STUDY PROTOCOL & STATISTICAL ANALYSIS PLAN (SUMMARY)

Official Title: Information Consultation by a Manipulator Radiotherapy: Impact on Information to Patients Treated With Radiotherapy for Cancer

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1. Study Objective : The medical teams are increasingly sought by patients to get the most possible information, probably expressed in a different form and thereby supplementing the information already received. Coulter et al. reached similar conclusions in their study of the writings of patient information documents. They point out, moreover, the best adaptation of the patients better informed compared to those with less or no information.

This need for information varies over time. It is present before treatment begins, continues during treatment and persists after treatment. Given the specific features of radiotherapy, the manipulators are important interlocutors to participate in the accompanying caregiver time.

In conclusion, the quality of information delivered to the patient has been poorly evaluated, let alone with validated tools in this area.

The impact of information on the tolerance of the treatment also needs to be confirmed, knowing that an informed patient seems less anxious and better prepared for future treatment.

2. Study Design & Population : Prospective, open-label, randomized, single-center study.

Patients will be randomized using a **1:1 allocation ratio** into one of the 2 following arms:

- **Arm A:** Standard of care (including a consultation with the radiation oncologist prior to the simulation CT scan).
- **Arm B:** A specific consultation with a radiation therapist added to the standard of care.

Randomization will be stratified based on 2 factors:

- Patient age (< 70 years; >= 70 years)
- Type of treatment received (exclusive radiotherapy; non-exclusive radiotherapy)

This single-center study will include patients treated at the Centre Antoine Lacassagne scheduled to receive radiotherapy (either alone or combined with chemotherapy/immunotherapy) as definitive or post-operative adjuvant treatment for

the following primary malignancies: stomach, esophagus, biliary tract, prostate, breast, lung, anal canal, head and neck (H&N), pancreas, or female genitalia.

3. Eligibility Criteria

Inclusion Criteria:

- Patients with cancer of the head and neck, esophagus, stomach, breast, rectum, anal canal, prostate, lung, bile duct, pancreas or female genital histologically proven

- Patient being treated by radiotherapy alone or combined with chemotherapy / immunotherapy, exclusive treatment or adjuvant

- Age over 18 years

Exclusion Criteria:

- Patient has been treated with radiation to the tumor site

- Patient with metastatic stage disease

- Patient targeted for hypofractionated radiotherapy

4. Statistical Analysis Plan (SAP)

- **Primary Outcomes:** Information received by patients as measured by the EORTC QLQ-INFO25 questionnaire.

The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire - Information Module (EORTC QLQ-INFO25) is a validated 25-item self-reported tool assessing the information received by cancer patients.

The multi-item scale scores are linearly transformed to a 0 to 100 scale according to the EORTC scoring manual. Higher scores represent a better outcome (a higher level of received information). The mean global information score will be compared between the standard care group (Arm A) and the experimental group (Arm B).

- **Analysis:** Descriptive statistics were used to calculate percentages and 95% Confidence Intervals (CI).
- **Safety:** All-cause mortality was tracked descriptively. No formal sample size calculation or complex sequential modeling was required for this observational study.