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Is hydrogen water intervention and cognitive-behavioral group therapy effective in women suffering from panic attacks?

Submission date
06/09/2021

Recruitment status
No longer recruiting

Registration date
10/09/2021

Overall study status
Completed

Last Edited
16/06/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Women are more likely than men to suffer from an anxiety disorder (AD), having a higher risk of developing depression in the future, along with other physical illnesses. In recent years, research has emerged about the relationship between the microbiome-gut-brain axis (MGBA) and the inflammatory response, as a common mechanism of AD and chronic inflammatory diseases. The 'gut–microbiota–brain axis' refers to the network of connections involving multiple biological systems that allows bidirectional communication between gut bacteria and the brain.
Chronic stress triggers physiological and behavioral responses that impair mental and gastrointestinal health, affecting the correct communication of the MGBA. The overactivation of the endocrine system and the release of high levels of cortisol, could change the state of the intestinal microbiota and trigger an inflammatory response affecting anxiety behavior and a depressed mood. Today, hydrogen-rich water has become a therapeutic strategy to prevent and intervene in stress-related disorders; due to its antioxidant and anti-inflammatory properties without causing adverse side effects. To study the inflammatory hypothesis in ADs, women who suffer panic attacks are selected because they constitute a significant chronic stressor.
The aim of this study is to test the inflammatory hypothesis and compare the effects of implementing a hydrogen-rich drink in women receiving group psychological treatment for panic disorder.

Who can participate?
Women over 18 years of age who are diagnosed with a panic disorder and who are willing to drink hydrogen-rich water and attend psychological treatment for three months.

What does the study involve?
Participants will be randomly assigned to receive either psychological treatment and placebo or psychological treatment and hydrogen-rich water. They must attend the referral center once a week to receive psychological treatment and do the corresponding homework. And drink a liter and a half of hydrogen-rich water until the group therapy is over. All participants must do an individual interview lasting one hour and complete a battery of questionnaires before and after treatment.

What are the possible benefits and risks of participating?
Participants can benefit from receiving evidence-based psychological treatment to reduce anxiety levels and improve quality of life. In addition, drinking hydrogen-rich water helps neutralize free radicals and reduce inflammation, helping to improve physical health safely and without side effects. The research does not imply any risk for participating

Where is the study run from?
Catholic University of Murcia UCAM (Spain)

When is the study starting and how long is it expected to run for?
November 2017 to October 2020

Who is funding the study?
The researcher and Osmostar Soriano S.L. Elche (Alicante) Spain

Who is the main contact?
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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
Possible inflammatory response in anxiety disorders. Effects of psychological treatment and hydrogen water in women with panic disorder from the perspective of the gut-brain-microbiota axis

Acronym
ADMGBA

Study objectives
The intervention aimed at the inflammatory response with a cognitive-behavioral psychological treatment and the administration of a hydrogen-rich water drink, reduce anxiety and depression symptoms more effectively, compared to those that only receive psychological intervention in a clinical sample of women with panic disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/04/2018, Ethics Committee of the Universidad Católica de Murcia UCAM (Campus de los Jerónimos nº 135, Guadalupe 30107, Murcia, Spain; (+34) 968278800; info@ucam.edu), ref: CE041807

Study design
Multicenter interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Anxiety disorder and associated inflammatory response in women with anxiety attacks from the perspective of the gut-brain-microbiota axis

Interventions
The present study consists of a clinical sample of women with panic disorder, drawn from a total of five psychological treatment groups. At each initiation of group therapy, participants who meet the selection criteria are randomly assigned to the control group and the treatment group. Measuring the variables at the beginning and at the end of each treatment group (pretest-posttest).
1. The treatment group receives cognitive-behavioral psychological treatment and a hydrogen-rich drink.
2. The control group receives psychological treatment and placebo in a presentation with similar characteristics.
The intervention time of each treatment group is approximately three months. Group therapy is made up of 12 weekly sessions of 90 minutes duration. And hydrogen-rich water is administered orally by drinking a liter and a half daily, distributed throughout the day (fasting, midday, before lunch, mid-afternoon, before dinner and before sleeping) at 250 ml.

Intervention Type
Mixed

Primary outcome(s)
Measured before and after treatment:
1. Anxiety is measured with the State-Trait Anxiety Inventory (STAI).
2. Stress assessment is measured with the Perceived Stress Scale (PSS).
3. Depression is measured with the Depression Inventory (Beck-II).
4. Gastrointestinal symptoms are measured with the Gastrointestinal Symptom Rating Scale (GSRS).
5. Health-related quality of life is measured with the Health Questionnaire (SF-36v2).
6. The inflammatory response is measured with the analysis of cortisol in saliva and the analysis of proinflammatory cytokines IL-1β, IL-6, IL-8, IL-12, IFN-γ, and TNF-α.

Key secondary outcome(s))
Measured at the beginning of the study:
1. Registration of variables through an interview: general sociodemographic data, data on habits and lifestyle, data on the history of physical illnesses, data on the consumption of antibiotics, psychotropic drugs and drugs for medical conditions, data on the type of diet.
2. Record of variables for the collection of biological samples: time of awakening, hours of sleep, spontaneous awakening or with an alarm clock, follicular phase, exact time of taking the samples.

Completion date
26/10/2020

Eligibility

Key inclusion criteria
1. Participants have to meet the diagnostic criteria for panic disorder according to ICD-10 (F41.0)
2. Over 18 years old and under 65 years old
3. Attend a minimum of eight group sessions
4. Cannot have another mental disorder

5. Consume a minimum of a liter and a half of water daily
6. Cannot consume glucocorticoids or any type of drug that affects the immune and endocrine system
7. They cannot have night work hours that affect the circadian rhythm
8. Not have serious diseases such as cancers, heart disease, digestive system, viral infections
9. Not have oral diseases, inflammations or injuries that could cause oral bleeding.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
31

Key exclusion criteria
1. Women diagnosed with a gastrointestinal disease
2. Women receiving psychological treatment
3. Women with anxiety scores lower than the clinical mean
4. Drug or alcohol abuse
5. Women with severe psychiatric disorder

Date of first enrolment
14/09/2018

Date of final enrolment
17/07/2019

Locations

Countries of recruitment
Spain

Study participating centre
Mental Health Center of Caravaca de la Cruz (area IV-Northwest)
C/ Junquico, s/n
Caravaca de la cruz
Spain
30400

Study participating centre
Mula Mental Health Center (I-Murcia Oeste area)
Avd. Juan Viñegla, s/n
Mula
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Sponsor information

Organisation
Universidad Católica San Antonio de Murcia

ROR
https://ror.org/05b1rsv17

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Hydrogen OSMOSTAR SORIANO S.L.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. psicosaludanabelen@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article		30/05/2022	16/06/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes