INFORMED CONSENT FORM

NEUROPSYCHOLOGICAL AND ELECTROPHYSIOLOGICAL EFFECTS OF DANCE THERAPY WITH PEOPLE WITH SEVERE MENTAL DISORDER

NCT ID not yet assigned

ASCATEC
15/12/2023

PARTICIPANT INFORMATION SHEET

TITLE OF THE STUDY	NEUROPSYCHOLOGICAL AND ELECTROPHYSIOLOGICAL EFFECTS OF DANCE THERAPY WITH PEOPLE WITH SEVERE MENTAL DISORDER
STUDY CODE	TFM_03_DANCE
PROMOTION GIRL	Nayra Caballero Estebaranz
PRINCIPAL INVESTIGATOR	Nayra Caballero Estebaranz
CENTER	*Canarian Association of Creative Therapies (ASCATEC)*

Introduction

We would like to inform you about a research study in which you are invited to participate. The study has been approved by an Ethics Committee for Research with Medicines of the University Hospital of Getafe and by the Spanish Agency for Medicines and Health Products, in accordance with current legislation, Royal Decree 1090/2015 of 4 December and European Regulation 536/2014 of 16 April, which regulates clinical trials with medicinal products.

Our intention is that you receive correct and sufficient information so that you can decide whether or not to participate in this study. To this end, please read this information sheet carefully and we will clarify any doubts you may have. If you have any questions, please contact Dr Nayra Caballero Estebaranz. You can also consult with the people you consider appropriate.

An estimated 47 persons are expected to participate in this study.

Voluntary participation

You are invited to participate in the study because you are diagnosed with schizophrenia and comply with all the requirements for inclusion.

Please note that your participation in this study is completely voluntary and that you may decide NOT to participate. If you decide to participate, you can change your decision and withdraw your consent at any time, without this altering your relationship with your professional caregiver or harming your care in any way.

Aim of the study

The aim of this study is to evaluate the impact of a therapeutic dance therapy program on memory and executive functions in people with severe mental disorders, by means of neuropsychological tests and the recording of brain activity by means of a machine called Electroencephalogram.

Description of the study

47 persons with severe mental disorder who want to participate in the study and comply with the requirements will be selected. These people will be randomly assigned to one of the 2 groups that will be formed, an experimental group of 26 participants who will receive dance therapy and a control group of 21 participants who will continue with their usual treatment (pharmacological), but will not receive any intervention with dance therapy or any other intervention apart from the usual one.

The 26 persons who will participate in a dance therapy program will attend 20 structured sessions (2 sessions per week) in which they will work for 1 hour on memory, attention and executive functions through dance and movement, ending with 10 minutes of breathing. The 21 persons in the control group will not receive any type of intervention apart from the pharmacological treatment they usually receive.

The expected duration of the program will be 1 year between the intervention and assessment sessions and will take place at the headquarters of the Canarian Association of Creative Therapies (ASCATEC).

Activities of the study

In addition to the weekly intervention sessions you will receive, assessments will be carried out before the start of the study and at the end of the 20-session program, as well as 3 months after the end of the program in order to compare results between groups.

These assessments will allow us to evaluate your mental functions, symptoms and brain activity. The assessments to be carried out are:

- Brief Assessment of Cognition in Schizophrenia (BACS).
- Montreal Cognitive Assessment (MoCA)
- Positive and Negative Symptom Scale (PANSS)
- Electroencephalogram (EEG).

Each assessment session will last approximately 1 hour/1 hour 30 minutes.

The group that does not present any mental pathology will only be tested with the EEG tests in order to be able to compare the results between groups.

All test results will be recorded anonymously and each person will be assigned an identification number.

The sessions in which each person will have to participate according to their group are summarized below. The days and times of each session will be specified individually later.

Group	Organisation of sessions
1: dance therapy group (people with Severe Mental Disorder)	1 pre-assessment session 2 weekly 1-hour dance therapy sessions for 10 weeks (from December to February). 1 post-assessment session after 20 weeks of intervention. 1 assessment session 3 months after the end of the program.
2: non-intervention group (people with Severe Mental Disorder)	1 pre-assessment session. 1 post assessment session after 10 weeks without intervention. 1 evaluation session 3 months after the end of the program.

Risks and inconvenience of participating in the study

There are no physical risks, discomfort or inconvenience of any kind from participating in this study. If, during the course of the study, relevant information becomes known that affects the risk/benefit ratio of your participation, it will be communicated to you so that you can decide to withdraw or continue.

Regarding your obligations as a participant:

- You must attend all sessions of the study, both evaluations and activities, understanding that your participation is essential to the research objectives.
- You should report any adverse events or changes (in medication, mood, health status, etc.). However, except in case of emergency, it is important that during the study, you modify as little as possible your habits and routines as well as the medication you are taking without first consulting with the referring professional of the study.

