

ARONCO

« Application of Art Therapy in Oncology: Evaluation of Its Impact on Patient Symptomatology »

CLINICAL RESEARCH PROTOCOL INVOLVING HUMAN PARTICIPANTS
INTERVENTIONAL STUDY WITH MINIMAL RISK AND CONSTRAINTS
(Article L.1121-1 of the French Public Health Code)

Version 5.7.1 dated 04/27/2023
ID-RCB No.: 2018-A03304-51

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ClinicalTrials.gov Registration Number : NCT04195217

Favorable opinion issued by the Ethics Committee (CPP Sud-Est II) on November 12, 2019

Authorization from the French Data Protection Authority (CNIL): 08 March 2019, No. 2212181v0, declaration of compliance with Reference Methodology MR-001

Signature Page for an Interventional Study (RIPH 2) Protocol

This study will be conducted in accordance with the protocol and applicable laws and regulations.

The study received a favorable opinion from the Ethics Committee ("CPP Sud-Est II")
on November, 12, 2019

Titre :

Version	Date	Reason for update
1.0	01/09/2019	Initial Draft
3.2	03/22/2019	
4.0	05/07/2019	Request for Amendment by the South-East II Research Ethics Committee
5.0	07/17/2019	Methodological Support from Limoges
5.2	08/09/2019	Exchange with CEBIMER
5.5	10/01/2019	Modifications by Various Project Stakeholders
5.5.1	12/11/2019	Favorable opinion for the conduct of this study by the Research Ethics Committee
5.5.1	March 2020	Urgent Measure – Study Suspension for 3 Months. Favorable Opinion
5.6	02/10/2022	Substantial Amendment – Study Extension – Favorable Opinion
5.7	02/28/2023	Substantial Amendment – Study Extension – Request
5.7.1	04/27/2023	Substantial Amendment – Study Extension – Favorable Opinion

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RESUME

Does the research fall within the scope of the Jardé Law?	Oui	Non
Is the purpose of this research to advance biological or medical knowledge?	☐	☒
Does this research involve human participants?	☒	☐
Does this research have no consequences for participants in terms of safety and is it free of risk?	☒	☐
Does this research in no way modify the usual standard of care (frequency of visits, additional examinations, therapeutic management)?	☐	☒
Are the collection and processing of data implemented in this research compliant with the MR001 reference methodology approved by the CNIL?	☒	☐

Title: “Application of Art Therapy in Oncology: Evaluation of Patient Symptomatology”	
Acronym : ARONCO	ID-RCB : 2018-A03304-51
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JUSTIFICATION / BACKGROUND

Patients with cancer are particularly vulnerable throughout their care pathway to symptoms such as pain, fatigue, nausea, and drowsiness, which may affect their quality of life throughout the course of the disease. Art therapy remains a relatively new systematic supportive care intervention.

It is a non-pharmacological approach that may help some patients cope with the consequences of cancer beyond standard medical treatment.

The growing emphasis on supportive care in the management of patients with cancer has broadened the scope of interventions provided by oncology healthcare professionals by offering patients and their families supportive care services for pain management, nutrition, psychological support, and other needs. Numerous systematic reviews comparing multiple studies have demonstrated the effectiveness of art therapy in reducing symptoms in patients with cancer.

However, research on this topic mainly consists of observational studies, while randomized controlled trials remain scarce.

In France, only two publications — *Art Therapy Among Palliative Care Inpatients With Advanced Cancer* by Wadih Rhondali, Evelyne Lasserre, and Marilene Filbet (*Palliative Medicine*, 2012), and *Art Therapy Among Palliative Cancer Patients: Aesthetic Dimensions and Impacts on Symptoms* by Cédric Lefèvre, Mathilde Ledoux, and Marilène Filbet (*Palliative and Supportive Care*, 2016) — have highlighted the effects of art therapy in patients with cancer. However, these were observational, non-randomized studies conducted in palliative care centers.

The aim of this study is to evaluate the impact of art therapy as a supportive care intervention on symptom burden in patients with cancer undergoing treatment in a day hospital setting, compared with a group of patients who do not receive this intervention.

This interventional study design will help demonstrate the scientific relevance of art therapy within the care pathway of patients with cancer, particularly in alleviating symptoms related to the disease and its treatment, as well as the positive impact of this practice on patients' quality of life.

METHODOLOGY / STUDY DESIGN

This is a randomized, controlled, parallel-group superiority study comparing standard care alone versus standard care combined with art therapy.

Patients will be randomized into the following groups:

- **Group 1:** Art therapy as a supportive care intervention during 6 consecutive anticancer treatment sessions, with or without additional supportive care.
- **Group 2:** 6 consecutive anticancer treatment sessions, with or without additional supportive care.

Symptom assessment using the ESAS (Edmonton Symptom Assessment System) scale will be performed before and after each treatment session for every patient.

The FACT-G questionnaire assessing quality of life will be administered at the beginning and at the end of the care period for both groups (the group receiving art therapy and the group not receiving art therapy). In addition, a questionnaire evaluating the contribution of art therapy will be administered at the end of the care period to participants in the art therapy group.

INDICATIONS / TARGET POPULATION

Adults receiving care in the oncology-hematology day hospital unit of the CHP.

Does the research include protected persons?: NO

- ☐ Minors
- ☐ Pregnant women, women in labor, or breastfeeding mothers
- ☐ Persons deprived of liberty by judicial or administrative decision
- ☐ Persons receiving psychiatric care under Articles L. 3212-1 and L. 3213-1 who are not covered by the provisions of Article L. 1121-8
- ☐ Persons admitted to a health or social institution for purposes other than the research
- ☐ Adults subject to legal protection measures or unable to provide informed consent
- ☐ Persons not affiliated with, or not benefiting from, a social security scheme

Does the research include healthy volunteers?

- ☐ Yes
- ☒ No

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OBJECTIVES

Primary Objective *(and Primary Endpoint)*

The primary objective is to evaluate the impact of art therapy as a supportive care intervention on the improvement of perceived well-being following an anticancer treatment session (chemotherapy, immunotherapy, etc.), over the course of 6 sessions, in patients with cancer.

The primary endpoint is the mean, across the 6 sessions, of the difference between the ESAS score associated with the patient's perceived well-being (the "well-being" symptom assessed in the ESAS evaluation), measured before and after each treatment session.

Secondary Objectives *(and Secondary Endpoints)*

1) Evaluate the impact of art therapy as supportive care on the reduction of ESAS symptoms following an anticancer treatment session over 6 sessions

Secondary endpoint No. 1 corresponds, for each of the other symptoms assessed by the ESAS scale — pain, fatigue, nausea, depression, anxiety, drowsiness, loss of appetite, shortness of breath, or any other symptom specified by the patient — to the mean, over 6 treatment sessions, of the difference between the ESAS score associated with the symptom being studied, measured before and after each treatment session.

2) Determine the impact of 6 art therapy sessions as supportive care alongside anticancer treatment on symptom progression, assessed using the ESAS scale before the first art therapy session and after the last session (6th)

Secondary endpoint No. 2 corresponds, for each ESAS symptom, to the difference in the ESAS score associated with the symptom being studied between the first and the last treatment session (6th session).

3) Evaluate the impact of 6 art therapy sessions, as supportive care in oncology treatment, on changes in quality of life

Secondary endpoint No. 3 is the difference in the total score obtained from the FACT-G quality-of-life questionnaire between inclusion and the end of the 6 anticancer treatment sessions.

4) Evaluate patient satisfaction after 6 art therapy sessions regarding this type of therapy as supportive care in oncology treatment

Secondary endpoint No. 4 is the art therapy satisfaction questionnaire administered exclusively to patients in the art therapy group.

Eligibility Criteria (Inclusion and Exclusion Criteria)Inclusion Criteria

- Patients receiving care in the oncology-hematology day hospital with a diagnosis of cancer
- Patient's informed consent obtained
- Patients affiliated with the French social security system

Exclusion Criteria

- Minor patients
- Patients under legal protection measures (guardianship or curatorship)
- Patients with severe impairment of vital and/or cognitive functions preventing participation in or understanding of the study
- Patients whose expected care duration in the Périgueux oncology-hematology day hospital is shorter than the study follow-up period (6 sessions)
- Individuals who have previously participated in an art therapy session at any point in their life
- Patients participating in another research study

Statistical Methodology

Statistical analyses will be performed by Thomas Chourreau using Epi Info 7.1.5

The level of statistical significance for all analyses will be set at 0.05. All analyses will be conducted according to the intention-to-treat principle.

Descriptive Analysis

Quantitative variables will be described using mean $\pm$ standard deviation, or median and interquartile range, depending on the distribution of the variable (assessed using the Shapiro–Wilk test).

Qualitative variables will be described using frequencies and percentages.

A flow diagram will be presented.

Primary Analysis

The comparison of the mean differences in ESAS scores measured before and after each of the 6 anticancer treatment sessions between the two randomized groups will be performed using a generalized linear model.

The dependent variable will be the mean difference in the studied score between before and after each of the 6 treatment sessions.

The main explanatory variable of interest will be the randomization group.

The adjustment variable will be the possibility for the control group to receive other supportive care interventions (such as socio-esthetic care, osteopathy, or psychological support).

Secondary Analyses

- 1) For each of the other symptoms assessed by the ESAS scale, the comparison of the mean differences in symptom scores measured before and after each of the 6 treatment sessions between the two randomized groups will be performed using a generalized linear model.

The dependent variable will be the mean difference in the studied score between before and after each of the 6 anticancer treatment sessions.

The main explanatory variable of interest will be the randomization group, and the adjustment variable will be the other supportive care interventions.

- 2) The comparison of the difference in total FACT-G questionnaire scores between baseline (before the first session) and after the 6th anticancer treatment session between the two randomized groups will be performed using a generalized linear model.

The dependent variable will be the mean difference in the studied score between before and after the 6 treatment sessions.

The main explanatory variable of interest will be the randomization group, and the adjustment variable will be the other supportive care interventions.

- 3) The comparison of the difference in total FACT-G questionnaire scores between before the first treatment session and after the 6th treatment session according to the randomization groups will be performed using a generalized linear model.

The dependent variable will be the difference in the studied score between the first and the last session.

The main explanatory variable of interest will be the randomization group, and the adjustment variable will be the other supportive care interventions.

- 4) Responses to the art therapy satisfaction questionnaire completed by patients in the art therapy group will be described according to the descriptive analysis methods defined above.

Planned Number of Patients (including sample size calculation, if applicable)

Based on the hypothesis of a 40% increase in well-being on the ESAS scale in the experimental group compared with the control group, with a mean score difference of 2.904 points $\pm$ 1.82 in the group receiving art therapy, a statistical power of 80%, and a two-sided alpha risk of 5%, a total of 43 patients per group will be required, corresponding to 86 subjects to be included in this study.

The sample size calculation was performed using the epiR package. 0.9-96

Study Duration

- Duration of the inclusion period: 60 months
- Duration of participation for each subject: during 6 consecutive anticancer treatment sessions, corresponding to approximately 4 to 6 months of participation
- Total study duration: 66 to 68 months

Description of the Research Site

This is a single-center study conducted in the oncology-hematology day hospital unit of the Centre Hospitalier de Périgueux, open Monday through Friday from 9:00 a.m. to 6:00 p.m.

Expected Outcomes

The aim of this study is to demonstrate the added value of art therapy in the comprehensive management of patients treated in an oncology-hematology day hospital setting.

We expect to observe a significant difference between the group receiving art therapy as supportive care alongside anticancer treatment and the group not receiving art therapy with regard to:

- The progression of symptom reduction before and after each treatment session, as well as between the first and the last anticancer treatment session
- Improvement in quality of life during the course of care
-

We also expect patients receiving art therapy as supportive care to report a high level of satisfaction with this intervention.

Finally, we hope that our results will confirm that art therapy reduces symptoms and improves the quality of life of patients with cancer, whether or not they also receive other supportive care interventions during anticancer treatment. A randomized study conducted in France would provide strong evidence to support the promotion of art therapy in healthcare settings.

LIST OF ABBREVIATIONS

Abbreviation

AMM	Marketing Authorization
ANSM	French National Agency for the Safety of Medicines and Health Products
ARC	Clinical Research Associate
CCTIRS	Advisory Committee on Information Processing in Health Research
CEREES	Expert Committee for Research, Studies and Evaluations in the Health Field
CHP	Périgueux Hospital Center
CIP	Implantable Port
CNIL	French Data Protection Authority
CPP	Committee for the Protection of Persons
CRF	Case Report Form
EI	Adverse Event
EIG	Serious Adverse Event
ESAS	Edmonton Symptom Assessment System: self-administered well-being questionnaire
FACT-G	Functional Assessment of Cancer Therapy – General: self-administered well-being questionnaire in oncology
HdJ	Day Hospital
IDE	State-Registered Nurse
MR	Reference Methodology
QdV	Quality of Life Questionnaire
TEC	Clinical Research Technician

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1.1. GENERAL INFORMATION

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2. SCIENTIFIC RATIONALE

2.1. Current State of Knowledge – Rationale

The numbers in parentheses correspond to the references listed at the end of the protocol.

Cancer management has significantly improved in recent years owing to advances in fundamental research, diagnostic technologies, and the development of new treatments. These developments have broadened the scope of interventions available to healthcare professionals in oncology, enabling the provision of supportive care to patients and their families (1).

Cancer, as well as the medical treatments associated with it, is experienced as a source of intense emotional stress. Prolonged feelings of insecurity and anxiety may negatively affect immune defenses. In the context of cancer, anxiety compounds the effects of the disease itself and may further complicate its progression (2). Pain, fatigue, anxiety, and other symptoms are common among patients with cancer (6)(13). In seeking relief, an increasing number of patients are turning to complementary and alternative therapies, reflecting the growing need for comprehensive management of cancer-related symptoms. These complementary therapies have been shown to reduce symptoms, improve quality of life, and enhance patients' ability to cope with distress (5).

Over the past 20 years, art therapy has been adopted as a complementary therapy by cancer centers and rehabilitation facilities worldwide. Several studies have provided preliminary evidence supporting the effectiveness of art therapy in reducing a broad spectrum of symptoms in diverse populations of hospitalized

cancer patients (7). Systematic reviews have explored art therapy techniques that may contribute to cancer care in adults, particularly in the management and relief of symptoms (11).

Art therapy refers to the therapeutic and humanitarian use of artistic expression. Its purpose is to address disorders related to expression, interpersonal relationships, and communication.

Art therapy is considered a form of supportive care. Supportive care addresses needs that may arise during the course of illness and its aftermath, particularly pain management, fatigue, nutritional issues, digestive, respiratory and genitourinary disorders, motor impairments, disabilities, and dental problems. It also addresses social difficulties, psychological distress, disturbances in body image, and end-of-life support (French Circular No. DHOS/SDO/2005/101 of February 22, 2005, relating to the organization of cancer care, section 1.6.2; Appendix 1).

Applications of visual art therapy (drawing, painting, collage, sculpture/modeling) have been studied in pediatric oncology, among patients in isolation, during chemotherapy and/or radiotherapy treatment, in rehabilitation settings, in palliative care, and as part of support measures for healthcare professionals (3).

International research has mainly focused on hospitalized patients during the first episode of illness and has largely consisted of case studies. These studies have generally been retrospective rather than prospective, linking current trauma to past traumatic experiences (2).

For end-of-life patients, the literature mainly consists of descriptive studies regarding the integration of art therapy into palliative care services, particularly in France (2)(12)(15).

In France, although the discipline is developing, it remains insufficiently studied in oncology.

Cancer patients are particularly vulnerable to depression and anxiety, while fatigue remains the most prevalent symptom among patients undergoing treatment.

The aim of this study is to determine whether an art therapy intervention improves quality of life and well-being, defined as the subjective feeling of “feeling well.”

Well-being is often associated with the perception of “feeling well” and is assessed subjectively and personally.

Art therapy interventions may make a significant contribution to the psychological well-being of patients with cancer (3).

There is a growing body of literature demonstrating that art therapy may be effective in improving cancer-related symptoms in both children and adults. Observational studies have provided preliminary evidence supporting the effectiveness of art therapy in reducing a broad spectrum of symptoms in diverse populations of hospitalized cancer patients (6)(12). In addition, painting-based art therapy has been shown to improve quality of life and reduce depression in cancer patients undergoing chemotherapy (15).

The Hematology-Oncology Day Hospital department at the Centre Hospitalier de Périgueux is constantly faced with the challenge of relieving pain, whether physical or psychological, using conventional therapeutic approaches that sometimes show their limitations. Supportive care has recently been integrated into both the medical project and the department’s care strategy. Art therapy is now fully integrated into supportive care services.

In 2015, funding granted by the Fondation de Brou de Laurière enabled the launch of this activity through the recruitment of a university-trained art therapist, whose position was renewed for an additional year. Over this two-year period, the project was initiated and its added value in patient care was demonstrated.

The use of the Edmonton Symptom Assessment System (ESAS) for cancer patients has demonstrated good reliability (8).

In 2017, a pilot feasibility study was conducted on a small sample of 19 patients in order to evaluate symptom reduction among patients treated in the Hematology-Oncology Day Hospital department following an art therapy session during anticancer treatment (chemotherapy, immunotherapy, etc.). The project evolved from a qualitative assessment of art therapy sessions toward quantitative evaluation using different items, ultimately allowing the application of statistical analyses on a patient sample in preparation for the present study.

In the long term, evaluations have shown a significant reduction in symptoms following sessions in a group of patients, and in some cases a complete cessation of symptom reporting because no symptoms were

observed anymore. Nevertheless, supportive care continued in order to maintain patient well-being and quality of life throughout the continuum of care.

2.2. Research Hypothesis

- Art therapy may help alleviate symptoms related to the disease and its treatment.
- Art therapy may have a beneficial effect on quality of life during this period.
- Art therapy may improve patient satisfaction among those participating in it.

This research will focus on hospitalized patients during the treatment period, from the first day of inclusion until the end of the observation period (6 sessions).

The art therapy intervention is multimodal and may include painting, drawing, creative activities, music listening, and other artistic media.

2.3. Justification of Methodological Choices

The interventional study design has rarely been used to evaluate the added value of art therapy compared with standard care in an Oncology-Hematology Day Hospital setting. Randomization, together with intention-to-treat analysis, will ensure and maintain comparability between the two groups.

Indeed, through the pilot feasibility study and the article *Effects of Creative Arts Therapies on Psychological Symptoms and Quality of Life in Patients With Cancer*, we identified the symptom “feeling well” as the most significant outcome for assessing the added value of art therapy. Furthermore, the FACT-G, evaluated as a secondary objective, is a quality-of-life scale that will support the primary objective.

The FACT-G questionnaire will be administered at the beginning and at the end of the follow-up period. As this questionnaire is comprehensive, administering it at every visit would not be appropriate. Assessing it only at baseline and at the end of follow-up will provide a clearer evaluation of changes in quality of life over the entire study period.

Administering the ESAS questionnaire to both groups at the beginning and end of treatment will allow the assessment of potential changes in symptoms, with or without art therapy support.

The art therapy-specific questionnaire, designed for this study and not formally validated, will provide more detailed information regarding whether art therapy met the patients’ needs.

In the analysis, other supportive care interventions available in the Day Hospital setting (such as socio-aesthetic care, psychological support, and osteopathy) will also be taken into account.

Consideration of participants’ personal resources aims to provide greater nuance in the interpretation of the results obtained.

2.4. Population cible

This study will involve adult patients with cancer receiving care in the Oncology-Hematology Day Hospital department of the Centre Hospitalier de Périgueux who voluntarily agree to participate in this research. Patients currently participating in another study will not be included.

2.5. Expected Outcomes

The purpose of this study is to demonstrate the added value of art therapy in the comprehensive care of patients with cancer receiving treatment in an Oncology-Hematology Day Hospital setting.

We expect to observe differences between the group receiving art therapy during treatment and the group not receiving art therapy, with regard to:

- A significant reduction in symptoms between the beginning and the end of the follow-up period.
- An improvement in quality of life during treatment and care.

This study also aims to highlight and validate the work carried out in art therapy through a scientific and objective approach.

3. RESEARCH OBJECTIVES

3.1. Primary Objective

The objective is to evaluate the impact of art therapy, as a supportive care intervention, on the improvement of perceived well-being following anticancer treatment sessions (chemotherapy, immunotherapy, etc.), over the course of 6 sessions, in patients with cancer.

3.2. Secondary Objectives

1. To evaluate the impact of art therapy, as a supportive care intervention, on the reduction of symptoms measured by the ESAS scale following an anticancer treatment session, over the course of 6 sessions.
2. To determine the impact of 6 art therapy sessions, as supportive care alongside anticancer treatments, on symptom progression assessed using the ESAS scale, between the assessment conducted before the first art therapy session and the assessment conducted after the final (6th) session.
4. To evaluate the impact of 6 art therapy sessions, as supportive care in oncology treatment, on changes in quality of life.
5. To assess patient satisfaction, after 6 art therapy sessions, regarding this type of therapy as supportive care in oncology treatment.

4. RESEARCH DESIGN

4.1. Type of Study

This is a Category RIPH 2 study: an interventional study with minimal risks and constraints, involving paramedical care, monocentric, and institution-sponsored, with the objective of validating innovative practices within the patient care pathway, excluding health products.

This is a randomized, controlled, parallel-group superiority study comparing standard care versus standard care combined with art therapy.

4.2. Outcome Measures

4.2.1. Primary Outcome Measure

The primary outcome measure is the mean, over the 6 sessions, of the difference between the ESAS score related to perceived well-being (the “feeling of well-being” symptom on the ESAS assessment) reported by the patient before and after the treatment session.

The Edmonton Symptom Assessment System (ESAS) questionnaire is an interdisciplinary tool available to patients for the assessment and monitoring of symptoms in palliative care settings, developed in Canada. This is a validated scale (Reference: Bruera E, Kuehn N, Miller MJ, Selmsler P, Macmillan K. *Journal of Palliative Care*, 1991, 7(2): 6–9).

In view of the symptoms reported by patients attending the Oncology-Hematology Day Hospital, we decided to use this tool for the present study.

It is a self-assessment scale for the most common symptoms: pain, dyspnea, fatigue, drowsiness, appetite, anxiety, depression, well-being, and any other potential symptoms. (17) (Appendix 2)

The ESAS questionnaire allows:

- Measurement of symptoms reported by the patient,
- Screening and assessment of symptoms,
- Monitoring symptom progression and evaluating these symptoms,
- Support for interdisciplinary communication.
-

The ESAS scale may be presented in visual analogue, numerical, or verbal form. To ensure the most accurate results, we will use the numerical scale.

Numerical Scale:

The patient is asked to circle the number corresponding to the intensity of the pain currently experienced, where 0 corresponds to “no pain” and 10 corresponds to “the worst possible pain.”

If the patient requests clarification regarding the terms used, the following definitions apply:

- **Fatigue:** a feeling of lack of energy or strength,
- **Depression:** a low mood,
- **Anxiety:** a vague feeling of discomfort or fear,
- **Drowsiness:** difficulty staying awake,
- **Well-being:** how you feel overall.

4.2.2. Secondary Outcome Measures

1. Secondary outcome measure No. 1 corresponds, for each of the other symptoms assessed by the ESAS scale, to the mean difference over 6 treatment sessions between the ESAS score associated with the symptom under study, measured before and after each treatment session.
2. Secondary outcome measure No. 2 corresponds, for each ESAS symptom, to the difference in the ESAS score associated with the symptom under study, measured before the first treatment session and after the final (6th) treatment session.
3. Secondary outcome measure No. 3 is the difference in the total score obtained on the FACT-G quality-of-life questionnaire between inclusion and the end of the 6 anticancer treatment sessions.
4. Secondary outcome measure No. 4 is the art therapy satisfaction questionnaire administered exclusively to patients in the art therapy group

The assessment of improved daily quality of life, using the FACT-G questionnaire, is performed at the beginning and at the end of the study participation period. The FACT-G, more commonly used in the United States but validated in France, meets or exceeds all requirements for use in oncology clinical trials, particularly with regard to administration reliability, brevity, validity, and responsiveness to clinical change. The FACT-G (Version 4) is a patient-reported outcome measure used to assess health-related quality of life in patients undergoing cancer treatment.

This questionnaire includes 27 items constructed on a 5-point Likert scale with the following coded response categories: 0 “Not at all” / 1 “A little bit” / 2 “Somewhat” / 3 “Quite a bit” / 4 “Very much”.

Four dimensions of well-being are assessed through these items: physical well-being, social/family well-being, emotional well-being, and functional well-being.

A score is calculated for each dimension. These scores range from 0 to 28, where 0 represents a low level of well-being and 28 a high level of well-being. For a score to be estimated, at least 50% of the items within the dimension must be completed.

The items of the FACT-G questionnaire are grouped by dimension, and the name of each assessed dimension precedes the corresponding items. In addition, an overall FACT-G score is calculated from the scores obtained for each dimension.

This overall score corresponds to the sum of the raw scores obtained for each dimension and ranges from 0 (low level) to 108 (high level of overall well-being). This global score can only be calculated if all subscale scores have been estimated.

The four well-being scores, as well as the overall FACT-G score, are generally standardized on a scale from 0 to 100 in order to facilitate comparison with other questionnaires.

The analysis of the art therapy questionnaire data from the art therapy group aims to determine whether this type of therapy met the patients' needs or expectations. It is a non-validated satisfaction questionnaire consisting of five questions focused on the patients' experience of art therapy during anticancer treatment.

4.2.3. Other Factors Taken into Account

- Participation in other supportive care services offered by the department: socio-beautician, psychologist, and osteopath.
- Participation in another workshop or therapy outside the day hospital.
- Gender
- Age
- Type of cancer

5. ELIGIBILITY CRITERIA

5.1. Inclusion criteria

- Adult patients
- Patients treated in the Hematology-Oncology Day Hospital for a cancer diagnosis
- Patient consent obtained
- Patients affiliated with the French social security system

5.2. Non-inclusion criteria

- Minors
- Patients under legal protection (guardianship or trusteeship)
- Patients with severe impairment of vital functions and/or cognitive abilities preventing participation in and understanding of the study
- Patients participating in another clinical study
- Patients who have previously participated in an art therapy session at any point in their life
- Patients whose anticipated treatment duration is less than 6 sessions in the Hematology-Oncology Day Hospital of Périgueux

Exclusion criteria

- Participants initially included but who no longer meet eligibility criteria before the fourth session (e.g., initiation of legal protection between the third and fourth session)
- Patients wishing to withdraw from the study before the fourth session
- Patients requesting deletion of their data
- Patients will not be replaced on an ongoing basis as recruitment progresses.

5.3. Recruitment Procedures and Feasibility

Recruitment procedures:

As a general rule, art therapy is presented to all patients attending the Hematology-Oncology Day Hospital through the standard disclosure process (disclosure consultation system).

For the purposes of this study, information about the study will also be displayed in the waiting areas of the Hematology-Oncology Day Hospital (both the consultation waiting room and the treatment waiting area).

A flyer will also be placed at each chair or bed.

No financial compensation will be provided for participation in this study.

Methodology:

The study will be proposed to all eligible patients in the department by the art therapist and the designated Clinical Research Assistant (CRA), both orally and in writing (Patient Information Sheet provided in Appendix 7).

If the patient expresses interest after a reflection period (minimum of 24 hours, up to a maximum of 7 days), they will be invited to sign the informed consent form together with the investigator/art therapist (written consent provided in Appendix 8).

Patients will be randomized into two balanced groups (1:1 ratio): a control group (standard anticancer treatment) versus an experimental group (standard anticancer treatment + art therapy).

The randomization list will be generated according to the study protocol methodology. It will be performed using variable block sizes.

It will then be recorded in the patient's medical file that the patient is participating in the study, along with their anonymisation number. It will also be indicated in the subsequent chemotherapy appointment schedules that the patient is enrolled in the study.

Study questionnaires for each arm will be brought and collected by the nurse or the Clinical Research Assistant (CRA) at the beginning and end of each treatment session.

The art therapy session, when applicable, will take place during the treatment session.

Description of the art therapy session:

The patient is usually located in a single room, but may also be placed in a treatment area with two or three chairs.

Once medical team approval is obtained for the art therapy intervention, the art therapist will meet the patient to introduce themselves and, if the patient agrees to participate in the study, provide an oral presentation supported by the patient information sheet. After signing the informed consent form, the art therapy sessions may begin.

Sessions are conducted individually, in the patient's room. Each session lasts between 30 minutes and 1 hour 30 minutes, depending on the patient's capacity. Materials are made available for artistic activities selected in line with the therapeutic approach (paper, paint, pastels, clay, watercolour pencils, art books, etc.). Music listening may also be offered during the session if the patient wishes.

The session may be interrupted by medical or nursing staff as required. The maximum duration of a session is set at 2 hours and 30 minutes, due to patient concentration capacity and organisational constraints within the department. However, the patient remains the active participant in their care and decides when the session ends—either upon completion of the artwork or when they wish to stop for various reasons (treatment-related fatigue, drowsiness due to premedication, or any other symptoms related to treatment or general condition).

At the end of the session, an appointment for the next session is scheduled, and a discussion takes place regarding planned activities for the following session. Intermediate objectives are defined by the art therapist.

6. GENERAL ORGANISATION

6.1. Study timeline

- Duration of the inclusion period: 60 months
- Duration of participation for each patient: 6 sessions (i.e., between 4 and 6 months)
- Total duration of the study: 66 to 68 months
- Start of recruitment: first quarter of 2020

From the first inclusion, the sponsor must immediately inform the Ethics Committee (CPP) of the actual study start date (defined as the date of inclusion of the first patient).

The study end date will be communicated by the sponsor to the CPP within 90 days. The end of the study corresponds to the completion of participation of the last subject enrolled in the research, or, where applicable, to the protocol-defined study end date.

6.2. General Study Design and Summary Table

FLOW CHART OF STUDY PROCEDURES

	Pre-inclusion visit	Inclusion visit	Follow-up visits (V1 to V6)	End of study
Verification of inclusion and non-inclusion criteria	X	X		
Oral and written information provided	X	X		
Informed consent collection (dated and signed)		X		
Anonymisation / inclusion		X		
Randomisation		X		
Art therapy (experimental group only)		X	X	
FACT-G questionnaire		X		X
ESAS questionnaire		X	X	X
Art therapy satisfaction questionnaire				X
Exit visit and end-of-study questionnaire				X

6.3. Temporary or Permanent Discontinuation Rules

In the event of absence from a treatment session, the reason will be recorded in the CRF, and the session will be rescheduled. Participants may also request that a session be postponed, where appropriate. Participant follow-up will consist of 6 sessions.

- **Discontinuation of an individual participant from the research:**

Participants may withdraw from the study at any time, without having to provide justification, regardless of the reason. In the event of premature withdrawal, the investigator must document the reasons as completely as possible.

The patient may agree to or refuse the use of data collected up to the time of withdrawal.

Patients who withdraw prematurely from the research will not be replaced progressively.

- **Discontinuation of part or all of the research:**

In the event of premature termination of the study for safety reasons, the sponsor will notify the CPP within 15 days.

7. SAFETY ASSESSMENT

An adverse event is any harmful and unintended reaction.

In accordance with Article L1123-10, the vigilance provisions applicable to each product or practice involved in the research shall apply.

The investigator must report any adverse event in accordance with the quality management and care procedures of their institution.

Adverse events will be recorded. They may justify certain session postponements and missing data.

The subject of the study (art therapy) is unlikely to cause such events.

The population participating in the study is particularly exposed to adverse events due to the fragility of their health condition, related to their cancer and/or general condition and/or the effects of their treatments.

Some events may be unrelated to the art-therapy intervention, including: skin reactions, nausea/vomiting, loss of appetite, anemia, issues related to the central venous access device (CVAD), hospitalization for various causes, or even death.

In accordance with Article L1413-14, any healthcare professional or healthcare institution that identifies a healthcare-associated infection or any other serious adverse event related to care provided during investigations, treatments, or preventive actions must report it to the Director General of the Regional Health Agency (Agence Régionale de Santé).

Health-related adverse events must be reported via the national adverse event reporting portal: www.signalement-sante.gouv.fr

8. STATISTICAL ASPECTS

8.1 Number of Subjects Required

The aim is to assess the evolution of the well-being symptom following anticancer treatment alone, or with the addition of an art-therapy session, using the ESAS scale administered before and after each of the 6 treatment sessions.

The sample size calculation was based on the results of the 2017 pilot feasibility study, which showed a mean difference in the ESAS score of 2.904 points $\pm$ 1.82 for the well-being symptom between before and after each of the 6 anticancer treatment sessions combined with art therapy.

Assuming a 40% improvement in the ESAS score in patients in the experimental group compared with the control group (considered to represent a clinically relevant difference), with a two-sided alpha risk of 0.05 and a statistical power of 80%, 39 subjects per group will be required.

The proportion of non-evaluable subjects is estimated at 10%. Therefore, a total of 43 patients per group, i.e., 86 subjects in total, will need to be included in this study.

The sample size calculation was performed using the epiR package version 0.9-96.

8.2 Description of Statistical Methods

Statistical analyses will be performed using Epi Info software version 7.1.5.

The level of statistical significance for all analyses will be set at 0.05. Analyses will be conducted on an intention-to-treat basis.

Descriptive Analysis:

Quantitative variables will be described using mean $\pm$ standard deviation or median and interquartile range, depending on the distribution of the variable (Shapiro–Wilk test). Qualitative variables will be described using frequencies and percentages. A flow chart will be presented.

Primary Analysis:

The comparison of the mean differences in ESAS scale scores before and after each of the 6 anticancer treatment sessions between the two randomization groups will be performed using a generalized linear model, with:

- the dependent variable: the mean difference in the studied score before and after each of the 6 treatment sessions;
- the main explanatory variable: the randomization group;
- the adjustment variable: whether or not the control group received other supportive care interventions (socio-aesthetic care, osteopathy, psychological support).

Secondary Analyses:

1. For each of the other ESAS symptoms, the comparison of the mean differences in scores before and after each of the 6 treatment sessions between the two randomization groups will be performed using a generalized linear model, with:
 - the dependent variable: the mean difference in the studied score before and after each of the 6 anticancer treatment sessions;
 - the main explanatory variable: the randomization group;
 - the adjustment variable: other possible supportive care interventions.
2. The comparison of the difference in total FACT-G questionnaire scores between baseline (before the first session) and after the 6th anticancer treatment session between the two randomization groups will be performed using a generalized linear model, with:
 - the dependent variable: the mean difference in the studied score before and after the 6 treatment sessions;
 - the main explanatory variable: the randomization group;
 - the adjustment variable: other possible supportive care interventions.
3. The comparison of the difference in total FACT-G questionnaire scores between baseline and after the 6th treatment session according to the randomization groups will be performed using a generalized linear model, with:
 - the dependent variable: the difference in the studied score between the first and last session;
 - the main explanatory variable: the randomization group;
 - the adjustment variable: other possible supportive care interventions.

Responses to the art-therapy satisfaction questionnaire among patients who benefited from art therapy will be described according to the descriptive analysis methods defined above.

8.3 Measures Taken to Minimize Bias

With regard to selection bias, the target population consists of patients with cancer attending the oncology-hematology day hospital. Participants will be recruited within this department.

With regard to confounding bias:

- Participation in other supportive care interventions offered within the department will be recorded.
- At the end of the intervention period, participants in both groups will be asked whether they received any additional well-being resources (workshops/therapies) other than those offered during their treatment.

These data will be taken into account in the statistical analysis.

With regard to measurement bias, all participants will complete internationally validated questionnaires (ESAS and FACT-G) at the same point in their care pathway.

The nurse specialists responsible for patient consultation announcements (IDE d'annonce) or the Clinical Research Associate (CRA), who will not be involved in the patient's medical management, will be trained by the investigator in the administration of these questionnaires.

The biostatistician will perform the analyses blinded to group allocation.

With regard to performance/follow-up bias :blinding is not feasible for either participants or the art therapist. Therefore, the department nurse will distribute the questionnaires to participants.

With regard to attrition bias : statistical analyses will be conducted on an intention-to-treat basis, as recommended for superiority trials. The number of included patients will exceed the required sample size by 10% in anticipation of losses to follow-up and missing data.

The study procedures are minimally burdensome for participants. The follow-up period is relatively short (6 sessions) for patients who are closely monitored within the study department. In the event of absence, the study team will be rapidly informed of both the absence and its reason. Sessions may be rescheduled whenever possible in order to complete 6 sessions. A minimum of 4 sessions is required; otherwise, the participant's file will be excluded, as will participants meeting the exclusion criteria described in section 5.2. These measures are intended to minimize missing data.

8.4 Method for Handling Missing Data

Analyses will be conducted on an intention-to-treat basis. A per-protocol analysis will also be performed. Per-protocol analysis will be considered feasible after completion of 4 sessions.

8.5 Management of Changes to the Statistical Analysis Plan

A detailed Statistical Analysis Plan (SAP) will be prepared prior to database lock. It will take into account any protocol amendments or unexpected events occurring during the study that may impact the analyses described above. Planned analyses may be supplemented in accordance with the study objectives.

Any subsequent modification to the Statistical Analysis Plan must be justified and will result in a new version of the document. Such deviations from the Statistical Analysis Plan will be reported in the final study report. All documents will be retained in the study file.

8.6 Person Responsible for the Analyses and Software Used

Doctor Sébastien Bouteux

Thomas Chourreaux, Data manager

Statistical analyses will be performed using Epi Info software version 7.1.5.

9. ACCESS RIGHTS TO DATA AND SOURCE DOCUMENTS

9.1 Access to Data

- The sponsor is responsible for obtaining the agreement of all parties involved in the research in order to guarantee direct access to all research sites, source data, source documents, and reports for the purposes of quality control and sponsor audits.
- Investigators shall make available to persons responsible for monitoring, quality control, or auditing of research involving human participants the documents and individual data strictly necessary for such control, in accordance with the applicable legislative and regulatory provisions (Articles L.1121-3 and R.5121-13 of the French Public Health Code).

Each participant has the right to access their personal data upon request to the investigator.

9.2 Source Documents

Source documents are defined as any original document or object enabling verification of the existence or accuracy of data or facts recorded during the clinical study. These documents will be retained for 25 years by the investigator or by the hospital if they form part of the hospital medical record.

- A single patient file, available in both paper and electronic format. Staff involved in other supportive care interventions use the electronic patient record system to document their reports and observations.

9.3 Data Confidentiality

In accordance with the provisions relating to the confidentiality of data accessed by persons responsible for quality control in research involving human participants (Article L.1121-3 of the French Public Health Code), and in accordance with the provisions relating to the confidentiality of information concerning, in particular, clinical trials, trial participants, and obtained results (Article R.5121-13 of the French Public Health Code), all individuals with direct access to data shall take all necessary precautions to ensure the confidentiality of information relating to the trials, the participants, and in particular their identity, as well as the results obtained.

Such individuals, as well as the investigators themselves, are bound by professional secrecy (in accordance with Articles 226-13 and 226-14 of the French Penal Code).

During the research involving human participants or upon its completion, the data collected from participants and transmitted to the sponsor by the investigators (or any other specialized personnel) will be anonymized.

Under no circumstances shall participants' names or addresses appear in clear text.

Anonymization code: inclusion number in chronological order of enrolment, followed by the first letter of the surname and the first letter of the first name. Example: Girard Daniel → anonymization code: 001 – GD.

Data collection will include only data that does not allow direct identification of the patient. After data consistency checks, the database will be fully anonymized (removal of all identifying data and deletion of the patient identification variable allowing linkage back to source documents).

Electronic data will be stored on a secure server accessible only to persons responsible for statistical analysis and data management, the Clinical Research Associate (CRA), the investigator, and the scientific lead.

10. QUALITY CONTROL AND QUALITY ASSURANCE

The investigators agree to accept quality assurance audits conducted by individuals mandated by the sponsor, as well as inspections carried out by Competent Authorities. All data, documents, and reports may be subject to audits and regulatory inspections, without the possibility of invoking medical confidentiality.

11. ETHICAL CONSIDERATIONS

11.1 Competent Authorities

The protocol, the participant information sheet, the case report form (CRF) of the study, and where applicable the questionnaire(s), will be submitted for review to the Committee for the Protection of Persons (Comité de Protection des Personnes – CPP) Sud-Est IIXX (specify the CPP number designated following approval).

The notification of the favourable opinion issued by the CPP will be transmitted to the French National Agency for Medicines and Health Products Safety (ANSM).

The sponsor commits to ensuring that the study will not begin until the favourable opinion of the CPP has been obtained.

11.2 Substantial Amendments

In the event of a substantial amendment to the protocol initiated by the investigator, such amendment shall be approved by the sponsor. Prior to implementation, the sponsor must obtain a favourable opinion from the CPP.

11.3 Patient Information

Patients will be informed, both orally and in writing (patient information sheet in Appendix 7), of their right to object to participation in the study, as well as their right to object to the use, for scientific purposes, of data collected and anonymised concerning them.

A consent form in two copies will be signed; one copy will be filed in the patient's medical record, and the other will be retained by the patient (Appendix 8).

Participants may request to receive the final overall results of the study.

11.4 Statement of Compliance

The sponsor and the investigator commit to conducting this research:

- in accordance with the protocol;
- in accordance with applicable national and international legislative and regulatory requirements.

12. DATA MANAGEMENT AND DATA STORAGE

12.1 Case Report Form (CRF)

The CRF will be in paper format.

The case report form will include only the data necessary for analysis and publication purposes. Other patient-related data required for routine clinical care outside the study will be recorded in the patient's medical record.

Age, diagnosis, and sex are included in the CRF as data items but are not considered inclusion criteria.

12.2 Data Management

The CRF will be a single copy, as this is a single-centre study. It will be completed by the investigator and the participant, with or without the assistance of the nurse (IDE) for questionnaire completion. The Clinical Research Associate (CRA) may contribute and will verify data completion.

Data will be entered using a single data entry process in the Epi Info software by the study investigator, with review by the data manager and/or the statistician.

Data will be validated within the Epi Info software by the data manager and/or statistician after entry by the investigator using the same software.

Data will be locked (database freeze) in Epi Info after validation by the data manager and may only be unlocked under the following condition:

- A signed agreement from the study investigator and the medical lead.

Data will be backed up after each entry on the investigator's computer. A copy of the backup will be made on an external storage device under the responsibility of the investigator after each study day. Once the data collection period is completed, both databases will be retained by the investigator for 25 years, after which they will be destroyed by formatting the storage drives.

12.3 CNIL (Data Protection Authority Compliance)

CNIL commitment of compliance no. MR001: 2212181 v0 dated 08 March 2019.

12.4 Archiving

For all research involving human participants, the retention period is 25 years.

The following documents will be archived by the Centre Hospitalier de Périgueux until the end of their useful operational period:

- Protocol and appendices, including any amendments
- Information sheets
- Individual participant data
- Study monitoring documents and correspondence related to the research
- Case Report Forms (CRFs)
- Statistical analyses
- Final study report

The sponsor will retain all study data for 25 years.

No transfer or destruction of documents may be carried out without the sponsor's approval. At the end of the 25-year retention period, the sponsor will be consulted prior to any destruction. All data, documents, and reports may be subject to audit or inspection.

13. PUBLICATION POLICY

Scientific communications and reports related to this study will be conducted under the responsibility of the Principal Investigator, with the agreement of the co-investigators.

Co-authors of the study report and publications will include investigators and clinicians involved, in proportion to their contribution to the study, as well as the biostatistician and associated researchers.

Publication policies will follow international recommendations (New England Journal of Medicine, 1997; 336:309–315).

The study will be registered in a publicly accessible clinical trial registry (clinicaltrials.gov) prior to the inclusion of the first participant.

Planned publications:

- Psycho-Oncology journal
- Cancer & Psy journal
- Médecine Palliative journal
- Vivre journal (French League Against Cancer)
- Synergie (internal journal, Centre Hospitalier de Périgueux)
- One poster presentation

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15. PROVISIONAL BUDGET / REQUESTED FUNDING AND PHASING

Funding request submitted to and approved by the *Fond de Dotation de Brou de Laurière* for the 2019/2020 period.

- **Investment / Operating costs:** €1,000
- **Personnel costs:** time allocated to interventions and questionnaire administration, as well as administrative time for data collection and interpretation: €62,000
- **Administrative costs:** reproduction expenses (questionnaires, posters, etc.): €1,000
-

Total: €64,000

As the study duration has been reassessed to 30 months, the same amount will be requested from the same funding body for the 2021/2022 period.

16. LIST OF APPENDICES

1. Circular No. DHOS/SDO/2005/101 dated 22 February 2005 relating to the organisation of cancer care (1.6.2)
2. ESAS symptom assessment
3. 2017 prospective study
4. FACT-G quality of life assessment
5. Art therapy evaluation form
6. Case Report Form (CRF)
7. Patient information sheet
8. Patient informed consent form
9. Investigator CV
10. CPP opinion, english and french version

APPENDIX 1

Circular DHOS/SDO No. 2005-101 of 22 February 2005
on the organisation of cancer care
NOR: SANH0530076C

1.6.2 Access to supportive care

All patients with cancer must henceforth, regardless of their place of care, including at home, have access to supportive care. In oncology, supportive care is defined as all the care and support required by patients throughout the course of the disease, alongside specific onco-haematological treatments where applicable (Oncologie, 2004-6: 7–15).

The report of the working group on supportive care in oncology, available on the Cancer Plan website, defines the scope of supportive care and the organisational arrangements it requires. Reference should be made to this report, a summary of which is provided in Appendix IV.

Supportive care does not constitute a new discipline; rather, it corresponds to coordination that must mobilise skills and organise their availability for patients and their relatives. This coordination is particularly established within multidisciplinary team meetings (MTCs), where it can then be implemented around the patient. Supportive care is an integral part of oncology management. When necessary, particular attention should be paid to its articulation with the palliative care approach.

APPENDIX IV

SUPPORTIVE CARE IN ONCOLOGY MEASURE 42 OF THE CANCER PLAN

The Cancer Plan provides for the development of supportive care in complementarity, in particular with national palliative care and pain management programmes.

This dimension is integrated into departmental and institutional projects as well as into territorial medical projects and must rely on existing actors, institutions, and structures.

1. Context and definition of supportive care

This holistic approach to the patient requires that all healthcare professionals involved in oncology take into account the supportive care dimension in patient management, particularly in terms of continuity of care. The care plan aims to ensure the best possible quality of life for patients throughout the course of the disease, on a physical, psychological, and social level, taking into account the diversity of their needs and those of their relatives, regardless of place of care.

Supportive care is not a new specialty but rather a coordinated organisation of different competencies involved alongside specific oncological treatments in patient management.

2. Supportive care addresses needs

During the course of illness and thereafter, in addition to specific cancer treatments, supportive care addresses needs mainly related to:

- pain;
 - fatigue;
 - nutritional problems;
 - digestive, respiratory and genito-urinary disorders, motor disorders and disabilities;
 - dental/oral health problems;
 - social difficulties;
 - psychological distress and body image disturbances;
 - end-of-life care,
- for both patients and their relatives.

Palliative care, as defined by law, is fully integrated within supportive care.

3. Implementation of supportive care

Patients may access supportive care at any stage of their illness.

Implementation requires joint reflection between clinical teams and supportive care resource teams.

This includes a coordinated assessment phase within each institution to identify available skills and resources, as part of a territorial healthcare approach including existing networks.

Depending on this assessment, the scope and modalities of intervention of the teams are defined to ensure access to all necessary competencies.

Given the complexity of certain situations, referral to expert or specialised competencies may be required at any stage of the disease. These include pain management specialists, palliative care teams, psycho-oncology professionals, social care professionals, nutrition specialists, and rehabilitation professionals.

Such referral may consist either of a one-off expert opinion or of full patient and family management, particularly in cases of severe sequelae, during remission or end-of-life care. In complex care pathways, coordination modalities are also developed, often within multidisciplinary team meetings.

4. Accessibility of supportive care for patients

It is essential that patients and/or their relatives are informed, from the beginning of the care pathway, about available supportive care resources so that they may access them throughout their disease trajectory, during and after treatment.

Supportive care is offered to all cancer patients within the personalised care plan, which may include contact details of a designated healthcare professional and/or an information centre (e.g., information kiosk, patient information space, cancer coordination centres, or any other information facility).

5. Supportive care and healthcare institution organisation

Each healthcare institution must include supportive care in its oncology programme to ensure that all cancer patients, regardless of location, have access to these aspects of care.

Supportive care provision is intended to be integrated within oncology coordination centres or units where established. These centres aim to improve and individualise patient follow-up and care pathways by mobilising all available competencies. Teams involved in supportive care across one or more institutions may be required to coordinate their activities within a given healthcare territory.

The monitoring of supportive care activities and evaluation of patient outcomes are part of the feedback expected under the Cancer Plan. Patient evaluation is also taken into account and should be subject to audit procedures, for example within healthcare networks.

6. Supportive care and teaching and research missions

This organisational framework contributes, through its components, to initial and continuing education in supportive care, both for healthcare professionals and within health training institutes and medical faculties.

APPENDIX 2: ESAS Symptom Assessment Questionnaire

ARONCO

ANONYMISATION CODE: I _ I _ I _ I _ I _ I

VISIT No.: I _ I _ I

DATE : I _ I _ I / I _ I _ I / I _ I _ I _ I _ I

Questionnaire completed: ☒ before ☐ after

No Pain	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Pain
	0 1 2 3 4 5 6 7 8 9 10	

No Fatigue	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Fatigue
	0 1 2 3 4 5 6 7 8 9 10	

No Nausée	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Nausée
	0 1 2 3 4 5 6 7 8 9 10	

No Depression	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum depression
	0 1 2 3 4 5 6 7 8 9 10	

No Anxiety	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Anxiety
	0 1 2 3 4 5 6 7 8 9 10	

No drowsiness	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum drowsiness
	0 1 2 3 4 5 6 7 8 9 10	

No Loss of appetite	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Loss of appetite
	0 1 2 3 4 5 6 7 8 9 10	

No Shortness of breath	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Shortness of breath
	0 1 2 3 4 5 6 7 8 9 10	

Feeling well	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Feeling unwell
	0 1 2 3 4 5 6 7 8 9 10	

Other symptom (sweating, dry mouth, dizziness, sleep disturbances, etc.): _____

I _ I _ I _ I _ I _ I _ I _ I _ I _ I
0 1 2 3 4 5 6 7 8 9 10

Date :

Investigator's signature:

Based on the ESAS (Edmonton Symptom Assessment System) scale, University Hospitals of Geneva.

APPENDIX 2: ESAS Symptom Assessment Questionnaire

ARONCO

ANONYMISATION CODE: I _ I _ I _ I _ I _ I _ I

VISIT No.: I _ I _ I

DATE : I _ I _ I / I _ I _ I / I _ I _ I _ I _ I

Questionnaire completed: ☐ before ☒ after

No Pain	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Pain
	0 1 2 3 4 5 6 7 8 9 10	

No Fatigue	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Fatigue
	0 1 2 3 4 5 6 7 8 9 10	

No Nausée	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Nausée
	0 1 2 3 4 5 6 7 8 9 10	

No Depression	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum depression
	0 1 2 3 4 5 6 7 8 9 10	

No Anxiety	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Anxiety
	0 1 2 3 4 5 6 7 8 9 10	

No drowsiness	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum drowsiness
	0 1 2 3 4 5 6 7 8 9 10	

No Loss of appetite	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Loss of appetite
	0 1 2 3 4 5 6 7 8 9 10	

No Shortness of breath	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Shortness of breath
	0 1 2 3 4 5 6 7 8 9 10	

Feeling well	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Feeling unwell
	0 1 2 3 4 5 6 7 8 9 10	

Other symptom (sweating, dry mouth, dizziness, sleep disturbances, etc.): _____

I _ I _ I _ I _ I _ I _ I _ I _ I _ I
0 1 2 3 4 5 6 7 8 9 10

Date :

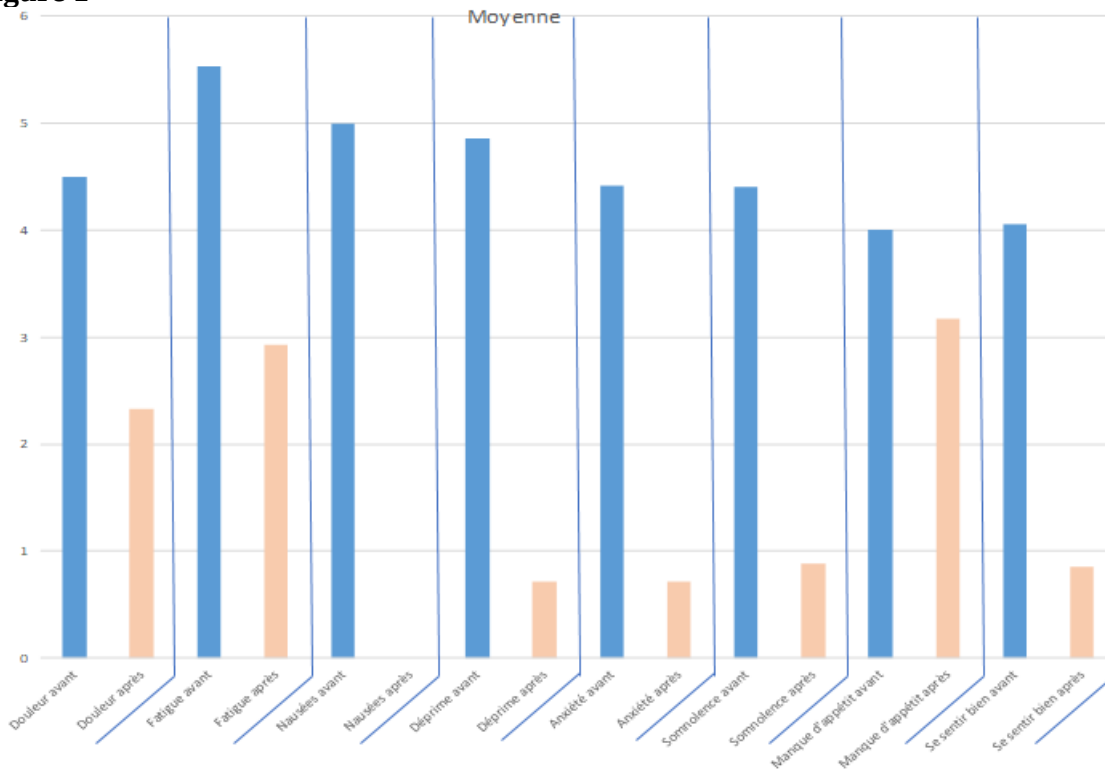
Investigator's signature:

Based on the ESAS (Edmonton Symptom Assessment System) scale, University Hospitals of Geneva.

ANNEXE 3

Preliminary results of a prospective statistical study on a small sample conducted in 2017:

Figure 1



Paired Samples Test: Table 1

Symptom	N	Minimum	Maximum	Mean	Median
Pain (before)	13	3	9	4.50	4
Pain (after)	12	0	7	2.33	2
Fatigue (before)	31	2	10	5.53	5
Fatigue (after)	30	0	7	2.93	2.5
Nausea (before)	2	0	5	5.00	2.5
Nausea (after)	1	0	0	0.00	0
Depression (before)	14	2	9	4.86	5
Depression (after)	14	0	2	0.71	0.5
Anxiety (before)	31	0	9	4.42	4
Anxiety (after)	31	0	7	0.71	0
Drowsiness (before)	17	0	8	4.41	5
Drowsiness (after)	17	0	5	0.88	0
Loss of appetite (before)	6	0	7	4.00	4
Loss of appetite (after)	6	0	7	3.17	2.5
Well-being (before)	47	0	8	4.06	4

Well-being (after)	47	0	5	0.85	1
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Paired Samples Test: Table 1

Pair	Paired Differences	Mean Difference	t	df	Sig. (2-tailed)
Pair 1	Pain (before) – Pain (after)	3.311	4.168	11	0.002
Pair 2	Fatigue (before) – Fatigue (after)	3.217	8.617	29	0.000
Pair 4	Depression (before) – Depression (after)	4.955	11.022	13	0.000
Pair 5	Anxiety (before) – Anxiety (after)	4.400	10.968	30	0.000
Pair 6	Drowsiness (before) – Drowsiness (after)	4.652	6.667	16	0.000
Pair 7	Loss of appetite (before) – Loss of appetite (after)	2.228	1.536	5	0.185
Pair 8	Well-being (before) – Well-being (after)	3.691	13.532	46	0.000

We can observe a benefit of art therapy on the different assessed symptoms.

In Table 1 and Figure 1, the scores for most symptoms show a statistically significant decrease, except for appetite loss, for which the difference is not statistically significant.

The positive impact of art therapy was assessed using a paired t-test. Table 2 shows that these differences are statistically significant, with a reduction in pain ($p = 0.002$) and fatigue ($p < 0.001$), among others.

In contrast, appetite loss did not improve ($p = 0.185$), which may be explained by the nature of this symptom, which is weakly correlated with the patient's psychological well-being and is mainly related to the disease itself and its treatments.

Data analysis was performed in collaboration with Dr Grillo Dias, medical oncologist at the Centre Hospitalier de Périgueux.

APPENDIX 4

FACT-G (Version 4)

Below is a list of statements that other people with your condition have found important. Please circle or select one number per line to indicate your response as it applies to the past 7 days.

PHYSICAL WELL-BEING

Item	Statement	Not at all	A little bit	Somewhat	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by the side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

SOCIAL / FAMILY WELL-BEING

Item	Statement	Not at all	A little bit	Somewhat	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I receive emotional support from my family	0	1	2	3	4
GS3	I receive support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with communication within my family about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	Regardless of your current level of sexual activity, please answer the following question. ☐ If you prefer not to answer, please tick this box and skip to the next section.					
GS7	I am satisfied with my sex life	0	1	2	3	4

EMOTIONAL WELL-BEING

Item Statement	Not at all	A little bit	Somewhat	Quite a bit	Very much
GE1 I feel sad	0	1	2	3	4
GE2 I am satisfied with how I cope with my illness	0	1	2	3	4
GE3 I am losing hope in the fight against my illness	0	1	2	3	4
GE4 I feel nervous	0	1	2	3	4
GE5 I am afraid of dying	0	1	2	3	4
GE6 I am concerned that my condition will worsen	0	1	2	3	4

FUNCTIONAL WELL-BEING

Item Statement	Not at all	A little bit	Somewhat	Quite a bit	Very much
GF1 I am able to work (including work at home)	0	1	2	3	4
GF2 My work (including work at home) is fulfilling	0	1	2	3	4
GF3 I am able to enjoy life	0	1	2	3	4
GF4 I have accepted my illness	0	1	2	3	4
GF5 I sleep well	0	1	2	3	4
GF6 I enjoy the things I usually do for fun	0	1	2	3	4
GF7 I am satisfied with the quality of my life at present	0	1	2	3	4

Date: _____ **Investigator's signature:** _____

APPENDIX 5 ARONCO Art Therapy Questionnaire

ANONYMISATION CODE: I _ I _ I _ I _ I _ I

VISIT No.: I _ I _ I

DATE: I _ I _ I / I _ I _ I / I _ I _ I _ I _ I

1. Were you aware of art therapy before?

☐ Yes ☐ No

2. Since you have been receiving art therapy during your treatments, do you feel an improvement in well-being?

2.a During treatment

0 1 2 3 4 5
I _ I _ I _ I _ I _ I

2.b After treatment

0 1 2 3 4 5
I _ I _ I _ I _ I _ I

2.c Before each new treatment

0 1 2 3 4 5
I _ I _ I _ I _ I _ I

3. Has your relationship with those around you changed since you started art therapy?

(Conversations are not solely focused on the illness)

☐ Yes ☐ No

4. Since you have been receiving art therapy during your treatments, do you feel you are:

4.a Valued

0 1 2 3 4 5
I _ I _ I _ I _ I _ I

4.b More communicative

0 1 2 3 4 5
I _ I _ I _ I _ I _ I

4.c More involved in projects

0 1 2 3 4 5
I _ I _ I _ I _ I _ I

5. Since you have been receiving art therapy, do you practice any artistic or visual activity at home related to what you did during art therapy sessions?

☐ Yes ☐ No

Date: _____ Investigator's signature: _____



APPENDIX 6

ARONCO Study

Case Report Form (CRF)

Version: 3.2 dated 25/09/2019

Application of art therapy in oncology: evaluation of patients' symptomatology

Patient anonymisation code: I__I__I__I - I__I__I

Principal Investigator: Élodie BARBUT PAILLARD, Art Therapist
elodie.paillard@laposte.net

Sponsor:

Centre Hospitalier de Périgueux
80, avenue Georges Pompidou
24019 Périgueux Cedex, France

Clinical Research Associate: Myriam KOCH
Tel: +33 (0)5 53 45 25 25, extension 1978

Date: _____ Investigator's signature: _____

INSTRUCTIONS FOR COMPLETING THE CASE REPORT FORM

- Use a black ballpoint pen to complete the questionnaire to ensure that the copy remains legible.
- Write legibly in capital letters, with one character per box, without abbreviations or acronyms, and in uppercase.
- The header (and footer if applicable) must be completed on each page.
- Standard medical terminology must be used when completing the CRF.
- **Anonymisation code:** inclusion number in chronological order, followed by the first letter of the surname and the first letter of the first name. Example: Girard Daniel → anonymisation code: |0|0|1| - |G|D|
- The number of boxes per variable must not be modified without prior approval from the data manager (e.g., adding decimals). Otherwise, data entry by the data entry team may not be possible.
- Enter data using one character per box only.
- If space is insufficient, complete the response on a separate sheet, indicating the section number of the questionnaire and signing it for authentication.

Numeric data entry rules:

- Align numbers to the right.
- Do not leave empty boxes; enter '0' if necessary. Example: incorrect |2|1|_| correct |0|2|1|

If the response is:

- “Not determined”: enter ND
- “Not done”: enter NF
- “Not applicable”: enter NA
- Dates must be entered in the format dd/mm/yyyy unless otherwise specified.
- Before entering a missing value code, ensure that this code is not a possible valid value. This code is obtained by filling the corresponding boxes with '9' (including decimals if applicable), only when it is certain that the item will never be completed in this way. These codes must be validated with the data manager before study start.
- When correcting data, the incorrect value must be crossed out (remaining visible), corrected clearly nearby, dated, and signed. Correction fluid must not be used.

STUDY FLOW CHART (INVESTIGATIONS)

Procedures	Pre-screening visit	Inclusion visit	Follow-up visits (V1 to V6)	End of study
Verification of inclusion and non-inclusion criteria	X	X		
Oral and written information provided	X	X		
Collection of dated and signed informed consent		X		
Anonymisation / inclusion		X		
Randomisation		X		
Art therapy for experimental group		X	X	
FACT-G questionnaire		X		X
ESAS questionnaire		X	X	X
Art therapy satisfaction questionnaire				X

Exit visit and end-of-study questionnaire				X
---	--	--	--	---

ANONYMISATION CODE: I__I__I__I - I__I__I

Art therapy arm: ☐

No art therapy arm: ☐

Sex: ☐ Male ☐ Female

Year of birth: I__I__I__I

Pathology: ☐ Hematological cancer ☐ Solid cancer (specify:)

INCLUSION CRITERIA

- Age $\geq$ 18 years ☐ YES ☐ NO
- Patients treated in the Day Hospital (Oncology / Hematology) with a cancer diagnosis
☐ YES ☐ NO
- Patient informed consent obtained ☐ YES ☐ NO
- Patient affiliated with a social security system ☐ YES ☐ NO

NON-INCLUSION CRITERIA

- Minor patient ☐ YES ☐ NO
- Patient under legal protection (guardianship / curatorship) ☐ YES ☐ NO
- Severe impairment of vital and/or cognitive functions preventing participation and understanding of the study ☐ YES ☐ NO
- Expected duration of care shorter than the follow-up period within the Day Hospital of Oncology-Hematology at Centre Hospitalier de Périgueux ☐ YES ☐ NO
- Previous participation in art therapy ☐ YES ☐ NO
- Current participation in another clinical study ☐ YES ☐ NO

VISIT DATES

Visite 1 : Inclusion	Visite 2	Visite 3	Visite 4	Visite 5	Visite 6	Sortie d'étude

Reason for postponement:

.....

Date: _____ Investigator's signature: _____

Anonymisation code: |_|_|_|_|_|_|_|_|_|_|

ARONCO



FACT-G (Version 4)

Below is a list of statements that other people with your condition have found important. Please circle or select one number per line to indicate your response as it applies to the past 7 days.

PHYSICAL WELL-BEING

Item	Statement	Not at all	A little bit	Somewhat	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by the side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

SOCIAL / FAMILY WELL-BEING

Item	Statement	Not at all	A little bit	Somewhat	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I receive emotional support from my family	0	1	2	3	4
GS3	I receive support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with communication within my family about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	Regardless of your current level of sexual activity, please answer the following question. ☐ If you prefer not to answer, please tick this box and skip to the next section.					
GS7	I am satisfied with my sex life	0	1	2	3	4

Anonymisation code: |_|_|_|-|_|_|

ARONCO



Please circle or select one number per line to indicate your response as it applies to the past 7 days.

EMOTIONAL WELL-BEING

Item Statement	Not at all	A little bit	Somewhat	Quite a bit	Very much
GE1 I feel sad	0	1	2	3	4
GE2 I am satisfied with how I cope with my illness	0	1	2	3	4
GE3 I am losing hope in the fight against my illness	0	1	2	3	4
GE4 I feel nervous	0	1	2	3	4
GE5 I am afraid of dying	0	1	2	3	4
GE6 I am concerned that my condition will worsen	0	1	2	3	4

FUNCTIONAL WELL-BEING

Item Statement	Not at all	A little bit	Somewhat	Quite a bit	Very much
GF1 I am able to work (including work at home)	0	1	2	3	4
GF2 My work (including work at home) is fulfilling	0	1	2	3	4
GF3 I am able to enjoy life	0	1	2	3	4
GF4 I have accepted my illness	0	1	2	3	4
GF5 I sleep well	0	1	2	3	4
GF6 I enjoy the things I usually do for fun	0	1	2	3	4
GF7 I am satisfied with the quality of my life at present	0	1	2	3	4

Date: _____ Investigator's signature: _____

APPENDIX 2: ESAS Symptom Assessment Questionnaire

ARONCO

ANONYMISATION CODE: I _ I _ I _ I _ I _ I

VISIT No.: I _ I _ I

DATE : I _ I _ I / I _ I _ I / I _ I _ I _ I

Questionnaire completed: ☒ before ☐ after

No Pain	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Pain
	0 1 2 3 4 5 6 7 8 9 10	
No Fatigue	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Fatigue
	0 1 2 3 4 5 6 7 8 9 10	
No Nauséa	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Nauséa
	0 1 2 3 4 5 6 7 8 9 10	
No Depression	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum depression
	0 1 2 3 4 5 6 7 8 9 10	
No Anxiety	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Anxiety
	0 1 2 3 4 5 6 7 8 9 10	
No drowsiness	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum drowsiness
	0 1 2 3 4 5 6 7 8 9 10	
No Loss of appetite	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Loss of appetite
	0 1 2 3 4 5 6 7 8 9 10	
No Shortness of breath	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Shortness of breath
	0 1 2 3 4 5 6 7 8 9 10	
Feeling well	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Feeling unwell
	0 1 2 3 4 5 6 7 8 9 10	

Other symptom (sweating, dry mouth, dizziness, sleep disturbances, etc.): _____

I _ I _ I _ I _ I _ I _ I _ I _ I _ I

0 1 2 3 4 5 6 7 8 9 10

Date :

Investigator's signature:

Based on the ESAS (Edmonton Symptom Assessment System) scale, University Hospitals of Geneva.



APPENDIX 2: ESAS Symptom Assessment Questionnaire

ARONCO

ANONYMISATION CODE: I _ I _ I _ I _ I _ I

VISIT No.: I _ I _ I

DATE : I _ I _ I / I _ I _ I / I _ I _ I _ I

Questionnaire completed: ☐ before ☒ after

No Pain	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Pain
	0 1 2 3 4 5 6 7 8 9 10	

No Fatigue	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Fatigue
	0 1 2 3 4 5 6 7 8 9 10	

No Nausée	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Nausée
	0 1 2 3 4 5 6 7 8 9 10	

No Depression	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum depression
	0 1 2 3 4 5 6 7 8 9 10	

No Anxiety	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Anxiety
	0 1 2 3 4 5 6 7 8 9 10	

No drowsiness	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum drowsiness
	0 1 2 3 4 5 6 7 8 9 10	

No Loss of appetite	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Loss of appetite
	0 1 2 3 4 5 6 7 8 9 10	

No Shortness of breath	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Maximum Shortness of breath
	0 1 2 3 4 5 6 7 8 9 10	

Feeling well	I _ I _ I _ I _ I _ I _ I _ I _ I _ I	Feeling unwell
	0 1 2 3 4 5 6 7 8 9 10	

Other symptom (sweating, dry mouth, dizziness, sleep disturbances, etc.): _____

I _ I _ I _ I _ I _ I _ I _ I _ I _ I
0 1 2 3 4 5 6 7 8 9 10

Date :

Investigator's signature:

Based on the ESAS (Edmonton Symptom Assessment System) scale, University Hospitals of Geneva.



APPENDIX 5

ARONCO

Art Therapy Questionnaire

ANONYMISATION CODE: I _ I _ I _ I _ I _ I

VISIT No.: I _ I _ I

DATE: I _ I _ I / I _ I _ I / I _ I _ I _ I _ I

1. Were you aware of art therapy before?

☐ Yes ☐ No

2. Since you have been receiving art therapy during your treatments, do you feel an improvement in well-being?

2.a During treatment

0 1 2 3 4 5
I _ I _ I _ I _ I _ I

2.b After treatment

0 1 2 3 4 5
I _ I _ I _ I _ I _ I

2.c Before each new treatment

0 1 2 3 4 5
I _ I _ I _ I _ I _ I

3. Has your relationship with those around you changed since you started art therapy?

(Conversations are not solely focused on the illness)

☐ Yes ☐ No

4. Since you have been receiving art therapy during your treatments, do you feel you are:

4.a Valued

0 1 2 3 4 5
I _ I _ I _ I _ I _ I

4.b More communicative

0 1 2 3 4 5
I _ I _ I _ I _ I _ I

4.c More involved in projects

0 1 2 3 4 5
I _ I _ I _ I _ I _ I

5. Since you have been receiving art therapy, do you practice any artistic or visual activity at home related to what you did during art therapy sessions?

☐ Yes ☐ No

Date: _____

Investigator's signature: _____

N° D'ANONYMISATION: I_I_I_I - I_I_I_I

ARONCO

ESAS DATA COLLECTION

Visit No.	Visit date	Pain (Before)	Pain (After)	Fatigue (Before)	Fatigue (After)	Nausea (Before)	Nausea (After)	Depression (Before)	Depression (After)	Anxiety (Before)	Anxiety (After)	Drowsiness (Before)	Drowsiness (After)	Appetite loss (Before)	Appetite loss (After)	Well-being (Before)	Well-being (After)
1																	
2																	
3																	
4																	
5																	
6																	

Date :

Signature Investigateur :

FACT-G (Version 4) DATA COLLECTION

ANONYMISATION CODE: I_I_I_I - I_I_I_I

Date	GP1	GP2	GP3	GP4	GP5	GP6	GP7	GS1	GS2	GS3	GS4	GS5	GS6	GS7	GE1	GE2	GE3	GE4	GE5	GE6	GF1	GF2	GF3	GF4	GF5	GF6	GF7
At baseline (start of treatment)																											
At end of treatment																											

Date :

Signature Investigateur :

ANONYMISATION CODE: I _ I _ I _ I -
I _ I _ I

Data collection: Supportive care

- Which supportive care services do you receive within the department?

- ☐ Art therapy (art therapy group) ☐ Socio-aesthetic care
☐ Psychologist ☐ Osteopath

- Apart from the care provided at the Day Hospital, did you participate in other workshops or therapies that improve your well-being?

- ☐ Yes ☐ No ☐ No opinion

If yes, please specify:

.....
.....
.....

END OF STUDY

Did the patient complete the study?

☐ YES: Date of last visit: | _ | _ | / | _ | _ | / | _ | _ | _ | _ |

☐ NO: Date of last contact: | _ | _ | / | _ | _ | / | _ | _ | _ | _ |

If no, reason for discontinuation (one answer only):

- ☐ Treatment limitation
☐ Major protocol deviation (e.g., non-compliance with inclusion/exclusion criteria, randomisation error)

If YES, please specify:

.....

☐ Patient decision but does not object to data use

☐ Patient decision and objects to data use

☐ Lost to follow-up

☐ Patient death

☐ Other reason:

Date: _____

Investigator's signature: _____

APPENDIX 7

INFORMATION LETTER

Version: 1.2 dated 01/08/2019

ARONCO

APPLICATION OF ART THERAPY IN ONCOLOGY ASSESSMENT OF SYMPTOMS IN PATIENTS WITH CANCER

Coordinating Investigator:

BARBUT PAILLARD ELODIE

Art Therapist of Hôpital de Jour d'Hématologie Oncologie

Sponsor

Centre Hospitalier de Périgueux

80 avenue Georges Pompidou

24019 PERIGUEUX CEDEX

You are invited to take part in a paramedical study. The aim of this study is to assess your experience of illness following an art therapy session during your Day Hospital treatment.

Art therapy uses the benefits of an artistic technique to help improve or maintain your abilities in expression, communication, and relationships. You may choose the technique (free or guided painting, watercolour pencils, pastels, clay, or other artistic activities) as well as your mode of expression, and are therefore an active participant in your care. The aim is to foster creative potential, self-assertion, and often a sense of well-being.

The Centre Hospitalier de Périgueux is the sponsor of this study; it is responsible for it and ensures its organisation. The hospital has taken out civil liability insurance with SHAM (Lyon, France).

Before deciding whether or not to participate in this study, it is important that you understand its purpose and implications. Please take the time to carefully read the following information and, if you wish, discuss it with your relatives. If any points are unclear or if you require further information, please do not hesitate to ask the healthcare team.

This research does not present any risk to your health. The results will not provide direct benefits for your individual health. However, they will contribute to the development of knowledge in the field of art therapy and to the validation of innovative practices in oncology care pathways.

To conduct this study, your personal data will be processed electronically in order to analyse the results. A computer file containing your data will therefore be created. For confidentiality reasons and to protect your privacy, your data will be coded. Only healthcare professionals directly involved in your care will have access to your identifiable information. This data may be used in scientific publications or communications.

In accordance with the French Data Protection Act (amended Law of 6 January 1978), Law No. 2018-493 of 20 June 2018 on personal data protection, and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (GDPR), you have the right to access, rectify, erase, transfer, and restrict the processing of your personal data. You may also lodge a complaint with a supervisory authority (CNIL for France: <https://www.cnil.fr/fr/plaintes>).

Your data may be transferred nationally or internationally between research teams in countries that may not have the same level of personal data protection requirements. These transfers, in anonymised form, are authorised by the CNIL. The data may be used in future research exclusively for scientific purposes. You may withdraw your consent to such future use or exercise your right to object at any time. You may exercise your rights of access and rectification with the investigator mentioned at the beginning of this document.

This project and this document were submitted to the Committee for the Protection of Persons (CPP) Sud-Est II and received a favourable opinion dated 12/11/2019.

You are free to accept or refuse participation in this study.

- If you accept, you may withdraw your consent at any time without providing justification, and this will not affect the quality of your care. In this case, data collected prior to withdrawal may still be used unless you explicitly object. Data collected after withdrawal will not be used for research and will remain exclusively for clinical care purposes.
- If you refuse to participate, your data will not be used for research and will remain exclusively for clinical care purposes.

The art therapist who proposed this study and provided you with oral information can answer any questions you may have and, upon request, inform you of the overall results of the study.

If you decide to participate in this study, the investigator or study personnel will ask you to sign a consent form. This signature confirms your agreement to participate in the study.

FORMULAIRE DE CONSENTEMENT

Version 1.2 en dated 27/07/2019

“Application of Art Therapy in Oncology: Assessment of Patient Symptomatology”

Coordinating Investigator:

BARBUT PAILLARD ELODIE

Art Therapist of Hôpital de Jour d'Hématologie Oncologie

Sponsor

Centre Hospitalier de Périgueux

80 avenue Georges Pompidou

24019 PERIGUEUX CEDEX

I, the undersigned (Surname, First name), confirm that I have read and understood the information sheet provided to me.

I have had the opportunity to ask any questions I wished to

..... (Surname, First name), who explained to me the nature, objectives, potential risks, and constraints related to my participation in this research.

I am aware that I may withdraw from this study at any time without having to justify my decision, and I will make every effort to inform the art therapist supervising my participation in the study. This will not affect the quality of my subsequent care.

I have been informed that all necessary medical decisions concerning my health will be made at any time in accordance with current medical knowledge.

I acknowledge that this research has received a favourable opinion from the Committee for the Protection of Persons (CPP) Sud-Est II. The study sponsor (Centre Hospitalier de Périgueux, 80 avenue Georges Pompidou, 24000 Périgueux, France) has taken out civil liability insurance with SHAM (Lyon, France).

I agree that the data recorded in the course of this study may be subject to computerised processing under the responsibility of the sponsor.

I acknowledge that, in accordance with data protection regulations, I have the right of access, rectification, and erasure of my personal data. I also have the right to object to the transmission of data covered by professional confidentiality that may be used and processed within this study. These rights may be exercised through the healthcare professionals responsible for my care within the study, who are aware of my identity.

My consent does not in any way release the investigator from their responsibility towards me. I retain all rights guaranteed by law.

The overall results of the study will be communicated to me directly, if I so wish, in accordance with the French law of 4 March 2002 relating to patients' rights and the quality of the healthcare system.

☐ I wish to receive the overall results of this study once they become available.

Done in

.....

On / /

Participant's signature:

Done in

On / /

Investigator's signature:

ANNEX 9

INVESTIGATOR CV

Last name: BARBUT PAILLARD **First name:** ELODIE
Date of birth: 08/07/1984

Status: Art Therapist
Current position: Art Therapist

Professional address:
Périgueux Hospital Center
Day Hospital – Hematology / Oncology
Périgueux Hospital Center
80, avenue Georges Pompidou - CS 61205
24019 PÉRIGUEUX Cedex

Phone: 06 66 55 69 90
Email: elodie.paillard@laposte.net

Professional Experience	
Position(s) / Department(s): January 2019 – Present: EHPAD Yvan Roque, Issigeac One day per week December 2015 – Present: Day Hospital, Hematology-Oncology Périgueux Hospital Center One day per week, then part-time since January 1st, 2019 January 2014 – March 2014: France Alzheimer Dordogne Périgueux outpatient service May 2012 – May 2013: EHPAD Les Jardins de Cybèle, Prigonrieux 1.5 hours, two Wednesday afternoons per month Protected Alzheimer unit July 2011 – November 2015: EHPAD Yvan Roque, Issigeac One day per week	January 2011 – July 2011: EHPAD Rivière Espérance, Lalinde via France Alzheimer Association August 2010 – December 2011: EHPAD Bourdeilles Working with elderly people with mental disabilities (Mural fresco project) – Fixed-term contract May 2010 – March 2014: Implementation of Music Therapy workshops St Jacques Nursing Home, Bergerac via France Alzheimer Dordogne 2 hours per week April 2009 – March 2014: Montoroy Nursing Home, Bergerac via France Alzheimer Dordogne 2 hours per week May 2009 – March 2011: Le Verger des Balans, Annesse-Beaulieu Cognitive and Behavioral Unit and Nursing Home 4 hours per week

Education

Name of State/Professional Qualification: University Diploma in Art Therapy

Year: 2009 **Location:** Faculty of Medicine, Poitiers

National Registration Number: (optional)

Additional training, other degrees (DU, Master, etc.):

2007 – Certificate of Competence in Cultural Support for Individuals, Tours (47)

2006 – National Diploma in Fine Arts, Higher School of Fine Arts of Cornouaille, Quimper (29)

2005 – Certificate of Fine Arts Studies (ESBAC) (experimental phase)

2003 – Literary Baccalaureate, Bertran de Born High School, Périgueux (24)

Mandatory option: History of Arts (3 years), optional subject: Visual Arts

Skills (Project management, trainer, languages, etc.):

English: Intermediate level

Spanish: Intermediate level

Research Experience

Affiliation with a research organization or accredited unit:

