MULTIDISCIPLINARY CONSULTATION TO SUPPORT RETURNING TO WORK AFTER CANCER TREATMENTS

CAP'Onco study

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Interventional research protocol involving people (category 2 for minimal risks and obligations)

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PROMOTER **INSTITUT BERGONIÉ**

Summary

Title of the study	**CAP'ONCO** **Measure to support returning to work**
Coordinator	**Ms GERAT-MULLER** Véronique, PhD Clinical psychologist Psychopathology/Neuropsychology
Scientific manager	**Ms WILKINS** Guilaine, social care framework
Number of centres planned	Single-centre Institut Bergonié study
Category	Research involving people that includes only minimal risks and obligations (Article L1121-1 2° of the French Public Health Code (*Code de la Santé Publique*)
Topic	Providing support when returning to work during and after cancer treatments. - social topic - psychological/neuropsychological topic
Target group	Patients who are living in Gironde, receiving follow-up care at the Institut Bergonié for cancer and in employment at the time of their diagnosis
Justification for the study	**1. Surviving cancer** – Improving the survival rate: cancer is becoming chronic (growing number of people affected by and living with the disease) – Cancer concerns more and more people who are working and have a long professional career ahead of them. – Reintegration into the workplace for those affected by cancer is an objective of each of the Cancer Plans. **2. Professional life and cancer** Of those who are affected by cancer in France every year, one third are working at the time of diagnosis. (DREES study Corroller-Soriano et al., updated in 2014 – ALD1 and VINCAN2 studies) – 82% of those interviewed aged 18 to 57 are in employment at the time of diagnosis. – This number became 61.3% two years later. – 15% of patients do not take a break from working. – 12% were on sick leave two years after diagnosis. – Feelings of isolation, rejection or discrimination in family, social and professional circles. **3. The Institut Bergonié's first action with regard to this issue ("*Coordination du parcours de soins pendant et après les traitements*" ("Coordination of treatment path during and after treatment") (2012) – national INCA call of projects), with conclusions that highlight:** – The difficulties for some patients who are anticipating returning to work during the treatment stage. – Isolation and lack of information for patients who are faced with multiple

	measures for readjusting to work. – A lack of cooperation between medical professionals with different authorities (specialist doctors and general practitioners, consultants and occupational health doctors), thus leading to contradictory guidance from these professionals. **4. A major factor in patient anxiety with regard to returning to work: cognitive problems** – the literature shows psychological difficulties with cognitive functions disrupted by chemo brain. – memory of work, attention, episodic memory, executive functions and processing speed are affected. – the impact of the indication and/or toxicity of treatments lead to cognitive after-effects that are significant and damaging to varying levels, altering quality of life and thus the return to work.
Methodology used	**Exploratory** study
Objectives	Enabling patients to receive active, practical and strategic support for returning to work over the course of treatment. Exploring the provision of the measure in terms of quality of life and motivation in returning to work, with the aim of also proposing an objective evaluation tool in order to confirm the relevance of a model for supporting patients treated for cancer over the course of their overall treatment. Our hypothesis is that early, lasting and multimodal support enables improvement in the patient's quality of life, improvement in cognitive complaint and strengthening professional motivation. Checking the practicability of the measure. Our hypothesis is that such a measure is feasible, helpful, easily accessible and recognised as being useful by patients.
Inclusion criteria	– Patients receiving follow-up care at Institut Bergonié – Signed information consent form – Patients who are members of a French social security scheme in compliance with Article L1121-11 of the French Public Health Code (*Code de la Santé Publique*) – Between 25 and 55 years old – Living in Gironde – Working at time of diagnosis – Treated for – breast cancer - non-cerebral Hodgkin or non-Hodgkin lymphoma - testicular cancer – CURATIVE treatment – At any stage of treatment
Exclusion criteria	– Patient deprived of liberty or the subject of a legal protection measure – Medical history of cancer – Cerebral pathology and/or cerebral metastasis
Roll-out of the study	**1. Inclusion**: Social and psychology assistant: - Gathering the consent forms - Execution of the evaluation scales: - QLQ-C30 version 3, Piper Fatigue Scale, Hospital Anxiety and Depression

