Participant Information and Consent Form

Title of Manuscript: The Effect of Mild Exercise While Receiving Chemotherapy on the Psychology of the Cancer Patient

NCT Number: NCT06943638

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You have been invited to take part in a research study conducted by Christina Mavrogiannopoulou, a postgraduate student in the "Oncology: from Oncogenesis to Treatment" program, which is carried out in collaboration with the Medical School of the University of Crete and the National Hellenic Research Foundation.

This form will provide you with all the necessary information to help you understand why this research is being conducted and why you have been invited to take part. It also describes what your participation will involve, what you will be asked to do, as well as any known risks, difficulties or discomfort that may arise from your participation. Please take as much time as you need to read it, think it over, and ask any questions you may have now or at any time. If you decide to participate, you will be asked to sign this form and you will receive a copy.

WHAT IS THE PURPOSE OF THE STUDY?

This study is being conducted to examine the effect of mild exercises and stretches on the psychological state of patients undergoing chemotherapy.

WHO IS PARTICIPATING IN THE STUDY? WHY HAVE I BEEN INVITED?

Patients receiving chemotherapy at the day care unit of the General Oncology Hospital "Agioi Anargyroi" are invited to participate if they are adults and do not have any of the following characteristics:

- Side effects from the treatment
- Low cognitive ability that prevents them from following simple instructions
- Hearing impairments that prevent them from participating and following simple instructions
- Inability to move independently from their position.

HOW WILL I PARTICIPATE IN THE STUDY? WHAT WILL I BE ASKED TO DO?

To participate, you will need to complete a questionnaire before and after the session to measure your anxiety levels.

After the initial questionnaire, you will perform the exercises and stretches. Specifically, for 5 minutes, you will do mild seated exercises for all major muscle groups, followed by a 1-minute break. Then, you will do mild standing exercises for another 5 minutes with another 1-minute break. Finally, you will do some easy stretches in both standing and seated positions to complete the program. In total, the session will last 15 minutes, and if at any point you feel any discomfort, you can stop immediately and rest. If after a while you feel better or wish to perform only part of the intervention, you are free to do so. If you prefer to remain lying on the bed, you may do so and the exercises will be adapted accordingly to allow you to participate.

WILL I BENEFIT FROM PARTICIPATING IN THE STUDY?

Your participation may benefit you in two main ways. It is widely known that cancer is one of the most serious diseases of our time and has a psychological burden on people. Through the exercise intervention, endorphins (happiness hormones) will be released, which may help you face the future more optimistically. Additionally, you will see, under the supervision of a specialist, that exercise can be an integral part of treatment without worsening any symptoms, but instead helping to manage some of them.

ARE THERE ANY RISKS FROM PARTICIPATING IN THE STUDY?

We believe that there are no known risks associated with this study. However, possible inconveniences may include the time required to complete the study, the potential risk of vein damage due to excessive movement, and possible nausea due to standing during the intervention. In any case, instructions will always be given at the start that if you have difficulty with the vein, you should avoid moving the corresponding arm, and during the exercises there will be specific instructions on which exercises to avoid. Finally, in the event of nausea or other symptoms, if you do not feel well at the start or during the session, you will be encouraged to perform the entire program in a seated position. Regardless of any discomfort, you may immediately stop your participation and you will receive appropriate care to alleviate any symptoms that have occurred.

AM I OBLIGED TO PARTICIPATE?

Your participation is completely voluntary. You can refuse to participate without any explanation or justification. If you agree to participate, please read this information sheet carefully, keep it, and sign the consent form. Even if you agree to participate, you can change your mind at any time and withdraw from the study without any explanation or justification and without any consequences for you. In this case, you may request that the data and information we have collected about you be deleted.

Your personal data can be deleted at any time. If you wish for your personal data or the information you have provided to be deleted, you may contact Christina Mavrogiannopoulou at: +30 6941464095.

HOW WILL MY PRIVACY BE PROTECTED?

In the context of this study, we will collect the following data about you: your age, gender, and the initials of your full name. We will collect the information you provide through the questionnaire and record it in an electronic file.

The information you provide will be anonymized so that your identity cannot be revealed to third parties. Your identity will not be disclosed in any potential publications, presentations or scientific reports resulting from this study.

Members of the research team are committed to maintaining the confidentiality of all the information you provide. Although we will ask participants not to disclose information obtained during the study, we cannot guarantee confidentiality by everyone. However, to ensure confidentiality as much as possible, we ask you to commit to a) not disclosing any information obtained in the context of this study, b) if you share or use information obtained in the context of this study, not to mention the name or any identifying details of other participants, and c) not to mention that you obtained this information through your participation in this study.

All electronic files (including all types of electronic files used, such as databases, spreadsheets, etc.) containing identifiable information will be password protected. Any computer hosting such files will also be password protected to prevent access by unauthorized users. Only members of the research team will have access to the passwords. The research files/data concerning you will be kept for one year, after which they will be destroyed.

WHO IS FUNDING THE STUDY?

The study does not receive funding from any source.

WHO HAS APPROVED THIS STUDY?

The study has been approved by the Ethics and Deontology Committee of the General Oncology Hospital of Kifisia "Agioi Anargyroi", protocol number 779/15-1-2024.

WHO CAN I CONTACT FOR MORE INFORMATION ABOUT THE STUDY?

For more information about the study, you can contact the researcher Christina Mavrogiannopoulou either by mobile: +30 6941464095 or by email: x.mavrogiannopoulou@gmail.com.

WHERE CAN I SUBMIT COMPLAINTS OR REPORT ISSUES?

For any complaints or reports regarding the conduct of the study, you may contact the Ethics and Deontology Committee of the University of Crete at ehde@uoc.gr. For any complaints regarding the management of your personal data, you may contact the Data Protection Officer of the University of Crete (dpo@uoc.gr) and in any case, the Hellenic Data Protection Authority (complaints@dpa.gr).

CONSENT STATEMENT TO PARTICIPATE IN THE STUDY

I have read and understood the information provided. I had the opportunity to ask any questions I had regarding my participation in the study. I understand that my participation is voluntary and that I may withdraw at any time without giving any reason and without any consequences. I will receive a copy of this form. I voluntarily agree to participate in this study.

Participant's signature: _____ Date: _____

Researcher's signature: _____ Date: _____