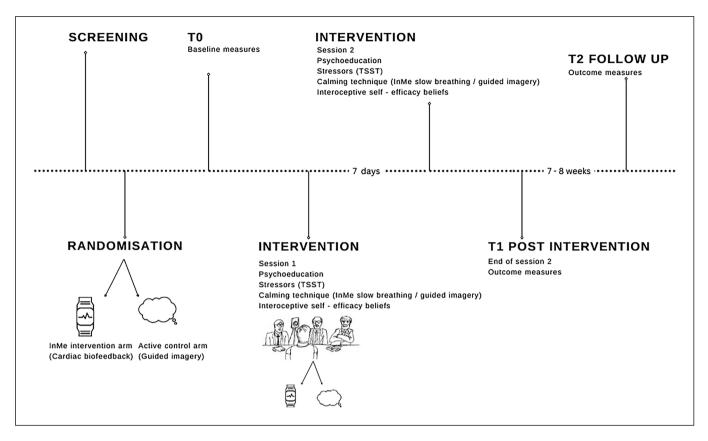
Group allocation used stratified randomisation following a 1:1 allocation ratio. Given our focus on individuals with low interoception and the established links between interoceptive disruption and elevated subclinical mental health symptoms, such as disordered eating [3], and that we were informed by preliminary evidence from a service audit indicating the potential benefits of training interoceptive beliefs in anorexia nervosa [35], participants were stratified based on their subclinical disordered eating symptoms and gender. Subclinical disordered eating symptoms were assessed using the Eating Disorder Examination Questionnaire (EDE-Q) norms [37], with a cutoff score set at the 70th percentile. Participants scoring at or above this threshold were classified as having "high disordered eating" and were evenly allocated across the study arms. Additionally, since our sample was predominantly drawn from a student population, we anticipated a higher proportion of women, necessitating gender (see [38] for gender differences in interoception) as another stratification factor to maintain balance.

Arm allocation (InMe or control) was performed only after participants consented to participate in the study using the sealed envelope technique. Specifically, once a participant was deemed eligible, the trial manager instructed the research team to invite them to the study. Upon receiving the participant's agreement, the research team notified the trial manager, who then contacted an external researcher responsible for opening the sealed envelope and revealing the pre-generated random arm allocation.

The study was conducted in a single blind manner, as preregistered. That is, while participants themselves were blind to their allocated arm, the team administering the intervention and assessments were not blind to this allocation. Nevertheless, all assessors remained unaware of participants' scores or whether they were classified as having "high disordered eating" throughout the trial. Data analysis was carried out by a statistician who was blind to the treatment and was not involved in the assessments or the intervention.

# Sample Size and Power Calculations

The target total sample size was set at 60 per arm (120 total); however, recruitment had to be stopped before reaching this target (N = 102; see modified "intention-to-treat (ITT)" sample) due to time constraints and budget limitations. The target sample size was calculated based on an a-priori power calculation using an observed effect size of Cohen's d = 0.45 from a previously published RCT [39], which used the Multidimensional Assessment of Interoceptive Awareness (MAIA [40]) subscales as outcomes measures. Based on this calculation (see preregistration), we determined the minimal sample size



**Fig. 1.** Overall study design, including assessment time points (T0, T1, T2), averaged time in days/weeks between the time points and intervention sessions.

to be 60 participants per group, allowing for 10% dropout rate. However, it should be noted that after completing our RCT, we discovered an error in our calculations, which, when corrected, yielded a Cohen's d=0.63. This suggests that our erroneous preregistered power analyses may have been conservative. We did not realise this error until after the completion of the study, so we address this issue in the discussion (see post hoc power analysis in online suppl. material).

#### General Procedure

Overview and timeline: the study comprised three parts (see Fig. 1).

# Baseline Assessment (T0)

This first phase included both online and in-person baseline assessments and took place after randomisation. The online baseline testing link was sent to the participants within 2 days after the randomisation. However, since some participants withdrew before completing this assessment, we have modified the ITT sample (see Fig. 2 and statistical analysis). The online

testing included demographic information (age, self-identified gender, education level, nationality, and occupation) and self-report measures mental health traits and symptoms (see "outcomes" and study protocol). In-person testing included the HRD task ([41]; see details below) and height and weight measurements to calculate BMI.

Intervention and Post-Intervention Assessment (T1)

Participants in both arms (InMe or control) underwent the corresponding intervention (procedures detailed below) twice within approximately 1 week (with an average interval of 7 days, SD = 1.86 between the two sessions). The post-intervention assessment (T1) took place at the end of the second session and included the same outcome measures as those used at T0.

#### Follow-Up Assessment (T2)

A follow-up assessment was conducted 7–8 weeks post-intervention (M = 7.5 weeks, SD = 0.76) to evaluate the sustained effects of the intervention and included the same outcome measures as at T0 and T1.

Intervention Procedures

Procedures Common to Both Arms

Psychoeducation. In both intervention arms, participants received psychoeducation focused on stress reactions and interoceptive self-regulation, conducted by the lead experimenter. Participants were informed that feeling stressed is a normal reaction and that there are ways that they can notice and regulate their reactions or feelings.

Familiarisation with Allocated Interventions. Following the psychoeducation and prior to any stressors, all participants underwent a familiarisation procedure with the technique they would subsequently use as part of their allocated intervention (see sections below "InMe/control main intervention" for specific details).

Trier Social Stress Test (TSST). Following familiarisation, the TSST protocol [42] was implemented to induce a stress response in both arms. The TSST involved a 3-min preparation period for a simulated job interview for a high-status managerial position or a prestigious university society, the order of which was counterbalanced between participants. After the preparation phase, participants delivered a 3-min speech in front of a panel of "judges" (i.e., three members of the research team; 19.6% of participants had two panel members due to scheduling issues; full details provided as part of the intervention feasibility analysis in [43]) while being video recorded. After the participant's speech, the panel members left the room, and the lead experimenter continued with the intervention (see details below for each arm) and instructed the participant to perform the calming technique they previously learnt. The InMe arm also involved the use of a POLAR® Ignite 2 watch and real-time biofeedback evidence their heart rate to learn about their physiological responses (see details below). For the second stressor (i.e., a verbal mental arithmetic task), the panel members re-entered the room, and the participant was asked to perform a 3min arithmetic task, which was also video recorded. In the InMe arm, participants were able to use the biofeedback from the watch (see details below) to learn about their heart rate response to the stressors and the calming techniques.

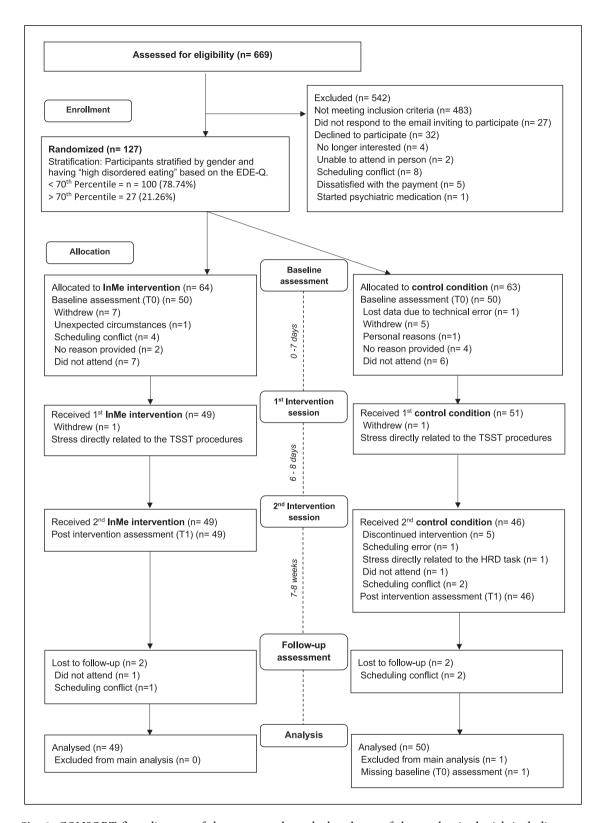
Interoceptive Self-Efficacy Beliefs. In both intervention arms, participants were asked to estimate their perceived ability to downregulate their heart rate using the calming technique they had learnt. These self-efficacy beliefs were assessed at four different time points: (1) before participants first practiced the calming technique of each arm ("baseline estimated beliefs"; Fig. 3), (2) before each stressor of the TSST, (3) after each stressor of the TSST

("retrospective estimate"; Fig. 3), as a global prospective estimate after both stressors ("global prospective estimate"; Fig. 3, 4), in relation to how well they will do if they had more practice opportunities (global prospective estimate 2 months; Fig. 3).

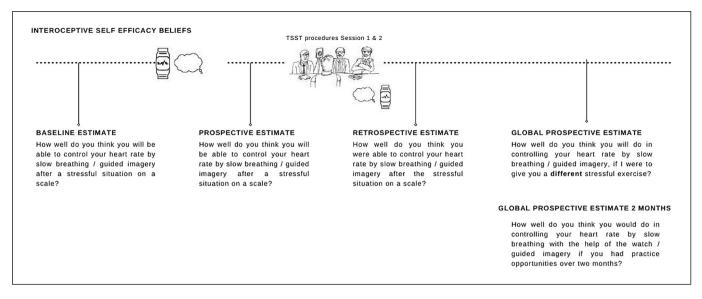
End of Visit Assessment. At the end of the session, participants were invited to share their experience with the lead experimenter. This part served two purposes: to reiterate the study's aim and enhance participants' metacognitive reflection on their experiences and to assess the feasibility and acceptability of the intervention (see [43] for findings regarding feasibility). Participants were also reminded about their next session (either the intervention second session or follow-up session). In both arms, the lead experimenter informed the participant that they might encounter stressful situations before their next visit and encouraged them to use the specific calming technique they had learnt.

Intervention Procedures Specific to Each Arm Active Arm: Interoceptive Insight and Metacognitive Efficacy Beliefs (InMe)

The active InMe arm was designed to enhance interoceptive sensitivity by providing participants with real-time biofeedback evidence of their ability to downregulate their own interoceptive signals under stress, through slow breathing. Participants were introduced to a POLAR® Ignite 2 watch, which was used to monitor heart rate and provide biofeedback evidence in the following steps. The lead experimenter first demonstrated the watch by wearing it on their own wrist and showing how heart rate could be monitored in real-time, for example, by performing a brief physical activity such as jumping on the spot to trigger a visible change in heart rate. Participants then wore had the watch on their dominant wrist and were informed that their physiological responses were being monitored. The lead experimenter guided them in observing their heart rate on the watch display and asked them to read it aloud. The experimenter also emphasised the participant's ability to notice their psychological reactions by saying: "Imagine your body is a book, and with the help of the watch app you may be able to explore the different ways in which you can 'read' this book. Reading this information will allow you to notice and learn about your body. Today we will focus on one kind of body reading: specifically, we will use the watch to teach you how you can use slow breathing to reduce tension and decrease your heart rate." During the familiarisation phase, participants were also introduced to the "slow breathing technique" using the Serene<sup>TM</sup> breathing exercise and its biofeedback



**Fig. 2.** CONSORT flow diagram of the progress through the phases of the randomized trial, including enrolment, allocation, randomisation, baseline (T0), post-intervention (T1) and follow-up (T2) assessments, intervention sessions, and analysis. EDE-Q, Eating Disorder Examination Questionnaire; HRD, heart rate discrimination; TSST, Trier Social Stress Test.



**Fig. 3.** Timeline and items of interoceptive self-efficacy beliefs assessed throughout the TSST and intervention procedure. Baseline estimations were recorded before the TSST, prospective estimations before each stressor, retrospective estimations after each stressor, and global estimations after both stressors.

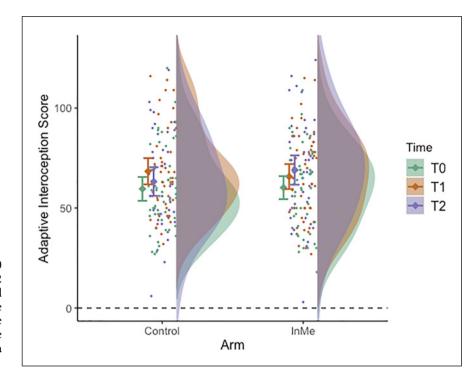
evidence (i.e., the change in their heart rate after following the slow breathing technique). The Serene<sup>TM</sup> watch application provided participants with multisensory feedback combining visual and tactile elements to guide participants to follow a slow-paced breathing at six cycles per minute for 3 min (see Introduction for how this pace can influence symptom reduction and reduce stress). The watch displayed an animated breathing guide consisting of a circular graphic that expended and contracted to represent inhalation and exhalation. In addition, the watch used synchronised, timed vibration, marking the transitions between inhalation and exhalation, allowing participants to maintain the rhythm even if they were not looking directly at the watch screen (see also https://www.polar.com/en/smart-coaching/serene).

To further ensure participants noticed the biofeed-back, after completing the slow-paced breathing, participants were instructed to read their heart rate from the watch and report it to the lead experimenter. The TSST protocol (see above) was then introduced. Participants were instructed to prepare for their speech and again asked to observe and report their heart rate just before and at the end of their speech. This aimed to facilitate their ability to notice heart rate changes in response to stress and the use of biofeedback. After each stressor of the TSST, participants again engaged in slow-paced breathing technique and reported their heart rate. This, in combination with the assessment of interoceptive self-efficacy beliefs, was intended to repeatedly

guide the participant's attention towards the biofeedback evidence of their ability to downregulate their heart rate. At the end of the session, participants were reminded that they could learn to notice physiological fluctuations during every day stressful situations like reading pages from their "body book" and were encouraged to use slow-paced breathing to try to control these responses.

# Active Control: Guided Imagery

The control arm followed a procedure parallel to the InMe arm but used guided imagery instead of the slowpaced breathing technique and the heart rate biofeedback monitoring. Participants were instructed to sit comfortably and were given the option to close their eyes. They then listened to a calming narrative, read aloud by the lead experimenter, which guided them through a vivid mental exercise to imagine a safe, peaceful place. Example prompts included the following: "Imagine a place where you feel calm and peaceful and easy. . . a place either make believe or real. . . a place from your past... or somewhere you've always wanted to go... It doesn't matter which place, as long as it's a place you feel safe and comfortable." This guided imagery session lasted 3 min, matching the duration of the slowpaced breathing technique used in the InMe arm. We chose this active control intervention, as guided imagery is a well-established relaxation technique that has been shown to reduce stress and anxiety (see [44] for systematic review), although it does not directly target



**Fig. 4.** Adaptive interoception at T0 (baseline), T1 (post-intervention), and T2 (7–8 weeks of follow-up) in InMe and control arms. Jittered dots represent the score for each individual participant. The error bars denote the standard error of the arm mean. The half violin provides data distribution.

interoception and physiological responses. To further control for procedural differences, participants in the control arm wore the POLAR® Ignite 2 watch on their dominant wrist and were informed that their physiological responses were being monitored. However, the watch screen display was covered with opaque paper preventing participants from seeing their heart rate arm participants. This ensured that only the InMe arm received real-time interoceptive feedback, maintaining the integrity of the intervention contrast.

# Outcome Measures Primary Outcome

The primary outcome measure was a self-report measure of interoception. We selected the Multidimensional Assessment of Interoceptive Awareness (MAIA [40]), a tool recommended for use in clinically focused studies [27], which assesses multidimensional aspects of "body awareness," including both adaptive and maladaptive ways to pay attention to signals from the internal body. Moreover, we followed a large scale systematic review [27] and latent factor analyses of the most commonly used interoception questionnaires, which found that 25 of the 37 items of the MAIA loaded in a single factor, namely, "adaptive interoception," with excellent internal reliability (Cronbach's  $\alpha = 0.94$ ). This factor included (1) the capacity to notice and focus on

uncomfortable, comfortable, and neutral body sensations (e.g., "I notice where in my body I am comfortable," (2) the capacity to regulate distress by attention to body sensations, (3) active listening to the body for insight (e.g., "when I feel overwhelmed I can find a calm place inside"), and (4) experience of one's body as safe and trustworthy (e.g., "I feel my body is a safe place"). Thus, as preregistered, these 25 items comprised the primary measure of the expected effects of InMe on interoception, which we assessed at baseline (T0), at post-intervention (T1) and at 2-month follow-up (T2; see online suppl. Table 1S for descriptive statistics), while the total MAIA score was a secondary measure (see below).

# Secondary Outcomes

Secondary Outcomes of Mental Health-Related Symptoms. The following secondary outcomes were selected based on findings suggesting that low levels of interoception are associated with mental health symptoms [1–3] and that improving interoception abilities may alleviate these symptoms even at subclinical levels (see online suppl. Table 1S for descriptive statistics).

Eating Disorder Risk. This was assessed at T1 and T2 relative to T0 using the Eating Disorder Inventory-3 (EDI-3; [45]), specifically the Eating Disorder Risk index [46], which is derived from the subscales measuring "Drive for Thinness," "Bulimia," and "Body Dissatisfaction" (see

online suppl. material for a more detailed account of this measure).

Symptoms of Anxiety, Somatisation, and Depression. These were assessed at T1 and T2, relative to T0, using the subscales of the Brief Symptom Inventory-53 (BSI-53 [47]). Additionally, the Global Score Index of the BSI-53 was used to measure overall psychological distress and the severity of participants' mental health symptoms at T1 and T2, relative to T0.

Difficulties in Emotion Regulation. Emotion dysregulation levels and the ability to manage emotions effectively were measured using the total score of the Difficulties in Emotion Regulation Scale (DERS [48]).

Secondary Outcomes of Other Interoception Measures

Self-Report Measures. In light of the ongoing debate regarding the validity of self-reported interoceptive measures, and as preregistered, we explored alternative factors of the primary outcome. This included the total score of the MAIA [40] and its validated "self-regulation" subscale at T1 and T2 compared to T0. Additionally, we assessed self-reported interoceptive deficits related to eating disorder at T1 and T2 compared to T0, using the Interoceptive Deficits Subscale of the EDI-3.

Behavioural Measures of HRD. [41] Behavioural performance was assessed using the HRD task [41] at T0, T1, and T2. This task measures perceptual interoceptive sensitivity (denoted as " $\alpha$ "), which reflects participants' ability to discriminate between tones that are synchronous or asynchronous with their heart rate. It also measures decision precision or uncertainty around this estimation (denoted " $\beta$ "), indicating participants' confidence in their discrimination ability. Additionally, metacognitive performance efficacy (Meta d') was assessed, reflecting how well participants could evaluate their own performance accuracy on the task. Further details about these task measures and the experimental settings, including the exteroceptive control condition, are provided in online supplementary Table 4S.

Mediators of the Main Outcomes: Interoceptive Self-Efficacy Beliefs as a Potential "Mechanism of Action"

Changes in 'Interoceptive Self-efficacy Beliefs' were preregistered as potential mediators based on our hypothesis that providing real-time cardiac feedback would enhance interoceptive self-efficacy beliefs, which could serve as a mechanism of action for our primary outcome (see Fig. 3 and the section on "Interoceptive Self-Efficacy Beliefs" for further details). Specifically, we hypothesised

that changes in individuals' estimated ability about to regulate their cardiac activity under stress could mediate the expected main outcome (i.e., changes in individuals' adaptive interoception).

# Moderators of the Main Outcomes

We also aimed to examine potential moderators of the main outcome (i.e., changes in individuals' adaptive interoception) as well as several secondary outcomes (i.e., changes in individuals' self-reported score of eating disorder risk, somatisation, anxiety, and depression symptoms). Specifically, we focused on key constructs that influence how individuals respond to stressful events and may benefit from the InMe intervention (see Introduction for specific hypotheses). These constructs include trait-level GSE at T0 (measured by the GSE scale [49]); intolerance of uncertainty at T0 (measured by the total score of the Intolerance of Uncertainty Scale-12 (IUS-12 [50]); alexithymia traits at T0 (i.e., difficulty identifying and describing emotions), measured by the total score of the Toronto Alexithymia Scale (TAS-20 [51]); and trait-level harm avoidance (e.g., fear of causing harm to oneself or others) and incompleteness (i.e., the inner feeling that things are not "just right") at T0, measured by the two subscales of the Obsessive-Compulsive Trait Core Dimensions Questionnaire (OCTCDQ [52]). A detailed description of these questionnaires and psychometric properties are provided in the online supplementary material.

#### Statistical Analysis

Statistical analyses were conducted based on a modified ITT principle by an independent statistician who was blind to treatment allocation. Since randomisation occurred after participants consented to participate, but before the baseline assessment (see Fig. 2, CONSORT flow diagram), we applied a modified ITT approach that excluded participants who withdrew before starting and therefore did not have baseline data (n = 102; see Table 1). This decision was made based on the rationale that engagement with the study was not influenced by group allocation, and completion of baseline assessment was essential for evaluating intervention effects. This approach supports an unbiased estimation of the intervention's effect among participants who adhered to a minimum level of intervention exposure, allowing a clearer understanding of the potential mechanisms and impact on study outcomes [53]. Moreover, while in clinical settings such modified ITT approaches may have some limitations, these are less likely to be relevant in a university setting (see discussion).

All analyses were pre-specified by the senior research team and executed before unblinding. Analyses were conducted using R [54]. Descriptive statistics, including means/standard deviations and percentages, were used to describe the baseline characteristics of the sample and the postintervention outcome measures at each time point by arm (online suppl. Table 1S). Intervention effects at each time point were estimated using multilevel (mixed-effects) models (MLM) with random-effects accounting for repeated observations. In each model, the outcome variable was treated as a continuous dependent variable, with time (T0, T1, and T2) and arm (InMe vs. control) serving as dummy coded fixed factors. Interaction terms for time by arm allowed the treatment effect to vary across time points. Participants' ID and stressor order were included as random-effects, and we controlled for BMI, age and stratification variables (i.e., selfidentified gender and being classified as having "high disordered eating"; 1 vs. 0). Pairwise comparisons for preregistered effects were corrected using Tukey correction.

Significance tests were based on two-sided  $\alpha = 0.05$ ; therefore, we also report 95% confidence intervals. To address missing data at T1 and T2, we applied the Baseline Observation Carried Forward approach, which assumes no change from baseline for participants who did not provide post-intervention data at T1 or T2. To address missing data due to attrition at T2 (N = 3), a complete case sensitivity analysis was conducted (see online suppl. Table 2S; results remained consistent).