☒ YES

☐

NO

If yes, specify: Clinical Research Unit, Périgueux Hospital Center

Participation in the design of research projects:

☐ YES

☒

NO

If yes, specify year / topic / call for projects (AAP):

•

Participation in the implementation of research projects:

☐ YES

☒

NO

If yes, specify year / topic:

•

Coordination of research projects:

☐ YES

☒

NO

If yes, specify year / topic / AAP:

•

Research Training:

☒ YES

☐

NO

If yes, specify type/title and year:

• August 1st, 2018: E-learning – Full FORMEDEA training program in Good Clinical Practice

Annexe 10

South-East II Research Ethics Committee Opinion on a Substantial Amendment

CPP

CPP Name: Ethics Committee for the Protection of Persons South-East II (Comité de Protection des Personnes Sud-Est II)

Address: East Hospital Group – Pinel Building – 59 Boulevard Pinel, 69500 Bron, France Email: cpp.sud-est-2@chu-lyon.fr

Telephon:

Sponsor / Applicant

Sponsor: Périgueux Hospital Center Legal

Representative (EU):

Authorized Representative:

Application File

SI Number: 19.01693.000030-MS01.3

National Number: 2018-A03304-51

Internal Reference: 2019-30

Regulatory Framework: Jardé Law

Study Category: Category 2

Product or Procedure: Outside the scope of health products (products not covered by Article L.5311-1 of the French Public Health Code)

Principal Investigator: BARBUT PAILLARD Élodie

Study Title: ARONCO

Information Substantial

Modification Number: 1.3

Reason for the Substantial Modification: Participant recruitment has taken longer than anticipated due to the COVID-19 pandemic, changes in patient management (occupational therapy, short-stay care pathway, etc.), recruitment of additional surgeons, and changes in treatment administration. We therefore request an extension of the recruitment period until 17 March 2025.

Overview of Previous Reviews

Files	Opinion	Date of Issuance (or Date of Validation of the Historical File in the SIRIPH 2G System)
19.01693.000030	Approved	11/02/2021 Previous determinations are available in the "Historical Information" section.
19.01693.000030-MS01.1	<i>Favorable</i>	02/10/2022

This submission was reviewed at the meeting held on April 26, 2023. Based on the responses received, the Ethics Committee issued the following opinion. This opinion became effective on the date the submission status was updated in the information system.

Having determined that the applicable ethical requirements, including those specified in Article L.1123-7 of the French Public Health Code, have been satisfied, the Ethics Committee concluded that the research may proceed and issued the following opinion:

Favorable opinion

Committee Members Participating in the Deliberation

Panel	Category	Last and first name
Panel 1	RIPH Qualification – Biostatistics or Epidemiology	CORNU Catherine
Panel 1	RIPH Qualification – Biostatistics or Epidemiology	GAILLARD Ségolène
Panel 1	RIPH Qualification – Biostatistics or Epidemiology	NGUYEN Kim An
Panel 1	RIPH Qualification – Other	BIENVENU Jacques
Panel 1	Hospital Pharmacist	NAGEOTTE Alain
Panel 2	Ethics Expertise	BEUVELOT Johanne
Panel 2	Ethics Expertise	SORDILLON Maxime
Panel 2	Ethics Expertise	LONCKE Cécile
Panel 2	Ethics Expertise	URSINI-MAURIN Carine
Panel 2	Ethics Expertise	MOREAU Justine
Panel 2	Representative of an Accredited Association	GALLAND Emma
Panel 2	Representative of an Accredited Association	POLICANTE Raymond
Panel 2	Representative of an Accredited Association	CHARDINY Marie
Panel 2	Representative of an Accredited Association	JARSAILLON Christine

Documents Reviewed by the Research Ethics Committee

Category	Title	Date of Submission
ASS - Assurance	<i>2018-A03304-51_Assurance_20230127_ARONCO.pdf</i>	03/10/2023
ASS - Assurance	<i>2018-A03304-51_Contrat assurance de responsabilité civile_20200128_ARONCO.pdf</i>	04/11/2023
ASS - Assurance	<i>2018-A03304-51_Assurance_20230420_ARONCO.pdf</i>	04/20/2023
COU - Courrier	<i>2018-A03304-51_Courrier de réponse_v1_20230411_ARONCO.pdf</i>	04/11/2023
COU - Courrier	<i>2018-A03304-51_courrier de réponse_v1_20230420_ARONCO.pdf</i>	04/20/2023
Courrier de demande de modification substantielle	<i>2018-A03304-51_Courrier de demande de modification substantielle_v1_20230228_ARONCO.pdf</i>	03/10/2023
DEM - Demande autorisation	<i>2018-A03304651_Demande de mesure substantielle_20230228_ARONCO.pdf</i>	03/10/2023
Formulaire de demande de MS	<i>2018-A03304-51_Formulaire de demande de mesure substantielle_v1_20230228_ARONCO.pdf</i>	03/10/2023
Les informations justifiant le bien-fondé de chaque modification	<i>2018-A03304-51_justification de la mesure</i>	03/10/2023

	<i>substantielle_v1_20230228_ARONCO.pdf</i>	
PRO - Protocole	<i>2018-A03304-51_Protocole_v5-7_20230210_ARONCO.pdf</i>	03/10/2023
Tableau comparatif mettant en évidence les modifications apportées dans les documents de la demande initiale	<i>2018-A03304-51_Tableau comparatif des modifications_v1_20230228_ARONCO.pdf</i>	03/10/2023
Tableau récapitulatif de l'ensemble des MS et MNS survenues depuis le DI	<i>2018-A03304-51_Tableau récapitulatif des demandes de mesure_v1_20230228_ARONCO.pdf</i>	03/10/2023

**Documents identified as non-compliant in the RIPH2G Information System (IS), or submitted for information or notification as part of this opinion request, were not reviewed by the Ethics Committee (CPP).*

**The titles of the documents reviewed by the Ethics Committee and listed in this opinion correspond to the file naming convention used by the applicant in the RIPH2G Information System (IS).*

For the South-East II Research Ethics Committee
The Chairperson, Miss Carine URSINI-MAURIN

Prepared on April 27, 2023

Carine Ursini-Maurin

Signé par Carine Ursini-Maurin

 Signé et certifié par **yousign** 

This document is a translation of the original French document.

Comité de protection des personnes Sud-Est II

Avis sur une modification substantielle

CPP

Nom du CPP : Comité de protection des personnes Sud-Est II
Adresse : Groupement hospitalier Est - Bâtiment Pinel - 59, Boulevard Pinel 69500 BRON France
Courriel : cpp.sud-est-2@chu-lyon.fr
Téléphone :

Promoteur / Demandeur

Promoteur : Centre Hospitalier Périgueux
Représentant légal (UE) : -
Mandataire : -

Dossier

Numéro SI : 19.01693.000030-MS01.3
Numéro national : 2018-A03304-51
Référence interne : 2019-30

Règlementation : Loi Jardé
Qualification : Catégorie 2
Produit ou acte : Hors produits de santé (produits non mentionnés à l'article L.5311-11 du code de la santé publique)

Investigateur : BARBUT PAILLARD ELODIE

Titre : ARONCO

Informations MS

Numéro de la MS : 1.3
Motif de la MS : Les Inclusions prennent plus de temps que prévu : arrêt COVID, modification prise en charge (TO, circuit court...),recrutement de chirurgien, modification administration des traitements...Nous demandons à repousser les inclusions jusqu'au 17 mars 2025.

Récapitulatif des avis antérieurs

Dossier	Avis	Date d'émission (ou date de validation du dossier historique sur le SIRIPH 2G)
19.01693.000030	Validé	02/11/2021 <i>Les avis précédents sont consultables dans la rubrique « informations historiques »</i>
19.01693.000030-MS01.1	Favorable	10/02/2022

Ce dossier a été étudié en séance le 26/04/2023 et au vu des réponses obtenues, l'avis suivant a donc été émis. Cet avis court à compter du changement de statut sur le SI.

Considérant que les conditions éthiques sont remplies notamment au regard des éléments de l'article L.1123-7 du code de la Santé Publique, l'examen du Comité permet de conclure que la recherche peut être réalisée et de rendre l'avis suivant :

Avis favorable

Personnes ayant délibéré

Collège	Catégorie	Nom et prénom
Collège I	Qualification RIPH - Biostatistique ou épidémiologie	CORNU Catherine
Collège I	Qualification RIPH - Biostatistique ou épidémiologie	GAILLARD Ségolène
Collège I	Qualification RIPH - Biostatistique ou épidémiologie	NGUYEN Kim An
Collège I	Qualification RIPH - Autre	BIENVENU Jacques
Collège I	Pharmacien hospitalier	NAGEOTTE Alain
Collège II	Compétence éthique	BEUVELOT Johanne
Collège II	Compétence éthique	SORDILLON Maxime
Collège II	Compétence juridique	LONCKE Cécile
Collège II	Compétence juridique	URSINI-MAURIN Carine
Collège II	Compétence juridique	MOREAU Justine
Collège II	Représentant d'association agréée	GALLAND Emma
Collège II	Représentant d'association agréée	POLICANTE Raymond
Collège II	Représentant d'association agréée	CHARDINY Marie
Collège II	Représentant d'association agréée	JARSAILLON Christine

Documents analysés par le CPP

Catégorie	Intitulé	Date de dépôt
ASS - Assurance	2018-A03304-51_Assurance_20230127_ARONCO.pdf	10/03/2023
ASS - Assurance	2018-A03304-51_Contrat assurance de responsabilité civile_20200128_ARONCO.pdf	11/04/2023
ASS - Assurance	2018-A03304-51_Assurance_20230420_ARONCO.pdf	20/04/2023
COU - Courrier	2018-A03304-51_Courrier de réponse_v1_20230411_ARONCO.pdf	11/04/2023
COU - Courrier	2018-A03304-51_courrier de réponse_v1_20230420_ARONCO.pdf	20/04/2023
Courrier de demande de modification substantielle	2018-A03304-51_Courrier de demande de modification substantielle_v1_20230228_ARONCO.pdf	10/03/2023
DEM - Demande autorisation	2018-A03304651_Demande de mesure substantielle_20230228_ARONCO.pdf	10/03/2023
Formulaire de demande de MS	2018-A03304-51_Formulaire de demande de mesure substantielle_v1_20230228_ARONCO.pdf	10/03/2023
Les informations justifiant le bien-fondé de chaque modification	2018-A03304-51_justification de la mesure	10/03/2023

	<i>substantielle_v1_20230228_ARONCO.pdf</i>	
PRO - Protocole	<i>2018-A03304-51_Protocole_v5-7_20230210_ARONCO.pdf</i>	10/03/2023
Tableau comparatif mettant en évidence les modifications apportées dans les documents de la demande initiale	<i>2018-A03304-51_Tableau comparatif des modifications_v1_20230228_ARONCO.pdf</i>	10/03/2023
Tableau récapitulatif de l'ensemble des MS et MNS survenues depuis le DI	<i>2018-A03304-51_Tableau récapitulatif des demandes de mesure_v1_20230228_ARONCO.pdf</i>	10/03/2023

**Les documents étiquetés non-conformes sur le SI RIPH2G ou transmis pour information/notification dans le cadre de cette demande d'avis n'ont pas été évalués par le CPP.*

**L'intitulé des documents examinés par le comité, listés sur le présent avis, reprend la nomenclature des fichiers utilisée par le déposant sur le SI RIPH2G.*

Pour le CPP SUD EST II,
La Présidente, Me Carine URSINI-MAURIN

Fait le 27/04/2023

Carine Ursini-Maurin

Signé par Carine Ursini-Maurin

 Signé et certifié par **yousign** 