PARTICIPANT INFORMATION SHEET

STUDY TITLE: DEM-BIOTA. Dementia and microbiota composition: the microbiota in dementia, is it possible to reverse dementia symptoms by reversing the microbiota composition?

PRINCIPAL INVESTIGATOR: Dr. Margarita Torrente Torné, Department of Psychology, 977558176, margarita.torrente@urv.cat

CENTRE: Department of Psychology, Faculty of Educational Sciences and Psychology, Rovira i Virgili University, Tarragona.

INTRODUCTION:
We would like to provide you with information about a research study that you are invited to participate in. This study has been approved by the Ethics Committee for Research with Medicines at our center (although in this study, you will not be asked to consume any medication).

Our intention is simply to provide you with accurate and sufficient information so that you can evaluate and judge whether or not you want to participate in this study. Therefore, please read this information sheet carefully and we will clarify any doubts you may have after the explanation. Additionally, you may consult with anyone you consider appropriate.

VOLUNTARY PARTICIPATION:
You should know that your participation in this study is voluntary and that you can decide not to participate or change your decision and withdraw consent at any time. Whether you decide to participate or not, your relationship with your doctor will not be affected, and there will be no harm to your treatment.

GENERAL DESCRIPTION OF THE STUDY:
The main objective of DEM-BIOTA is to explore the possible differences between dementias regarding the composition of intestinal microbiota and to characterize them in relation to neurocognitive and neuropsychiatric symptoms, as well as the functionality of the patient (level of dependence). The microbiota describes the set of different microorganisms that live in our body. In this study, we will analyze only your intestinal microbiota, through a stool sample. The kit for collecting the sample will be provided by your doctor at the time you sign the consent form to participate. The use of this stool analysis kit does not pose any risk to your health. If you sign the informed consent after reading this document, you agree that your doctor will provide your contact information and relevant medical history data for this study to the research team so that a team member will contact you later to schedule a comprehensive evaluation of your neurocognitive, neuropsychiatric, and functional levels. This evaluation will specifically include:

- Identification of the patient, gender, age, level of education, years of schooling, weight and height, and diagnosis (other sociodemographic data) and review of inclusion/exclusion criteria.
- Medications, diseases (diabetes, cholesterol, hypertension, etc.).
- Tests / scales:
    - MEDLIFE (*Mediterranean lifestyle index interview*), (Sotos-Prieto et al, 2015), which provides information on how the patient follows the Mediterranean diet and lifestyle habits.
    - CSV (Life Events Questionnaire, adapted from the Predimed-Plus study), (Soldevila-Domenech et al, 2021), which provides information on successfully overcome stressful events that could affect and modify the main variables under study.
    - Cognitive screening tests/scales: MMSE, GDS-FAST, CDR, MMSE (Folstein et al, 1975), GDS-FAST (Reisberg, 1982, 1988), CDR (*Clinical Dementia Rating*) (Hughes, 1982).
    - Reserve cognitive scale (León-Estrada et al, 2017).
    - ADLs (Barcelona-2 Test), (Peña-Casanova, 2019).
    - Anxiety and Depression Scale (Goldberg et al, 1988).
    - Neuropsychiatric Symptoms (Barcelona-2 Test), (Peña-Casanova, 2019).

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- MIS (Memory Impairment Screen) (Buschke et al, 1999).
- Categorical Recall Test (Barcelona-2 Test), (Peña-Casanova, 2019).
- Orientation in Time (Barcelona-2 Test), (Peña-Casanova, 2019).
- FCSRT (*Free and Cue Selective Reminding Test*) (Buschke, 1984).
- TMT A y B (Reitan, 1958).
- Boston Abbreviated Naming Test (Kaplan et al, 2001).
- Verbal Span (Barcelona-2 Test), (Peña-Casanova, 2019).
- Clock Test (Shulman, 2000).
- Orientation in Time and Person (Barcelona-2 Test), (Peña-Casanova, 2019).
- FAB (*Frontal Assessment Battery*), (Dubois et al, 2000).
- Simple and semicomplex constructive praxis (Barcelona-2 Test), (Peña-Casanova, 2019)

BENEFITS AND RISKS

There is no expected personal health benefit for participating in this study. The results of this study will benefit society as they will help advance the knowledge of the variables that may

contribute to a poor prognosis in dementia and potential treatments. There are no risks to your health from participating in this study.

ALTERNATIVE TREATMENTS:
No specific treatment or clinical intervention is used in this study.

CONFIDENTIALITY AND DATA PROTECTION
In accordance with the current legislation on data protection applicable to the Rovira i Virgili University (URV) and published in the "Applicable Legislation" section of the "Personal Data Protection" space of the Electronic Headquarters (https://seuelectronica.urv.cat/rgpd/), the following information is made available to interested parties:

a) Who is responsible for the processing of your data?

Identification	Rovira i Virgili University CIF: Q9350003A
Postal Address	Calle Escorxador, s/n 43003 Tarragona
Contact details of the Data Protection Officers	Data Protection Officers of URV Email: dpd@urv.cat

b) What personal data do we process and for what purpose?
The personal data provided (informative, personal characteristics, and special category data) are processed in order to participate in the DEM-BIOTA study "Dementia and microbiota composition: microbiota in dementia, is it possible to reverse dementia symptoms by reversing microbiota composition?"
c) Who will your data be communicated to?
In the context of the aforementioned processing, your data will not be disclosed to third parties unless there is a legal obligation.
d) What is the legitimacy for the processing of your data?
The legitimacy of this processing is based on the consent expressed by the interested party by completing and signing the informed consent document.
e) What security measures do we apply in the processing of your data?
The University is responsible for applying the security measures and the rest of the obligations derived from the personal data protection legislation in accordance with the National Security Scheme, Royal Decree 3/2010. In this regard, the Rovira i Virgili University has been provided with a Security Policy that can be consulted in the "Legislation and Regulations" section of the University's website, within "Own Regulations" and "Other Regulations", http://www.urv.cat/ca/universitat/normatives/altresnormes/. Specifically, the data collected for the study will be treated in a pseudonymized manner, that is, they will be identified with a code that will be recorded in the informed consent form, which will be properly safeguarded so that only authorized personnel can know the identity of the person to whom the data belongs. Additionally, specific security measures that will be taken into account during the study are specified in the participant information sheet.
f) What are the rights of the interested parties?
The interested party will have the right to access their personal data, to request the rectification of inaccurate data, to request cancellation and deletion, to object to processing, including profiling, to limit the processing of their data until a certain date and to portability of their data in electronic format. You may exercise your rights of access, rectification, cancellation, opposition, limitation, and portability by means of a written communication, detailing the motivation of the request, addressed to the General Registry (C/Escorxador, s/n, 43003 Tarragona) or by submitting it to the General Registry of the University, in person or electronically, as indicated in https://seuelectronica.urv.cat/registre.html. Likewise, we inform you that you have the right to lodge a complaint with the Catalan Data Protection Authority through the mechanism established. You can consult more information at https://apdcat.gencat.cat/ca/inici. Finally, we inform you that you may request information related to the protection of personal data via email to our data protection delegates at dpd@urv.cat.
g) How long will we keep your data?

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The University will process the personal data provided until the consent is revoked or will delete them after 6 years.

SAMPLING.
As part of this project approved by the Ethics Committee for Research with Medicines, you will be asked to provide a stool sample for research purposes, in order to increase knowledge about the pathology or process under study and develop new strategies and therapies applicable to patients.

STOOL: Collecting the stool sample spontaneously poses no risk to you.

The samples obtained will be stored at the Faculty of Medicine and Health Sciences (FMCS) of the URV, and the person responsible for them will be Dr. Margarita Torrente Torné, belonging to the Department of Psychology and the TecnaTox Research Center.

The samples will be stored at -80ºC in the FMCS until they are analyzed by an external specialized laboratory with the objective of responding to the study's objectives.

Once the research is completed, if there are any remaining samples, they will be destroyed.

I have received this Information Sheet

Date:
Name:
Signature:

INFORMED CONSENT

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PRINCIPAL INVESTIGATOR: Dr. Margarita Torrente Torné, Department of Psychology, 977558176, margarita.torrente@urv.cat

CENTRE: Department of Psychology, Faculty of Educational Sciences and Psychology, Rovira i Virgili University, Tarragona.

Me (name and surname)
.....

- ✓ I have read the information sheet of which I have been given a copy. I have received information about the characteristics of the study, I understand the risks and benefits involved, that my participation is voluntary, and that I can withdraw or ask for the withdrawal of my data and/or samples whenever I wish, without having to give explanations and without this affecting my medical care.
  YES ☐ NO ☐
- ✓ I understand my participation according to the information sheet.
  YES ☐ NO ☐
- ✓ I have been able to ask questions about the study.
  YES ☐ NO ☐
- ✓ I freely agree to participate in the study.
  YES ☐ NO ☐
- ✓ I consent to the access and use of my data under the conditions detailed in the information sheet.
  YES ☐ NO ☐

	Name and Surname	Date	Signature
Patient			
Legal representative			
Relationship with the patient:			
Inform			

PERSONAL DATA PROTECTION INFORMATION	
Responsible	The responsible for the treatment of your personal data is the Rovira i Virgili University with CIF Q9350003A and with fiscal address at Carrer del Escorxador, s/n, 43003 Tarragona.
Purpose	Participate in the DEM-BIOTA study "Dementia and microbiota composition: the microbiota in dementia, is it possible to reverse dementia symptoms by reversing the microbiota composition?".
Rights	You may exercise your rights of access, rectification, deletion, portability, limitation or opposition to processing by writing to the General Registry of the URV at the same address as your tax domicile or by presenting them at the General Registry of the University, in person or online, as indicated at http://seuelectronica.urv.cat/registre.html.
Additional information	You can consult additional information about this processing of personal data called DEM-BIOTA study and your rights in the Register of Processing Activities of the URV published in http://seuelectronica.urv.cat/rgpd where you can also consult the Privacy Policy of the URV. Additionally, you can direct any queries about personal data protection to our data protection delegates at the e-mail address dpd@urv.cat.