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Mantra meditation to improve wellbeing in urticaria patients attending St James's Hospital

Submission date	Recruitment status	[_] Prospectively registered
09/09/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/09/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/08/2021	Skin and Connective Tissue Diseases	

Plain English summary of protocol

Background and study aims
Urticaria and angioedema are terms used to describe hives and swellings, which can be very distressing, recurrent and sometimes difficult to treat. While the exact cause of this condition is not known, it is known 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 the body responds to stress, mast cell activity and therefore hives and swelling can be limited. There is growing evidence to support the potential benefits of attention based training (ABT) on psychological and physiological wellbeing. Therefore, the aim of this study is to find out whether ABT could help to improve the wellbeing of urticaria patients attending St James's' hospital. Based on the results of the study, the researchers hope to develop an ABT programme that can be used to help reduce stress and improve wellbeing among urticaria patients throughout Ireland.

Who can participate?
Patients aged over 18 with chronic spontaneous urticaria that is poorly controlled

What does the study involve?
The study involves a preliminary appointment with a researcher where participants fill out questionnaires and have a blood sample taken. They will then attend eight sessions of attention based training. These sessions aim to teach skills in meditation. It is hoped that these skills might improve symptoms of urticaria. Participants then attend a follow-up appointment with a researcher where they again complete questionnaires and have a blood sample taken.

What are the possible benefits and risks of participating?
The researchers do not anticipate any risks from taking part. There will be no direct benefit from taking part although it is hoped that participants might find the skills taught in the programme useful and informative.

Where is the study run from?
St James's Hospital (Ireland)

When is the study starting and how long is it expected to run for?
September 2017 to January 2022

Who is funding the study?
St James's Hospital (Ireland)

Who is the main contact?
Dr Katie Ridge
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Attention-based training programme in the management of chronic spontaneous urticaria and angioedema

Acronym
ABT in the management of CSUA

Study objectives
It is hypothesised that an attention-based training programme based on meditation will reduce individual perceived symptoms in patients with chronic spontaneous urticaria and angioedema.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/01/2018, SJH/AMNCH Research Ethics Committee Secretariat (Tallaght University Hospital/St James's Hospital Joint Research Ethics Committee, Tallaght University Hospital, Tallaght, Dublin 24, D24 NR0A, Ireland; +353 (0)1 414 2199; ResearchEthics@tuh.ie/ Sadhbh.ONeill@tuh.ie), REC ref: 2019-11 List 41 (8), Previous REC Ref: 2018-01 Chairman's Action (5)

Study design
Prospective single-arm single-site study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic spontaneous urticaria and angioedema

Interventions
This study has one arm, which is attendance at an attention-based training programme based on meditation for patients with chronic spontaneous urticaria. The attention-based training programme consists of 8 x 90-minute sessions that are delivered by a qualified psychologist.

Intervention Type
Behavioural

Primary outcome(s)
1. Barriers to implementation of the intervention identified through convergent interviewing techniques at baseline and 1-week post completion of the intervention
2. Recruitment and retention of participants measured by recording participant attendance throughout the intervention over an 8-week period
3. Adherence to daily practice using individual biofeedback tools (HeartMath software) throughout the intervention over an 8- week period
4. Feasibility of collecting outcome assessment data measured by assessing the return of data from participants at baseline and 1-week post completion of the intervention
5. Qualitative assessment of participant experiences of the programme collected via interview 1-week post completion of the intervention

Key secondary outcome(s))
1. Perceived individual symptoms measured using the urticaria control test (UCT) at baseline, 1 week before and 1 week after completion of the ABT programme
2. Depression, anxiety and stress measured using the depression-anxiety-stress score (DASS) at baseline and post 8-week ABT programme
3. Bio-psycho-social health measured using the PERMA-profiler at baseline, 1 week before and 1

week after completion of the ABT programme
4. Traits associated with sustained meditation practice (attention, observational skills, non-reactivity and non-judgemental skills) measured using the five-facet mindfulness questionnaire (FFMQ) at baseline, 1 week before and 1 week after completion of the ABT programme

Completion date
01/01/2022

Eligibility

Key inclusion criteria
1. Adults with a clinical diagnosis of chronic spontaneous urticaria (CSU) with or without angioedema
2. Symptoms on at least one day per week
3. Urticaria control test score of <12 indicative of poorly controlled symptoms

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
12

Key exclusion criteria
1. Patients who had started an anti-depressant medication in the past 3 months
2. Diagnosis of an Axis I mental health disorder

Date of first enrolment
01/01/2020

Date of final enrolment
01/01/2021

Locations

Countries of recruitment
Ireland

Study participating centre

St. James's Hospital
James's Street
Dublin
Ireland
D08 X4RX

Sponsor information

Organisation
St. James's Hospital

ROR
https://ror.org/04c6bry31

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/05/2021	13/08/2021	Yes	No
Participant information sheet	version V1.0	07/11/2017	08/10/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes