Institut de Cancérologie de l'Ouest
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Short title :	**SOPHNEURO**
Ref ICO :	ICO-2020-12
N° IDRCB:	2021-A02313-38
NCT:	NCT05189366

Brief Protocol

PROTOCOL SOPHNEURO

A) IDENTIFICATION OF THE CLINICAL TRIAL			
TITLE OF THE TRIAL:	***Study evaluating the benefits of combining sophrology treatment with speech therapy for patients with glial tumours requiring speech therapy***		
SHORT TITLE:	**SOPHNEURO**		
COORDINATOR:	Céline THOMAS		
METHODOLOGISTS :	Dr Audrey BLANC-LAPIERRE and Julie PAUL		
ESTIMATED NUMBER OF CENTERS:	1 (ICO Nantes and Angers)	**NUMBER OF SUBJECTS:**	40

B) IDENTIFICATION OF THE SPONSOR	
SPONSOR:	INSTITUT DE CANCEROLOGIE DE L'OUEST
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C) RATIONALE

Patients with brain tumors experience a loss of autonomy, which may occur suddenly or progressively. Communication with the patient can be rapidly impaired due to altered levels of consciousness, language disorders, and/or neurocognitive impairments.

In addition to these clinical symptoms, patients frequently present with high levels of anxiety and depression as a result of the severity of the diagnosis, leading to a major impact on quality of life.

Alongside standard oncological management, including surgery, radiotherapy, and chemotherapy, a **multidisciplinary rehabilitation approach** is recommended due to impairments related both to the pathology itself and to treatment-related neurotoxicity. This rehabilitation may involve physical therapists, occupational therapists, speech and language therapists, neuropsychologists, among others.

In this study, we will focus primarily on the subgroup of patients presenting with **communication disorders**, for whom speech and language therapy plays a key role.

In order to better address anxiety—which is often difficult to verbalize due to communication impairments—**sophrology** may be proposed as an alternative to psychological support, which can be overly complex or poorly adapted in this population.

Within the framework of **integrative oncology**, sophrology is considered a mind–body technique comparable to mindfulness meditation or hypnosis. Its aim is to positively enhance patients' personal resources and abilities. It induces modified states of consciousness and enables individuals to achieve a balance between thoughts, emotions, and behaviors.

If sophrology has a positive impact on patients' emotional well-being, it may also lead to improvements in motor function, interpersonal relationships, and overall quality of life.

After observing positive patient feedback following a combined speech therapy and sophrology intervention, this study aims to evaluate the benefits of integrating sophrology into the care of patients with **glial tumors** requiring speech and language therapy.

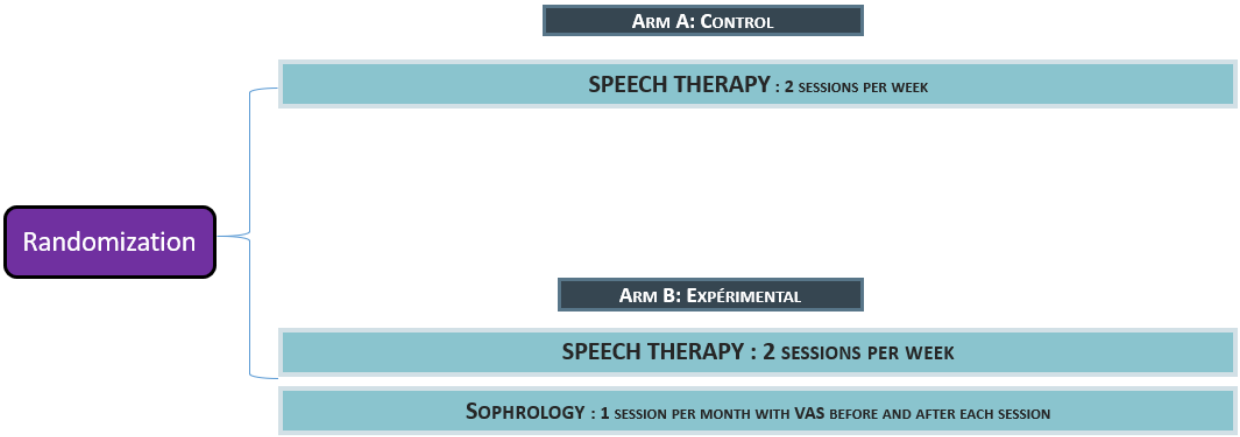
Our hypotheses are that this combined approach may reduce anxiety levels, improve quality of life, and positively influence the outcomes of speech and language rehabilitation.

D) GENERAL INFORMATION ABOUT THE TRIAL	
POPULATION:	Patients with grade II, III, and IV glial tumors requiring speech and language therapy.
METHODOLOGY	Randomized study (1:1), with stratification criteria: • Tumor grade: grade 2- 3 or grade 4 • Type of surgery: excision or biopsy • PS: 0-1 or 2-3 • Speech therapy started: yes or no
MAIN OBJECTIVE:	The primary objective is to compare the level of anxiety in the experimental arm with the control arm at 6 months.
PRIMARY EVALUATION CRITERION:	Primary endpoint is anxiety levels will be measured using the Hospital Anxiety and Depression Scale at 6 months in both treatment arms.
SECONDARY OBJECTIVE:	Secondary objectives are to evaluate: a) the impact of the practice of sophrology on the patient's quality of life. b) the impact of the practice of sophrology during speech therapy on the improvement of communication disorders; c) the effect of a sophrology session on anxiety; d) Level of anxiety in both arms at M0 and M3.
SECONDARY EVALUATION CRITERION:	Secondary endpoints are: a) Quality of life will be assessed using quality of life questionnaires at M0, M3 and M6. These are the EORTC QLQ-C30 v3 questionnaire and the EORTCBN20 brain-specific module; b) Improvement in communication disorders will be assessed by standard speech and language tests at M0, M3 and M6. These are standardized tests, adapted to the population, reproducible and validated by speech therapists; c) Anxiety will be assessed using the Visual Analog Scale (VAS) of anxiety and help before and after each sophrology session; d) The description of the level of anxiety in the two treatment arms at M0 and M3 will be carried out using the HADS.

INCLUSION CRITERIA:	1) Patients with histologically proven grade II, III and IV glial tumours requiring speech therapy; 2) Patient willing to start and/or continue outpatient speech therapy; 3) Patient aged 18 years and over; 4) Informed patient who has signed consent; 5) Patient affiliated to a social security scheme.
EXCLUSION CRITERIA:	1) Patient who has already had an initiation to sophrology in the context of his pathology; 2) PS ≥ 4 ; 3) Patients suffering from psychiatric disorders; delusional phases, schizophrenia against the practice of sophrology; 4) Patient unable to follow the protocol (filling in questionnaires, attendance of sophrology and/or speech therapy sessions) for geographical, social or psychological reasons; 5) Patients who do not speak French; 6) Persons deprived of their liberty, under court protection, under curators or under the authority of a guardian; 7) Women who are pregnant, likely to be pregnant or breastfeeding.

E) DESCRIPTION OF THE STUDY INTERVENTIONS

After randomization, patients who have signed a consent form receive the study procedures assigned to them.



CONTROL ARM : ***Arm A: Speech therapy*** Patients (control and experimental groups) will receive two speech therapy sessions per week for 6 months, lasting from 30 minutes to 1 hour, depending on the patient's general condition. The speech therapist will carry out a speech assessment to highlight the nature of the patient's disorders. This assessment is carried out at M0, M3 and M6. A session is divided into 3 parts. In the 1st part, the speech therapist will talk to the patient to discuss his or her state of health, his or her feelings about the previous session, and the compensatory strategies put in place during the previous session. In the second part, the speech therapist will begin the actual re-education, through a series of exercises based on a therapeutic plan (e.g. working memory with executive functions). Finally, the speech therapist will suggest an activity that the patient will be able to perform successfully, while reviewing the session and suggesting exercises to be carried out at home until the next session.
ARM EXPERIMENTAL: ***Arm B : Speech therapy + Sophrology*** In the experimental arm, patients will benefit from 6 sessions of sophrology. Sessions are individual and last around 50 minutes. During these sessions, the patient may be accompanied by a third party. The 1st sophrology session will take place at +/- 7 days from M0. Subsequent sessions are scheduled every 30 days, at +/- 7-day intervals. A sophrology protocol, i.e. a series of sessions, can be broken down into 3 key techniques: - SBV: Sophronisation de Base Vivantielle. This technique consists of adding mobilization or contraction of the body to facilitate perception. - PSL: Sophro-Liminal Protection. This technique involves associating an evocative word representing calm with the breath. - SPR: Sophro-Presence Relaxation. This technique consists in evoking "something" pleasant and putting as much detail as possible into it During the 1st session, a period of dialogue between the sophrologist and the patient will enable the latter's anamnesis to be taken. The sophrologist will then begin with the SBV technique. In subsequent sessions, the sophrologist will repeat the 1st SBV technique and complete it with the 2 other techniques, PSL and SPR. Before and after each session, the patient will be shown the Visual Analogue Scale for Anxiety and Help (VAS). Depending on the patient's state of health, sessions will be adapted and last between 30 and 45 min.

INTERVENTION DURATION :	6 months

F) STATISTICAL CONSIDERATIONS	
DETERMINATION OF SAMPLE SIZE	At the ICO, it is possible to include 40 patients per year with communication disorders. In a study including a control group of 19 patients with glioblastoma treated with hormonal therapy, chemotherapy and radiotherapy, a difference of 1.73 points in the HADS score was observed after 4 months (PMID: 29892240). The intra-individual standard deviation (calculated from the paired t-test value indicated s=√n*md/t) was approximately 3 points. The null hypothesis we wish to refute is that sophrology doesn't allow to show a difference in anxiety after 6 months (H0: md = 0). The inclusion of 20 patients per arm (i.e. 40 in total) will enable us to highlight, with an alpha risk of 5%, two-sided, and a power of 85%, a difference of 3 points at 6 months between the 2 groups compared.
STATISTICAL AND ANALYTICAL PLANS:	**Descriptive analysis of the study population** Categorial variables will be presented in terms of the number and associated percentage of each modality of the variable. Quantitative variables are described by mean and standard deviation or median, minimum and maximum, where applicable. The number of missing data is presented for each variable studied. **Analysis of primary endpoint** The level of anxiety (HADS) at M6 will be compared between the two groups using a Welch's test or a Mann-Whitney test (in case of non-Gaussian distribution of the variable). **Analysis of secondary endpoints** Quantitative variables will be compared between the two groups using a Welch's test or a Mann-Whitney test (in case of non-Gaussian distribution of the variable). Qualitative variables will be compared between the two groups using a Chi2 test or a Fisher test (in the case of theoretical numbers less than 5).

G) TRIAL SCHEDULE	
INCLUSION PERIOD:	36 months
INTERVENTION DURATION :	6 months
FOLLOW-UP PERIOD :	NA
OVERALL STUDY DURATION:	42 months