Research Study

Improving Urticaria through Attention-based Training

Principal Investigators:

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Research team details:
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CNS Anne Sloan
Researcher and co-facilitator Sridevi Bindiganavile Ranganath

[Informed Consent Form for _____]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

My name is Dr Niall Conlon and I am a consultant immunologist at St. James's Hospital, Dublin. Along with my colleagues from Trinity College, I am carrying out a study investigating the effect of an 8-week Attention-based Training (ABT) programme on the wellbeing of patients with Urticaria. As you have been diagnosed with Urticaria, you might be eligible to take part in this study and therefore I would like to provide you with all the information you might want to know. You do not have to decide today whether or not you will participate in this research study. Before you decide, please read the information in this leaflet for more information or ask the staff member who provided you with this consent form.

Purpose of the research

1. To examine the current wellbeing of urticaria patients attending St. James's Hospital using three questionnaires.

2. To examine the impact of a mantra ABT programme on urticaria patient wellbeing as well as their physical symptoms.

The problem: Urticaria

Urticaria and angioedema are terms used to describe hives and swellings, which can be very distressing, recurrent and sometimes difficult to treat. While we do not know the exact cause of this condition, we do know that a specialised cell called the 'mast cell' is important. Mast cells can be affected by many factors, one of which might be chemical signals released **when the body is under stress**. These signals might make the condition worse.

It has been suggested that by controlling how we respond to stress we can limit mast cell activity and therefore hives and swelling.

There is growing evidence to support potential benefits of ABT on the psychological and physiological wellbeing. Therefore, we are interested to examine if ABT could help to improve the wellbeing of urticaria patients attending St. James's' hospital. Based on the results of the current study, we hope to develop an ABT programme that can be used to help reduce stress and improve wellbeing among urticaria patients throughout Ireland.

Type of Research Intervention – Attention-based Training (ABT)

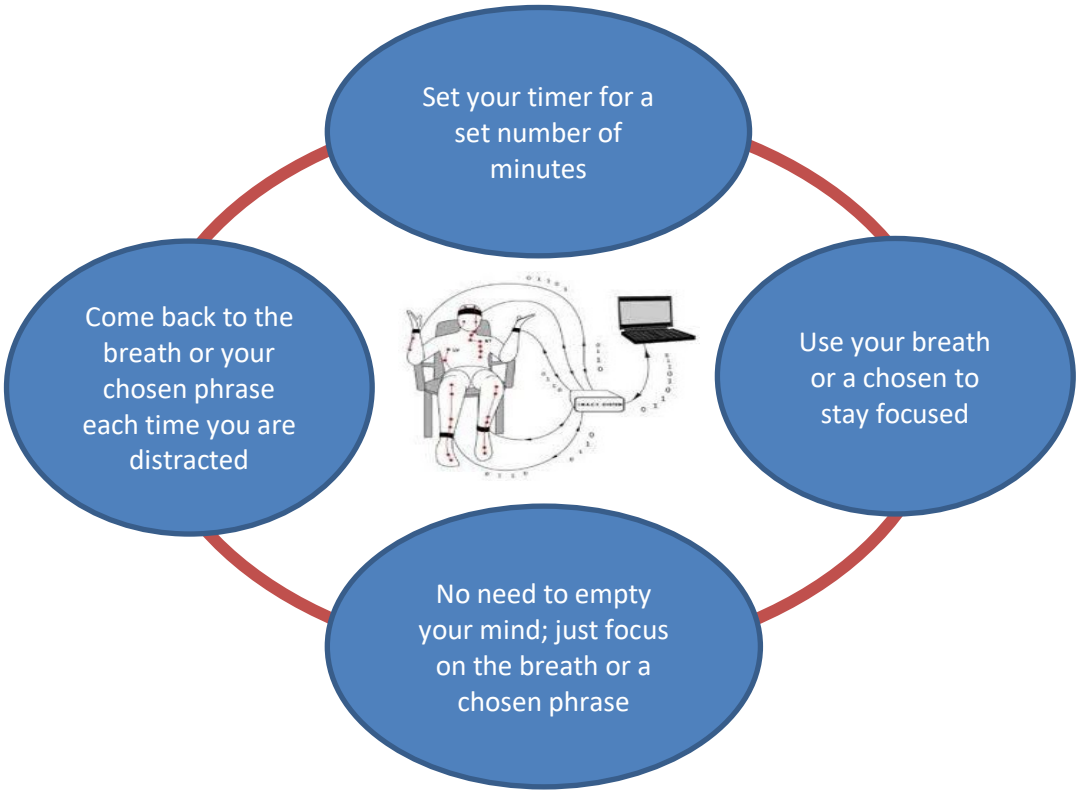
You will participate in a **free eight-week programme** where you will be taught ABT by an experienced facilitator and researcher. Each session will last 1 hour and 30 minutes and occur weekly for 8 weeks. Meetings will take place in the Clinical Research Facility, St. James's Hospital. Part of each meeting will involve group discussion around Chronic Urticaria and its impact on your life, as well as how to engage in ABT practice.

It is important to note that these weekly sessions are not regarded as group therapy.

There will be a maximum of 15 people in the practice group. You will also be asked to complete 2 minutes of ABT practice at home (morning and evening) on a daily basis, which will increase to 10 minutes by the end of the programme.

What is Attention-based Training (ABT)?

ABT involves using either the breath or a phrase (for example I-AM-HERE-NOW) that is used as an anchor to keep you in the present moment; this present moment practice helps you to disengage from thought, emotion, sensation and memory, on a moment by moment basis. Over time, ABT practice enhances long term focus and concentration, maintains a present-moment oriented mind-set and reduces stress.



Participant Selection

Inclusion criteria

- Clinical diagnosis of chronic spontaneous urticaria with or without angioedema with symptoms on at least one day per week and an urticarial control test of <12 indicative of poorly controlled symptoms
- Preference to participate in the study
- Over 18 years of age

Exclusion criteria

- Allergic urticaria or angioedema as defined by assessment of clinical history
- Disease dominated by chronic inducible urticaria (CIndU)
- C1 esterase inhibitor deficiency
- Clinical or histological evidence of urticarial vasculitis
- Current use of omalizumab
- Current use of oral steroids
- Alcohol or substance abuse within the past 6 months
- A history of psychiatric illness (schizophrenia, psychotic events)
- Currently using (at time of enrolment) anti-psychotic medication or recently started on anti-depressant ABT (less than 3 months at the time of enrolment).
- Participants on a stable dose of anti-depressant medication (for more than 3 months) will be permitted but advised to consult with their GP or psychiatrist prior to enrolment
- Not available to attend all programme dates

You are being invited to take part in this research because you have been diagnosed with urticaria and therefore represent the ideal candidate. ***Your participation can contribute much to our understanding and knowledge of ABT interventions for urticaria and will hopefully help to improve the wellbeing of similar patients throughout Ireland***.

Programme dates

	Date and time
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	
Week 6	
Week 7	
Week 8	

All study participants will be asked to complete questionnaires and provide blood samples, at two time points:
Time 1: one week before Session 1
Time 2: one week after Session 8

***Check in**: Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation

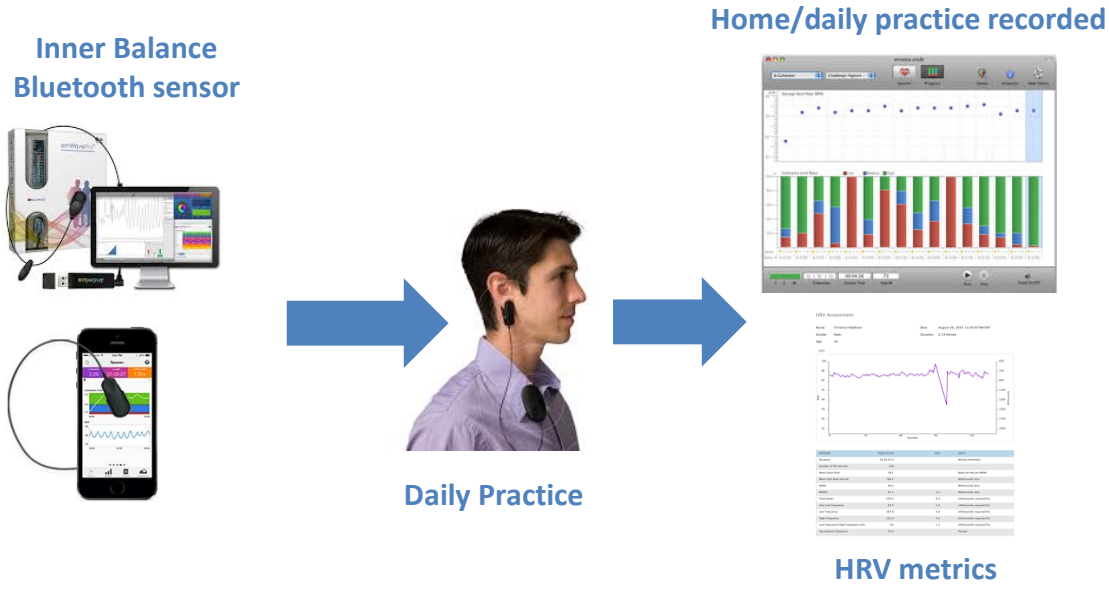
Your participation in this research is entirely voluntary. It is your choice whether you participate or not. If you choose not to participate, it will have no consequences for your current employment.

You may change your mind later and withdraw from the study at any stage.

***Check-in questions for participant**: Do you have any questions?*

Technology used during the study

Inner Balance Bluetooth sensors by HeartMath will be used measure practice adherence and record daily heart rate variability (HRV) metrics. All data will be semi-anonymised and gathered for analysis at the end of the 8-week programme, in accordance with current GDPR guidelines.



You will be provided with a semi-anonymised coded HeartMath account, linked to your Inner Balance device. HRV and practice adherence data will be stored (semi-anonymised) in a password-protected account in the HeartMath cloud system.

Note – semi-anonymised means that only the data controller will access to your identity and personal data.

The type of questions that participants are likely to be asked in the study group, and in the relevant questionnaires.

Programme session discussions
Programme session discussions will centre on prescribed texts and your feelings and thoughts on your ABT practice. These discussions will be guided by an experienced meditator, Dr Padraic Dunne.

You do not have to share any knowledge that you are not comfortable sharing. You will not be asked to discuss any issues unrelated to ABT practice.

The sessions will take place at the Clinical Research Facility, St. James's Hospital.

Questionnaires, biological sampling and technology used in the study

You will be asked to fill out questionnaires on your personal wellbeing, which will be provided and collected by a researcher on the research team. Furthermore, blood samples will be obtained with your consent before and after the 8-week programme. Participants will be asked to use an Inner Balance Bluetooth sensor by HeartMath for the 8 weeks of the programme duration.

Questionnaires:

DASS Stress Scale (21 question inventory);
The DASS was devised in 1995 and represents a widely used, valid and reproducible screening tool to assess symptoms of stress in different community settings, including hospitals. It comprises three sub-scales: (a) the depression sub-scale which measures hopelessness, low self-esteem, and low positive affect; (b) the anxiety scale which assesses autonomic arousal, musculo-skeletal symptoms, situational anxiety and subjective experience of anxious arousal; and (c) the stress scale which assesses tension, agitation, and negative affect.

Five Facet Mindfulness Questionnaire (FFMQ) (39 question inventory)[5];
Devised by R. Baer and colleagues in 2006, the FFMQ is a reliable and validated 39 point questionnaire that has been applied to test the principle mindfulness skills acquired by participants of mindfulness-based ABT programmes. The five subsets examined by this survey instrument include: observing (watching internal experiences both physical and mental), describing (labelling internal experiences), acting with awareness, non-judgement and non-reactivity (to internal and external stimuli). Although this study will not apply mindfulness-based techniques, the core of mindfulness is ABT; therefore, we expect the FFMQ responses to change in individuals randomised to the mantra ABT group

PERMA (Positive Emotion, Engagement, Relationships, Meaning, and Accomplishment) – Profiler.
This is a general measure, developed for adults, which measures flourishing in terms of 5 domains: positive emotion, engagement, relationships, meaning, and accomplishment.

Biological sampling

Two blood samples will be taken (plasma and serum) for analysis of blood markers related to urticaria. Samples will be stored at -80^{o}C by an immunologist in a monitored freezer at the St. James' Hospital Pathology Laboratory or at the Clinical Research Facility, also based at St. James' Hospital.

Check-in questions for participant*: If you decide to take part in the study, do you know how much time will the interview take? Where will it take place? Do you know how much time each session will take? If you agree to take part, do you know that you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Do you have any more questions?*

Benefits

We expect that those who participate in this programme will feel relief from Urticaria symptoms and learn to manage stress more effectively. By taking part in the study, you be contributing to the development of a new programme designed to improve the wellbeing of patients with Urticaria.

Risks

There is a possibility that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion or questionnaire if you feel the question(s) are too personal or if talking about them makes you uncomfortable. ***We advise participants who may have concerns about their physical or mental health in relation to participation in the trial, to contact their health care practitioner for advice.***

Confidentiality

All participants will be instructed on keeping anything that comes up in the group discussions as strictly confidential. Similarly, we will not be sharing information about you to anyone outside of the research team. All information collected during this research project will be collected anonymously and kept private. Any information about you will be stored under a unique number instead of your name. Only the data controller will know what your number is and that information will be stored on encrypted computers.

Furthermore, any volunteer who experiences psychological distress as a result of the ABT programme will be referred to the clinical director of the study (Dr Niall Conlon).

Sharing the Results

The knowledge that we get from this research will be shared with you and your group before it is made available to the public in the form of presentations to health professionals and in scientific conferences or in scientific publications. Each participant will receive a summary of the results.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your current employment in any way. You may stop participating in the programme at any time that you wish. As all data will be anonymised, once you hand in your questionnaires or provide blood samples, it will be impossible to withdraw the data from analysis.

Who to Contact

Anne Sloan Clinical Nurse Specialist in Immunology on 0876862782 / 014162928
This proposal has been reviewed and approved by the Tallaght Hospital / St. James's Hospital Joint Research Ethics Committee (REC), whose task it is to make sure that research

participants are protected from harm. If you wish to find out more about the Tallaght Hospital / St. James's Hospital Joint Research Ethics Committee (REC) please see the following website: **http://www.amnch.ie/About-Us/Research-Ethics-Committee/**

Check-in questions for participant*: Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the ethics committee who have approved the study? You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?*

Part II: Certificate of Consent

I have been invited to participate in research investigating the effect of a mantra ABT programme on the wellbeing of patients with urticaria.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it. These questions have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant and, to the best of my ability, made sure that the participant understands the purpose of the study, participation requirements, risks, rights, and issues of confidentiality.

I confirm that the participant was given an opportunity to ask questions about the study and that all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year