#### Results

Participants were recruited between July 8, 2022, and February 23, 2023. Of the 669 individuals who completed the screening form, 186 were found eligible and were invited to participate in the study. The modified ITT sample included 50 participants in the InMe arm and 52 participants in the control arm (see Fig. 2 and Methods for recruitment and consent details). Ninety-five participants completed both intervention sessions and the T1 assessment (49 participants [98%] in the InMe arm and 46 participants [88%] in the control arm; see Figure 2; Table 1). At the T2 follow-up assessment, 4 participants (2 from the InMe arm and 2 from the control arm) did not attend, leaving 91 participants (InMe: n = 47; control: n = 44) who were assessed at this final time point. Demographic characteristics from the screening and baseline are displayed in Tables 1, 2 (see also online supplementary Table 1S for descriptive summaries of primary and secondary outcome measures across time points [T0, T1, and T2]).

#### Primary Outcome

To test our hypothesis regarding the effect of the InMe intervention on the primary measure, adaptive interoception, a MLM was used. The change in adaptive interoception from T0 was treated as a continuous dependent variable.

At T1, both intervention arms demonstrated significant improvements, as indicated by a significant effect of time (b = 7.90; SE = 2.07, 95% CI [3.82; 11.97], p < 0.001). However, there were no significant interactions between time and arm, suggesting no treatment effects (b = -2.14; SE = 2.89, 95% CI [-7.83; 3.55], p = 0.46).

Importantly, at T2, the interaction between time and arm indicated a significant treatment effect (b = 6.31; SE = 2.92, 95% CI [0.56; 12.05], p < 0.03; Figure 4). Specifically, participants in the InMe arm exhibited a significant increase in their adaptive interoception scores at T2 compared to T0 (adjusted M difference = 9.25, 95% CI [3.37; 15.13], p < 0.001), whereas participants in the control arm did not show a significant change (adjusted M difference = 2.94, 95% CI [-3.07; 8.96], p = 0.72).

The pattern of results suggests that while participants in both arms showed improvement in adaptive interoception following the intervention (T1), only the InMe arm maintained this improvement 7–8 weeks post-intervention at T2, partly supporting our hypothesis about the effect of the InMe intervention. As preregistered, we also conducted this analysis after excluding participants whose heart rate response during the TSST or following the slow breathing technique did not show the expected change (i.e., insufficient increase/decrease of 5 beats per minute or 2.5 SD change below the group arm average). These exclusions did not change the pattern of the reported effects (see online suppl. Table 3S for further exploratory analyses on outliers).

# Secondary Outcomes

Measures of Subclinical Mental Health Symptoms

As preregistered, we assessed the impact of the InMe intervention on secondary mental health-related measures individually. Changes in "eating disorder risk" scores from T0 were treated as a continuous dependent variable. There were no significant interactions between time and arm, suggesting no treatment effects (see Table 3). However, when exploring the model without the interactions, we found a significant reduction in eating disorder risk scores over time at both T1 and T2 (T1: b = -1.44, SE = 0.37, 95% CI: -2.17; -0.71, p < 0.001; T2: b = -1.05, SE = 0.37, 95% CI: -1.79; -0.32, p = 0.001; T2: b = -1.05, DE = 0.37, 95% CI: -1.79; -0.32, DE = 0.37, 95% CI: -1.79; -0.32, DE = 0.37

Table 1. Screening information of the modified ITT in both arms

	Modified ITT		Received 1st intervention		Received 2nd intervention		Attended follow-up (T2)	
	InMe	control	InMe	control	InMe	control	InMe	control
Self-identified geno	Self-identified gender							
Female	41	43	40	43	40	38	39	36
Male	7	8	7	7	7	7	6	7
Non-binary	2	1	2	1	2	1	2	1
Age	22.38 (3.14)	21.48 (3.65)	22.67 (3.67)	21.45 (3.21)	22.67 (3.67)	21.08 (3.07)	22.63 (3.73)	21.15 (3.12)
BAQ screening score	54.94 (8.75)	54.42 (9.11)	54.16 (9.53)	55.27 (8.34)	54.02 (9.58)	55.76 (8.38)	54.17 (9.69)	55.77 (8.57)
EDE-Q screening score	1.08 (1.05)	1.35 (1.32)	1.07 (1.06)	1.37 (1.32)	1.07 (1.06)	1.40 (1.37)	1.10 (1.08)	1.34 (1.29)
High DE	11	10	11	9	11	8	11	7
Total	41	42	49	51	49	46	47	44

Data presented in mean (SD). BAQ, Body Awareness Questionnaire; DE, disordered eating; EDE-Q, Eating Disorder Examination Questionnaire; high DE, individuals scoring above the 70th percentile; ITT, intention-to-treat.

0.005) indicating general improvement in eating disorder symptoms across the study duration (Fig. 5; Table 4). This pattern of results suggests that the InMe intervention did not produce a specific effect, as both arms demonstrated improvements in "eating disorder risk" at T1 and T2 compared to T0 scores. In relation to other secondary outcomes related to subclinical mental health symptoms, we did not observe any significant main effects or interactions with arm at either time point. While there was a non-significant reduction in participants' DERS scores, all the BSI measures did not improve in both arms (see Table 4 for estimated mean differences at each time point and Table 3 for interaction effects).

# Secondary Interoception Measures

HRD Measures. To test whether the InMe intervention affected participants' ability to perceive their own heart rate, we used the preregistered measures of a recently validated HRD task [41]. These measures include perceptual interoceptive sensitivity (" $\alpha$ "), decision precision or uncertainty around this estimation (" $\beta$ ") and metacognitive efficacy (Meta d'; see Methods and online suppl. material for further details on task measures, experimental settings, and the exteroceptive control condition in Table 4).

We first compared our sample's baseline performance on these measures to that of participants reported in the original HRD task paper [41]. Notably, even though this study's sample was screened for low self-reported interoception using the BAQ (see procedure), all task measures were found to be within one standard deviation of the values reported in the original paper ( $M_{\alpha} = -7.54$ ;  $M_{\beta} = 11.0$ ,  $M_{d'} = 0.81$ ;  $M_{Meta\ d'} = 0.27$ ).

A MLM was used for each measure separately, treating them as a continuous dependent variable (see Statistical Analysis above). When  $\alpha$  was used as a continuous dependent variable, there were no significant main effects or significant interactions between arm and time (Table 3), indicating neither intervention affected participants' perceptual interoceptive sensitivity.

For  $\beta$ , the interaction between arm and time indicated a significant treatment effect at T1 (T1: b = 2.45, SE = 0.94, 95% CI [0.61; 4.30], p = 0.009; T2: b = 1.02, SE = 0.97 95% CI [-0.88; 2.92], p = 0.29). Group comparison at T1 also showed a significant difference favouring the InMe arm (adjusted M difference = -2.43; 95% CI [-4.62; -0.25], Cohen's d = -0.74, p = 0.02). Post hoc comparisons within each arm showed that neither arm demonstrated a significant change from baseline. However, while participants in the InMe arm exhibited an increase in their uncertainty scores at T1 compared to T0 (adjusted M difference = 1.45, 95% CI [-3.37; 0.43], p = 0.23), participants in the control arm showed a decrease in their uncertainty scores (adjusted M difference = -0.98, 95% CI [-0.92; 2.90], p = 0.67).

**Table 2.** Demographic information of the modified ITT (N = 102) sample in both arms

	·	
	Control, n (%)	InMe, <i>n</i> (%)
Ethnic group		
White	14 (22%)	14 (22%)
Asian or Asian British	31 (49%)	29 (45%)
Black/African/Caribbean/Black British	1 (0.1%)	2 (0.3%)
Other ethnic group	1 (0.1%)	4 (1%)
Mixed/multiple ethnic groups	4 (0.6)%	0 (0%)
Prefer not to say	0 (0%)	1 (0.2%)
Missing data	12 (19%)	14 (22%)
Work status		. ,
Student	44 (70%)	39 (61%)
Employed or self-employed	7 (11%)	10 (16%)
Not working	0 (0%)	1 (1%)
Missing data	12 (19%)	14 (22%)
Education	.= (.,,,,,	(== /=/
Secondary school	28 (44%)	22 (34%)
University/post-graduate qualifications	24 (38%)	28 (43%)
No formal qualifications	0 (0%)	0 (0%)
Do not know/prefer not to answer	1 (1%)	0 (0%)
Missing data	12 (19%)	14 (22%)
<u> </u>	12 (1370)	14 (22/0)
Income	5 (80%)	7 (110%)
< GBP 15,000	5 (8%)	7 (11%)
GBP 15,000-GBP 49,999	15 (24%)	15 (23%)
GBP 50,000- GBP 99,999	11 (17%)	10 (16%)
>GBP 100,000	6 (10%)	2 (3%)
Prefer not to say	14 (22%)	16 (25%)
Missing data	12 (19%)	14 (22%)
Relation status	44 (000)	12 (252)
Never married and in a stable relationship	11 (22%)	13 (26%)
Never married and single	37 (59%)	33 (52%)
Married/civil partnership/cohabiting for more than 5 years	3 (5%)	1 (2%)
Prefer not to say	0 (0%)	3 (5%)
Missing data	12 (19%)	14 (22%)
Income support as a child		
Yes	6 (10%)	5 (8%)
No	41 (65%)	39 (61%)
Prefer not to say	1 (1%)	0 (0%)
Missing data	15 (24%)	20 (31%)
School meals as a child		
Yes	10 (16%)	2 (3%)
No	38 (60%)	46 (72%)
Missing data	15 (24%)	16 (25%)
Education of parents	, ,	. ,
Yes	44 (70%)	39 (61%)
No	7 (11%)	10 (16%)
Prefer not to say	1 (1%)	1 (0.1%)
Missing data	12 (19%)	14 (22%)
	12 (12/0)	17 (ZZ/U)

This pattern of results suggests that participants in the InMe arm showed greater uncertainty at T1, as compared to the control arm. When Meta d' was used as a continuous dependent variable of metacognitive efficacy, no significant main effect or interactions were found (Table 3).

Changes in Interoceptive Self-Efficacy Beliefs as Potential Mediators (Mechanisms of Action)

As preregistered, we examined whether the effects of InMe on the primary outcome were mediated by changes in explicit interoceptive self-efficacy beliefs (Fig. 3) using a simple mediation model in PROCESS for R [55]. At both time points, the mediation analysis revealed a significant direct effect of adaptive interoception at T0 on adaptive interoception at T1 (b = 0.86, p < 0.001) and T2 (b = 0.88, p < 0.001). However, the indirect effect via the mediator (i.e., change in interoceptive self-efficacy beliefs) was not significant (BootLLCI = -0.02; BootULCI = 0.03), indicating no evidence for mediating role. We repeated this analysis for each intervention arm separately, but again no significant effects were found (InMe: BootLLCI = -0.01; BootULCI = 0.02, and control: BootLLCI = -0.04; Boot-ULCI = 0.03). However, exploratory analyses of belief updating (online suppl. Table 5S) showed that participants in both intervention arms significantly increased their prospective estimates of how well they would perform if given additional 2 months of practice the calming technique they have learnt. As preregistered, advanced computational modelling of belief updating during the trial will form part of a separate paper (see exploratory analysis in online suppl. material).

Measures of Potential Moderators for the Primary Outcome

To test the effects of the preregistered, potential moderators on our main effect (i.e., change in adaptive interoception from T0 to T1/T2), we used MLM. As preregistered, we first entered the key moderators (i.e., harm avoidance, incompleteness, and intolerance of uncertainty). However, these 3-way interactions were not significant (see online suppl. Table 6S). As a secondary moderation analysis, and according to our preregistration to minimise the number of exploratory tests, we first conducted a Pearson correlation analysis between participants' scores on all the preregistered moderators at T0 and adaptive interoception at T0. This analysis revealed significant correlations between adaptive interoception and the total scores on the GSE

scale, TAS-20, and DERS; thus, we retained those moderators for further analysis (see online suppl. Table 7S).

A 3-way interaction between GSE scores at T0, time and arm emerged (T2: b = 1.33, SE = 0.68, p = 0.051; 95% CI [-0.01; 2.66]; T1: b = 0.41, SE = 0.67, p = 0.541; 95% CI [-0.90; 1.72]). Further probing of the interaction at T2 showed that the moderation effect was only in the InMe arm (InMe: b = 1.06, SE = 0.42, p = 0.01; 95% CI [0.22; 1.90]; control: b = -0.25, SE = 0.54, p = 0.39; 95% CI [-0.46; 0.18]; Figure 6). Further exploration of this interaction in the InMe arm revealed that, at T2, individuals with higher GSE scores at T0 showed greater improvement in their adaptive interoception scores from T0 (b = 1.14, SE = 0.49, p = 0.03; 95% CI [0.15; 2.12]. When DERS or TAS-20 scores at T0 entered as moderators, we did not find a significant 3-way interaction nor a trend (TAS-20: b = 1.14, SE = 0.25, p = 0.51; 95% CI [-0.65; 0.33]; DERS: b = -0.10, SE = 0.13, p = 0.43; 95% CI [-0.36; 0.16]; Table 5), indicating no moderation effects.

Measures of Potential Moderators for the Secondary Outcomes

Based on the secondary outcome results, we examined only the preregistered potential moderators on the changes in eating disorder risk at T1 and at T2. As before, we first employed a Pearson correlation analysis between participants' scores on the potential preregistered moderators at T0 and their scores on eating disorder risk and somatisation at T0. This analysis revealed significant correlations between all registered moderators and these measures at T0 (online suppl. Table 5S). However, we did not find any significant interactions with time across all moderators (see online suppl. Table 8S).

Exploratory Analysis - Practicing the Calming Technique

As part of evaluating the acceptability and feasibility of the InMe intervention (see also [43]), we explored whether the arms differed in their reported frequency of practicing the calming technique they learnt during the study (slow-paced breathing or guided imagery) between sessions. At T1, there was no significant difference between the arms (t = -0.91, df = 92, p = 0.36, Cohen's d = -0.19, 95% CI [-0.59; -0.22]). However, by T2, a significant difference emerged (t = -2.57, df = 87, p = 0.01, Cohen's d = -0.54, 95% CI [-0.96; -0.12]), indicating that participants in the InMe arm practiced the calming technique more frequently than those in the control arm. Given this

