Effect of Probiotic Supplementation on Cognitive Function and Gut-Brain Axis Modulation in Females with Mild Depression.

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Informed Consent Form for Participation in Research

Study Title

Effect of Probiotic Supplementation on Cognitive Function and Gut-Brain Axis Modulation in Females with Mild Depression

Student Name

Marina Shaker Riad Girgis

Researchers

- Prof. Marwa Mostafa Saeed, Professor of Family Medicine, Cairo University
- Prof. Eman El-Sayed Sedeeq, Assistant Professor of Family Medicine, Cairo University
- Prof. Ola Osama Khalaf, Assistant Professor of Psychiatry and Neurology, Cairo University
- Dr. Rehab Hanafy Mahmoud, Lecturer of Family Medicine, Cairo University

Purpose of the Study

To evaluate the effect of taking probiotic supplementation for 12 weeks on improving cognitive function, depressive symptoms, and gut-brain axis-related parameters (such as inflammation and autonomic nervous system function) in Egyptian women experiencing mild depressive symptoms.

Procedures / Tasks Required from the Participant

- Answering questionnaires related to mood, socio-economic data, and cognitive function.
- Measuring weight, height, and body mass index.
- Measuring heart rate variability using a smartphone application (photoplethysmography) for 5 minutes, using the Welltory app.

Heart rate variability will be measured using the phone camera and a sensing technology that detects changes in blood flow through the finger. The participant will be asked to sit comfortably for 10 minutes before the measurement, after which the measurement will be taken for 5 minutes inside a quiet room at a suitable temperature. This procedure causes no pain and involves no surgical intervention; it is used only to assess autonomic nervous system response.

The data and recordings resulting from this measurement will be stored under a code number without using the participant's name, maintaining full confidentiality. Only the researchers conducting the study will have access to them, and they will be used solely for scientific research purposes, then disposed of or deleted after the study is completed and the results have been analyzed, in accordance with the applicable scientific research regulations and rules.

- Drawing a venous blood sample (after 8–12 hours of fasting) to measure of high sensitivity C-reactive protein(hs-CRP)
- Taking one capsule daily (either probiotic or placebo) with breakfast for 12 weeks.

Time Required for Participation and Number of Required Visits per Patient

Approximately twenty minutes to complete the questionnaire forms, for all participating women, at the initial study visit. A further visit will take place at the end of week 12, in addition to brief monthly follow-up visits to collect the capsules.

Risks

- Minor risks related to blood sample collection.
- Possibility of rare allergic reactions.
- Slight discomfort or time commitment during interviews.

Benefits to the Participant and the Community

- Contributing to the development of innovative and effective therapeutic strategies that target both the psychological and cognitive aspects of depression together.
- Improving gut bacterial balance and enhancing nervous system function.
- The results will also contribute to developing new and safer treatment methods for depression that do not rely on chemical medications, benefiting the scientific and health community.

Protection of Participant Privacy and Data Confidentiality: Definitely

Data is kept solely by those conducting the study and may not be accessed by others. Files are kept in a secure location and used only for scientific purposes. Only the research team will have access to the data, through the use of codes assigned to the forms instead of recording the participant's full name. Sessions are also conducted in closed, secure rooms, and communication with each participant is handled in the manner most appropriate for her, without informing any other party.

Voluntary Participation: Definitely

Women are given the right to freely accept or decline participation without needing to provide any reason.

Cost of Patient Participation in the Research None.

The patient bears no costs.

Compensation

No compensation is provided to study participants.

Right to Withdraw

The participant has the right to withdraw from the research at any time, without giving any reason.

Available Alternatives if the Patient Does Not Wish to Participate

The patient will continue to receive full healthcare at the hospital without any effect on any of her rights. (Signing this consent form does not waive any of your legal rights in any way, nor does it exempt the researchers, sponsor, or participating institution from their professional or legal responsibilities.)

Contact Information

- To learn more about this study, you may contact Dr. Marina Shaker Riad Girgis, tel: 01287128004
- Or contact Dr. Rehab Hanafy Mahmoud, tel: 01015772989
- In case of an emergency outside official working hours, contact Dr. Rehab Hanafy Mahmoud, tel: 01015772989
- In case of any health problems resulting from participation in the study, you may contact Dr. Marina Shaker Riad Girgis, tel: 01287128004, or go to the Department of Family Medicine, Kasr Al-Ainy, Cairo University.
- In case of a complaint, please contact the Research Ethics Committee office, telephone: 01222166937

Consent

If you agree to participate in this study, please indicate in the appropriate place below:

All the information contained in this agreement has been explained to me:

_____

I have read and understood the information contained in this agreement:

_____

Participant's name: _____ Participant number: _____

Signature: _____

Name of the person responsible for the participant (guardian):

_____

Signature: _____

Witness to the consent process:

_____

Signature: _____

Signature of the study official: _____

Date: _____

Valid from: __ / __ / 20__ to __ / __ / 20__

One copy is given to the participant; the original is kept with the researcher in the participant's file.