Potential benefits

It is not expected that you will benefit directly from participating in this study. It is not known whether the dance therapy program will benefit your cognition and symptoms or any other factors that may improve your quality of life. This is precisely the reason for the research. The only benefit we seek, therefore, is to discover its usefulness and to understand how it works in order to improve the interventions we propose to our users.

Alternative treatments

This study is framed within the paradigm of creative therapies that underpin our practice and all our interventions with people with mental disorders. In this case, we will investigate dance therapy and mindfulness, but you should know that there are currently other therapies and interventions that could allow you to improve your cognitive functions and symptoms. If you wish, you can receive more information from the professional in charge of the study about possible interventions that could be interesting for you and/or currently exist to work on these specific functions.

Insurance

The Promoter of the study has an insurance policy 036352408/00000 with the company ALLIANZ SEGUROS Y REASEGUROS, S.A through the contract 140622278, which complies with current legislation (Royal Decree 1090/2015) and which will provide compensation and indemnification in the event of damage to your health or injuries that may occur in relation to your participation in the study, provided that they are not a consequence of the disease being studied or the evolution of your disease itself as a result of the ineffectiveness of the treatment.

For more information regarding this section, please consult with the principal investigator of the study in ASCATEC.

Protection of personal data

The processing, communication and transfer of the personal data of all participating subjects will comply with the provisions of Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights, and with the application of Regulation (EU) 2016/679 of the

European Parliament and of the Council of 27 April 2016 on Data Protection (GDPR), so it is important that you are aware of the following information:

- In addition to the rights you already know about (access, rectification, opposition and cancellation of data) you can also limit the processing of data that is incorrect, request a copy or transfer the data you have provided for the study to a third party. If you decide to withdraw your consent to participate in this study, no new data will be added to the database, but data already collected will be used to ensure the validity of the research and to comply with legal obligations. You also have the right to contact the Data Protection Agency if you do not agree. To exercise your rights, please contact the principal investigator of the study.
- Both the centre and the sponsor and the researcher are respectively responsible for the processing of your data and undertake to fully comply with current data protection regulations. The data collected for the study will be identified by a unique code, so that no information that could identify you is included, and only the study leader and collaborators will be able to relate this data to you and your medical history. The Research Ethics Committees, the Health Authority's representatives in matters of inspection and the personnel authorised by the sponsor will only have access to check personal data, the clinical study procedures and compliance with the standards of good clinical practice (always maintaining the confidentiality of the information).

  The researcher and the sponsor are obliged to keep the data collected for the study for at least 5 years after its finalisation. Thereafter, your personal information will only be retained by the centre and the sponsor for other scientific research purposes if you have given your consent to do so, and if permitted by applicable law and ethical requirements. The sponsor will take appropriate measures to ensure that your privacy is protected and will not allow your data to be cross-referenced with other databases that could allow your identification. The coded data may be transmitted to third parties and to other countries for the purposes of the study described or for use in scientific publications, but in no case will it contain information that can directly identify you, such as name and surname, initials, address, social security number, etc.

Other relevant information

As required by law, in order to participate you must sign and date the informed consent document to agree to comply with the study procedures that have been outlined to you.

If you wish, you will be provided with a summary of the study results. You may also receive the results of the tests performed on you on request. These results may not have

a clear clinical application or interpretation, so if you wish to have them, you should consult with the corresponding professional.

Please be aware that you may be excluded from the study if the study sponsor or investigators consider it appropriate, either for safety reasons, because of any adverse events that occur, or because they feel that you are not complying with the established procedures. In either case, you will receive an adequate explanation of the reason for your withdrawal from the study.

What treatment will I receive at the end of the clinical trial?

When your participation ends, you will be able to participate in the dance therapy activities offered by ASCATEC or any of the centre's therapies that are suitable for your situation, but the sessions will be different from those experienced during the study.

Contact in case of doubts

The principal investigator for this study at ASCATEC is Dr. Nayra Caballero Estebaranz.

The principal investigator of this study at this centre is Dr. Nayra Caballero Estebaranz.

If you have any questions during the study, please contact Dr. Nayra Caballero at investigacionascatec@gmail.com

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I, *<<first name and surname of the participant>>*,

❑ I have read the information sheet I have been given about the study.

❑ I was allowed to ask questions about the study.

❑ I have received sufficient information about the study.

❑ I have spoken to Dr. Nayra Caballero Estebaranz.

❑ I understand that my participation is voluntary.

❑ I understand that I can withdraw from the study:

- Whenever I want.
- No explanations needed.
- Without affecting the care I receive.

I will receive a signed and dated copy of this informed consent document I freely agree to participate in the study.

Participant's signature Investigator's signature

Date: / / Date: / / / /

Signature of the legal representative,
family member or de facto related person

Signature of the researcher

Date: / / /

Date: / / /

I wish to be informed of information derived from the research that may be relevant to my health:

YES

NO

Participant's signature Investigator's signature

Date: / / Date: / / / /