**Table 3.** Treatment effects (arm\*time) on the change in the primary and secondary outcome at T1/T2 from T0

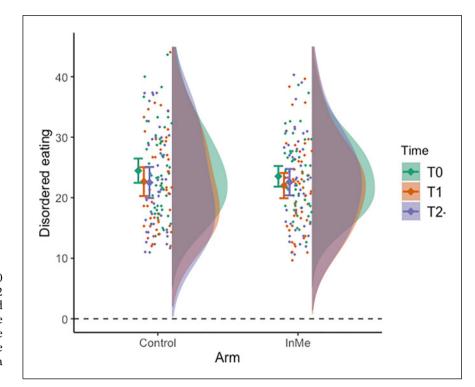
Predictor	В	SE	95% CI	p value	Marginal R <sup>2</sup>	
Adaptive interoception						
Arm*T1	-2.14	2.89	-7.83; 3.55	0.46	0.09/0.12	
Arm*T2	6.31	2.92	0.56; 12.05	0.03		
Eating disord	er risk					
Arm*T1	-0.11	0.75	-1.58; 1.36	0.88	0.08/0.08	
Arm*T2	0.06	0.75	-1.42; 1.54	0.94		
BSI somatisat	ion					
Arm*T1	0.41	0.79	-1.14; 1.96	0.60	0.02/0.02	
Arm*T2	0.11	0.79	-1.45; 1.68	0.88	0.01/0.02	
BSI depression	n					
Arm*T1	-0.43	0.68	−1.77; −0.90	0.52		
Arm*T2	0.73	0.68	-0.61; 2.08	0.28		
BSI anxiety						
Arm*T1	0.60	0.77	-0.92; 2.12	0.43	0.01/0.01	
Arm*T2	0.32	0.78	-1.20; 1.85	0.67		
BSI GSI						
Arm*T1	0.00	0.08	-0.16; 0.17	0.98	0.01/0.01	
Arm*T2	0.09	0.08	-0.08; 0.26	0.30		
DERS						
Arm*T1	-0.79	2.78	-6.26; 4.68	0.77	0.01/0.01	
Arm*T2	-0.81	2.80	-6.33; 4.71	0.77		
HRD: alpha						
Arm*T1	-3.36	2.28	-7.85; 1.14	0.14	0.02/0.025	
Arm*T2	-3.69	2.36	-8.3; 0.95	0.12		
HRD: beta						
Arm*T1	2.45	0.94	0.61; 4.30	0.009	0.03/0.04	
Arm*T2	1.02	0.97	-0.88; 2.92	0.29		
HRD: Meta d						
Arm*T1	0.19	0.18	-0.16; 0.53	0.29	0.02/0.02	
Arm*T2	0.15	0.18	-0.21; 0.50	0.42		

Model effect size is presented as the difference between (Marginal  $R^2$  without the treatment effect)/(Marginal R with the treatment effect). Statistically significant results are in bold. BSI, Brief Symptom Inventory; DERS, Difficulties in Emotion, Regulation Scale; HRD, heart rate discrimination task; GSI, General Score Index.

result, we also conducted an exploratory analysis testing the interaction between participants' practice and the primary outcome at T2. However, this interaction was not significant (b = 2.28, SE = 3.22, p = 0.48; 95% CI [-4.15, 8.70]).

#### Discussion

In this preregistered, subclinical RCT, we compared the effects of a novel, interoception-based, stress regulation intervention (InMe) with an active control arm that involved imagery-based stress regulation. We hypothesised that the InMe intervention, which combines slow breathing and cardiac biofeedback to help individuals regulate their heart rate following stress induction, would enhance individuals' ability to notice and regulate their interoceptive signals. This improvement was expected to be reflected in the primary outcome of interceptive sensibility, both immediately post-intervention (T1) and at the 7–8 weeks of follow-up (T2). We also expected that the InMe intervention would reduce symptoms of mental health, particularly subclinical symptoms of disordered eating and somatisation. Additionally, we hypothesised that changes in interoceptive self-efficacy beliefs would mediate the anticipated



**Fig. 5.** Disordered eating score at T0 (baseline), T1 (post-intervention), and T2 (7–8 weeks of follow-up) in InMe and control arms. Jittered dots represent the score for each individual participant. The error bars denote the standard error of the arm mean. The half violin provides data distribution.

improvement in the primary outcome. Finally, we aimed to explore whether certain individuals' traits moderated the outcomes.

In partial support of our main preregistered hypotheses, we found that while both intervention arms showed a beneficial effect (main effect) on adaptive interoception at T1, only the InMe intervention sustained this improvement at the follow-up time point (T2), suggesting a longer lasting impact on the primary measure compared to the control intervention. Additionally, as predicted, baseline GSE moderated the effect of InMe on adaptive interoception at T2, although in the opposite direction than expected. Specifically, individuals with higher GSE experienced greater long-term benefits from the intervention. Moreover, contrary to our hypotheses, we found no evidence that changes in explicit, self-efficacy interoceptive beliefs mediated the observed improvements in adaptive interoception. It is worth noting, however, that potential late effects on these beliefs may have been missed, as they were only measured as mediators during the intervention phase and not as outcomes at the follow-up (T2). Finally, although both intervention arms showed some beneficial effects on disordered eating, the InMe intervention did not outperform the active control condition in this regard. Below, we discuss the immediate and follow-up effects on the primary and secondary measures of interoception, followed by an examination of the broader impact on disordered eating and other mental health symptoms.

The immediate (at T1) post-intervention improvement in self-reported adaptive interoception across both arms can likely be attributed to general expectancy effects. All participants were aware that they were taking part in an RCT (albeit blinded to their allocated arm) and completed multiple interoceptive assessments, which may have heightened their awareness and monitoring of bodily signals. It should also be noted that, based on our initial conservative power calculations, this study may have been underpowered to detect significant differences between the arms (see online suppl. material). However, less conservative, post hoc considerations, along with the pattern of significant results observed at other time points, suggest otherwise.

The main effect and the lack of interaction at T1 may instead be attributed to certain shared therapeutic elements across both arms. For example, the self-calming techniques used after stress induction (TSST), may have contributed to the observed primary interoceptive effect at T1. This interpretation is consisted with prior research showing that even short-term intervention focused on self-regulation and mindful attention can lead to improvements in interoception [4, 56]. In the present study, both interventions arms involved

**Table 4.** Estimated mean of the outcome change from T0, for both intervention arms at T1 and T2

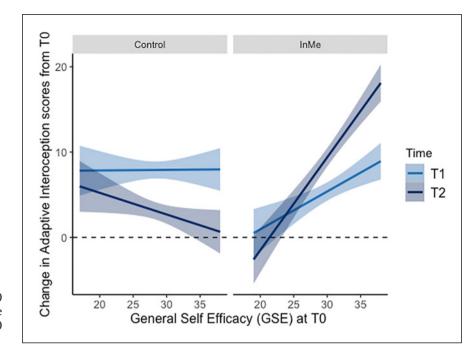
Adaptive interoception InMe	Group	Time	EMEAN	SE	95% CI
InMe	Adaptive intere	oception			
Control 1 7.82 2.82 -7.96; 23.3 11.63; 17.4   Eating disorder risk			5.82	2.59	-10.60; 22.2
Control 1 7.82 2.82 -7.96; 23.3 11.63; 17.4   Eating disorder risk		2	9.30	2.62	·
Eating disorder risk InMe	Control				
InMe					
Control 1	Eating disorde	r risk			
Control 1	InMe	1	-2.05	0.85	-4.62; 0.51
Control 1		2		0.85	-4.13; 0.94
BSI somatisation InMe	Control	1			
InMe		2	-1.74		
Control 1	BSI somatisation	on			
Control 1	InMe	1	0.47	0.72	-4.62; 5.58
Control 1		2		0.73	
BSI depression InMe	Control				
InMe	Control				
InMe	BSI depression				
Control 1 0.10 0.61 -11.2; 11.4   Control 1 0.16 0.66 -13.5; 13.8   2 0.66 0.85 -12.7; 12.8    BSI anxiety InMe 1 0.75 0.79 -2.89; 4.38   2 0.46 0.79 -3.15; 4.08   Control 1 0.01 0.85 -3.59; 3.60   2 0.007 0.80 -3.82; 3.98    BSI GSI InMe 1 0.05 0.07 -0.32; 0.42   2 0.10 0.07 -0.32; 0.42   Control 1 0.04 0.08 -0.34; 0.44   2 0.01 0.08 -0.34; -0.43    DERS InMe 1 -1.89 2.54 -11.76; 7.97   2 0.50 2.57 -9.13; 10.15   Control 1 -1.35 2.74 -11.58; 8.87   2 1.06 2.73 -8.83; 10.95    HRD: alpha InMe 1 0.10 2.25 -13.9; 14.15   2 -1.50 2.28 -12.9; 9.91   Control 1 3.30 2.35 -11.0; 17.66   2 2.02 2.39 -10.2; 14.22    HRD: beta InMe 1 1.45 0.80 -2.44; 5.34   Control 1 -0.98 0.84 -4.92; 2.95   2 0.09 0.85 -3.34; 3.53    HRD: Meta d' InMe 1 0.17 0.14 -2.22; 2.58   2 0.21 0.14 -1.50; 1.94   Control 1 0.06 0.15 -2.52; 2.65			0.19	0.61	-12; 12.3
Control 1 0.16 0.66 -13.5; 13.8 2 0.66 0.85 -12.7; 12.8   BSI anxiety InMe 1 0.75 0.79 -2.89; 4.38 2 0.46 0.79 -3.15; 4.08 2 0.46 0.79 -3.15; 4.08 2 0.007 0.80 -3.82; 3.98   BSI GSI InMe 1 0.05 0.07 -0.32; 0.42 2 0.10 0.07 -0.32; 0.42 2 0.10 0.07 -0.32; 0.42 2 0.01 0.08 -0.34; -0.43 2 0.01 0.08 -0.34; -0.43   DERS InMe 1 -1.89 2.54 -11.76; 7.97 2 0.50 2.57 -9.13; 10.15 2.74 -11.58; 8.87 2 1.06 2.73 -8.83; 10.95   HRD: alpha InMe 1 0.10 2.25 -13.9; 14.15 2 0.10 2.25 -13.9; 14.15 2 0.10 2.25 -11.0; 17.66 2 0.20 2.39 -10.2; 14.22   HRD: beta InMe 1 1.45 0.80 -2.44; 5.34 10.95    HRD: beta InMe 1 0.10 0.82 -2.17; 4.37   Control 1 -0.98 0.84 -4.92; 2.95 2 0.09 0.85 -3.34; 3.53   HRD: Meta d' InMe 1 0.17 0.14 -2.22; 2.58 10.94   Control 1 0.06 0.15 -2.52; 2.65					
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		2	0.10	0.15	-1./0; 1.9/

BSI, Brief Symptom Inventory; DERS, Difficulties in Emotion Regulation Scale; EMEAN, estimated mean; HRD, heart rate discrimination task; GSI, General Score Index. psychoeducation and behavioural practices aimed at fostering self-regulation following stress, as well as repeated assessments targeting interoceptive self-efficacy beliefs. Similarly, individuals with higher intolerance of uncertainty or lower self-efficacy did not derive any additional benefits from the InMe arm. Therefore, it appears that during the early post-intervention stages, the biofeedback component of InMe was not effective in enhancing certainty and self-efficacy, and in turn, self-reported interoception.

The immediate post-intervention effect should also be considered in the context of our methodological design, which included only two active sessions and no targeted practice in between sessions. This design choice was driven by our aim to develop an accessible and feasible intervention with translational potential, supported by prior research on the effectiveness of short-term biofeedback interventions [4, 56]. Additional factors, such as the potential for habituation effects with repeated exposure to the TSST beyond two sessions [57], as well as budget and time constraints also played a role. Moreover, limiting the number of sessions helped reduce potential attrition rates and the variability that might have been introduced by additional sessions. However, we acknowledge that by not increasing the number of active sessions in both arms, we may have missed the opportunity to detect more pronounced intervention effects, particularly in the InMe arm, which showed higher levels of self-initiated practice at T2.

It is also important to note that the InMe intervention employed a fixed breathing rate of 6 breaths per minute, a common practice but one that may not be optimal for all individuals due to noted physiological differences in cardiac-respiratory regulation patterns [58]. Tailoring the breathing rate to individual participants could potentially increase intervention efficacy, but this would also increase the technical complexity of the study. This aspect was considered detrimental by patients and other users of research in a previous audit [35] and in the PPI components of the work [26], who advocated for simpler wearables, like those used in this study, as more likely to improve use and adherence in clinical studies. In summary, our results suggest that the novel, simple biofeedback elements of InMe intervention were not more effective than the established visual imagery intervention [44] in enhancing immediate adaptive interoception as tested in this subclinical study.

The sustained improvement in the InMe group at follow-up (T2), suggests that biofeedback and slow breathing practice may have a more enduring impact



**Fig. 6.** General Self-Efficacy (GSE) at T0 (baseline) moderate the change in adaptive interoception scores at T1 and T2 from T0 in InMe and control arms.

**Table 5.** Results of the potential moderators on the primary outcome change in T1/T2 controlling for BMI, age, and stratification variables

Dependent variable: change in adaptive interoception
from T0

predictor	b	SE	95% CI	p value
InMe arm				
GSE*T1	0.41	0.41	-0.40;1.23	0.32
GSE*T2	1.06	0.42	0.22;1.90	0.01
DERS*T1	-0.10	0.08	-0.26;0.06	0.22
DERS *T2	-0.12	0.08	-0.28;0.04	0.15
TAS*T1	-0.14	0.16	-0.46;0.18	0.39
TAS*T2	-0.14	0.16	-0.46;0.18	0.39
Control arm				
GSE*T1	-0.00	0.53	-1.05;1.05	0.99
GSE*T2	-0.25	0.54	-1.32;0.81	0.63
DERS*T1	0.02	0.24	-0.44;0.49	0.92
DERS *T2	0.20	0.24	-0.68;0.28	0.41
TAS*T1	-0.06	0.10	-0.27;0.14	0.54
TAS*T2	-0.01	0.11	-0.22;0.19	0.88

GSE, General Self-Efficacy; DERS, Difficulties in Emotion Regulation; TAS-20, Toronto Alexithymia Scale.

on interoceptive processes compared to imagerybased regulation. Unlike the active control arm, participants in the InMe intervention received direct cardiac biofeedback on their heart rate changes during

both the TSST and after the calming practice. Interestingly, although interoceptive self-efficacy beliefs, as sampled during the training, were not found to mediate this effect, our exploratory analyses revealed a significant increase in participants' prospective, future-oriented, self-efficacy beliefs. Similar findings have been observed in the updating of motor selfefficacy beliefs following stroke, where real-time feedback had a different effect on immediate versus future-oriented self-efficacy beliefs [59]. Future studies could benefit from a direct manipulation of interoceptive self-efficacy beliefs, actively reinforcing a sense of control over physiological regulation, which may amplify intervention effects. For example, using false biofeedback to alter perceptions of one's ability to regulate stress could clarify the role of interoceptive self-efficacy beliefs in mediating intervention effects. Specifically, exaggerating physiological feedback to suggest enhanced regulation ability could strengthen self-belief and, in turn, lead to more sustained improvements in interoceptive sensibility and stress regulation.

To further enhance and strengthen this intervention, future research should extend training duration and increase the frequency of biofeedback sessions. A recent systematic review on the effectiveness of heart rate variability biofeedback for interoception reported mixed evidence, with many studies showing null effects across different interoception modalities.

However, the review suggested that improvements in interoception are more likely when protocols are more intensive and incorporate resonance frequency breathing [60]. Additionally, while our study primarily assessed interoceptive improvements postintervention, future research should whether these effects translate into real-world settings. Using ecological momentary assessment to track fluctuations in interoceptive sensibility, interoceptive self-efficacy, and disordered eating behaviours in daily life could provide a more nuanced understanding of the sustained impact of interoceptive training. Integrating brief, real-time biofeedback sessions within ecological momentary assessment protocols may further enhance interoceptive sensibility and improve daily stress regulation, increasing the intervention's potential applicability for both clinical and at-risk populations.

Interestingly, individuals with various mental health symptoms have been found to underestimate the reliability of their interoceptive bodily signals during stress, compared to healthy controls [17]. This underestimation has been linked to low precision of bodily signals which hinders effective belief updating [17, 18]. However, in the current study, although the sample was screened for low self-reported interoception, participants' "accuracy" and "precision" scores on the HRD task, a separate, cardiac discrimination task [41], fell within one standard deviation of values reported in the larger validation sample of this paradigm [41]. This finding confirms the noted dissociations between different levels of interoception [1, 3, 6, 24] and suggests that there may have been less margin for improvement on these secondary measures of interoception compared to the primary self-report measures.

Indeed, there were no significant differences between the arms in interoception accuracy or precision at T2 on the HRD task. If anything, InMe selectively decreased the precision of signals at T1 as compared to the control arm. This effect could indicate either a decline or a recalibration of interoceptive precision following biofeedback. Previous studies have suggested that biofeedback can make participants more critically aware of the challenges involved in accurately sensing bodily signals [61, 62]. Future computational studies are needed to examine whether cardiac biofeedback can enhance the precision of interoceptive signals in clinical samples with low baseline interoceptive precision, or whether alterative mechanisms mediate therapeutic effects in such populations. For instance, in the current study, participants in the InMe arm reported greater self-guided engagement compared to those in the active control condition (see also [43]). Systematic reviews of similar RCTs have indicated that psychological interventions targeting both the processing of interoceptive signals and higher order beliefs about those signals tend to have a greater therapeutic impact than those focusing on either element in isolation [4]. This dual focus may have equipped InMe participants with both the practical skills and the confidence needed to continue these practices post-intervention, potentially explaining the observed long-term benefit at T2.

Interestingly, our results confirmed that participants with higher baseline GSE derived greater benefits from the InMe intervention at T2 compared to those in the control arm. Higher self-efficacy is well known to be associated with greater willingness to exert effort and persistence (see [63] for review). Therefore, individuals with lower self-efficacy may require additional sessions and therapeutic elements, such as explicit reminders to practice, in order to achieve comparable benefits. In all cases, for the healthy individuals sampled here, brief and simple cardiac biofeedback during slow breathing after stress appeared to facilitate more lasting improvements in selfreported interoceptive abilities than other active interventions. These results therefor warrant future. clinical studies on the therapeutic use of such biofeedback as part of broader therapeutic protocols.

Regarding secondary mental health outcomes, we found no specific advantage of the InMe intervention compared to the control arm. Given the well-established links between disordered eating and disrupted interoception [1-3], we stratified our sample based on subclinical disordered eating. We hypothesised that improving interoceptive awareness might also contribute to reducing disordered eating, such as restraint eating or body weight concerns. Although the InMe intervention did reduce such symptoms, there were no significant differences between the arms, suggesting that the novel, simple biofeedback elements of InMe intervention were not more effective than the more established visual imagery intervention [44] in reducing disordered eating as tested in this subclinical study. Similar to other main effects observed in this RCT, the beneficial effects seen in both arms might result from general therapeutic expectancy, regression to the mean, repeated testing or other common therapeutic elements of both interventions. Another possibility is that both interventions positively affected disordered eating, albeit through different mechanism of action. However, we were unable to identify such mechanisms based on mediation or

moderation analyses in this study. It is possible that larger, more powerful clinical studies with more training sessions will be needed to demonstrate such effects. Second, we did not observe reductions in other secondary mental health outcomes, suggesting neither intervention selectively impacted outcomes beyond eating disorder risk. In addition to the study limitations mentioned above, this result may also be explained by the subclinical nature of this study, with our participants having a relatively low and unequal amount of these symptoms in the two arms and hence relatively small margins for improvement by our brief intervention protocols.

Moreover, while poor interoceptive awareness, including aberrant interoceptive beliefs, has been consistently linked to eating symptomatology in both clinical and subclinical disordered eating samples [4, 13, 15, 17, 64], the relationships between interoception and anxiety, as well as interoception and depression, appear more complex and varied in the literature [65–68]. Notably, there is stronger evidence that interoception-based interventions can improve symptoms in eating disorders compared to other mental health conditions, such as anxiety and depression (reviewed by [4]). For instance, recent meta-analyses have failed to establish a consistent association between cardiac interoceptive accuracy and anxiety or depression. Instead, anxiety and depression may be more closely linked to disruptions in other interoceptive domains or to difficulties in integrating or interpreting interoceptive signals [67]. These findings highlight the multidimensional nature of interoception and underscore the importance of considering a broader spectrum of interoceptive processes beyond cardiac measures when examining its role in different mental health conditions. Future research should explore whether targeting noncardiac interoceptive pathways could yield more consistent therapeutic benefits in anxiety and depression, similar to the improvements observed in disordered eating.

This study has several limitations that warrant further consideration. First, while we aimed at conducting an ITT analysis, modifications were made due to attrition before the trial began. Although this decision was made based on the rational that engagement with the study was not influenced by group allocation, and that completion of baseline assessments was essential for evaluating intervention effects, it may have impacted the robustness and power of our findings. Second, the demographic characteristics of the sample may limit the generalisability of the results. The majority of participants were university students (70%), predominantly women, and nearly half (49%) identified as Asian or Asian British. While this offers some degree of diversity, it may also

reflect cultural or demographic factors unique to the university setting, potentially affecting the observed outcomes. Last, despite efforts to standardise procedures, some methodological factors, such as different assessors during the TSST, may have introduced variability in stress exposure, potentially influencing the observed effects. Future studies should address these issues by including more diverse, representative populations and ensuring consistency across protocols.

In conclusion, our findings indicated that the InMe intervention had a more lasting effect on interoceptive sensibility at follow-up compared to the active control intervention, particularly among individuals with higher baseline self-efficacy. These patterns, as well as the observed higher self-initiated practice in the InMe arm at T2, highlights the need for future clinical studies with enhanced practice opportunities, and further sessions. While both interventions improved subclinical, selfreported disordered eating, neither demonstrated effects on broader mental health symptoms. Larger trials with clinically diverse samples are needed to create the necessary margins for improvement and to better understand the underlying mechanisms. Nevertheless, given the interoceptive gains observed with our brief intervention, we believe this RCT provides justification for testing an extended and optimised version in future trials, particularly for individuals with subclinical and clinical disordered eating. Improving interoceptive sensibility could therefore serve as a valuable target for intervention, helping individuals with both subclinical and clinical eating disorders in better understanding and regulating their physiological and emotional states.

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#### Statement of Ethics

Ethical approval was granted by the Departmental Ethics Committee at University College London, UK (reference: CEHP/2019/577, entitled: Body to Mind Awareness). Participants received written information about the study's objectives, procedures, and potential risks before providing written informed consent. Those who participated in the RCT were offered a choice of either GBP 37 or credit points (1 credit point per hour of participation, applicable to UCL psychology students only), as reimbursement upon completing the study.

#### **Adverse Events**

No adverse events were reported during participant testing sessions. However, it is noteworthy that one participant reported feeling unwell following the HRD task and asked to withdraw from the study (see [43] for further details on this event and acceptability of the stressors).

#### **Conflict of Interest Statement**

The authors declare no conflicts of interest.

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#### **Author Contributions**

A.F.: conceptualization of the overarching research, writing – original draft, writing – review and editing, supervision, and funding acquisition. A.K.: formal analysis, visualization, and accessed and verified underlying data. A.S.: manuscript editing, writing – review and editing, and data collection for audit. C.S.: funding acquisition. M.B.: data collection, data curation, accessed and verified underlying data, and manuscript editing. M.T.: project administration, writing – original draft, writing – review and editing, data collection, data curation, formal analysis, accessed and verified underlying data, and contribution to conceptualization. P.M.J.: critical review and revision. S.N.: critical review, revision, and supervision of statistical analysis. All authors read and approved the final version of this manuscript.

#### **Data Availability Statement**

The data that support the findings of this study and collected during the trial after de-identification as well as the study protocol are available at OSF and ISRCTN16762367, respectively.

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