	Scale (HADS), cognitive complaint scale (French FACT-COG version 3), motivation to return to work scale (not validated – IB doc) - Reinstating a schedule for the COGIT'Onco and TIC'Onco workshops - Proposing a date for a neuropsychological assessment (STROOP test - GREFEX array (2001), Trail Making Test - GREFEX array (2001), Baddeley's double test, Cardebat et al. verbal fluency test, (1990) - GREFEX array (2001), Rey figure test, memory of figures - Wechsler Adult Intelligence Scale (4th edition), Symbols and Code - 16-item "*Épreuve de rappel libre/rappel indicé*" (French adaptation of the Free and Cued Selective Reminding test) - Grober & Buschke test, 1987, TAP by Zimmerman & Fimm. - Proposing a social assessment. A medical questionnaire will be completed on inclusion (on the basis of the medical file) **2. Proposing access to an individual social and/or psychological assessment and/or follow-up** **3. In this CAP'Onco measure, the patient can take part in 2 workshops:** The TIC'Onco workshop is a collective information time, an informative meeting shared with an unrestricted patient group The COGIT'Onco workshop is a re-education workshop on post-treatment cognitive problems. The patient is enrolled in the workshops of their choice. They can participate in as many workshops as they like. There is no obligation or limitation to a particular process. After participating, there will be an evaluation of the workshop(s) visited. **4. the patient will be seen again 5 months** after the first consultation: Social and psychology assistant. Execution of the evaluation scales: QLQ-C30 version 3, Piper Fatigue Scale, Hospital Anxiety and Depression Scale (HADS), cognitive complaint scale (French FACT-COG version 3), motivation to return to work scale (not validated – IB doc), responses to the workshop evaluation questionnaires and the questionnaire on general satisfaction with the measure, questionnaire on social and medical situation at the end of the measure.
Evaluation criteria	**<u>Primary evaluation criteria</u>** 1. **Efficacy of the intervention felt by the patient in terms of improvement at 5 months** on quality of life, cognitive complaint and initial cognitive problems and professional motivation the CAP'Onco intervention will be judged effective if one of the following conditions is observed at 5 months in the CAP'Onco group: - Improvement in the quality of life and no deterioration of cognitive complaint and professional motivation - Improvement in the cognitive complaint and no deterioration in the quality of life and professional motivation - Improvement in professional motivation and no deterioration in the quality of life and cognitive complaint OR, if we do a comparison and see average scores that are significantly more positive for quality of life and professional motivation during the visit at 5 months. [Significant improvement in score: significant average difference between the scores at T0 and T1-5 months afterwards]

	Secondary evaluation criteria **2. Patient satisfaction: according to several scores** - satisfaction score for psychological/ neuropsychological consultations - satisfaction score for social consultations - satisfaction score for COGIT'Onco workshops - satisfaction score for TIC'Onco workshops **Patient satisfaction will be judged as good if the evaluation score for consultations, workshops and the general measure is higher than 20 for the TIC'Onco and COGIT'Onco workshops and higher than 4 for the overall CAP'Onco measure.** **3. Neuropsychological, emotional and asthenia evaluations** - Scores for the proposed neuropsychological assessment tests - Score for anxiety and depression-related problems - Score for the fatigue scale **4. Practicability and flexibility of the measure for receiving the patient** - period for arranging the first consultation: The reactivity of the measure will be judged as good if the period between the patient giving consent and the multidisciplinary consultation is less than 3 weeks. - Number of psychology/neuropsychology consultations - Number of social consultations - Number of participants in the COGIT'Onco workshops - Number of participants in the TIC'Onco workshops - Period between starting treatment and inclusion in the measure
Planned number of patients in the study	30 patients
Planned study duration	Inclusion period: 2 months Duration of follow-ups and evaluations: 5 months Duration of participation for a patient: 5 months. Study duration: 7 months. End of the study: 5 months after evaluating the last patient.
Statistical and data analyses considered	**Exploratory and descriptive study**: use of **multidimensional, exploratory statistical data analysis** techniques with the objective of a descriptive study (method, median, percentile, average, standard deviation, comparing averages) and a quantitative analysis of semi-structured interviews concerning motivation to return to work.
Anticipated impacts	Returning to work is a process that can bring up new vulnerability factors. The anticipated impact will be that this measure is noted, recognised and identified by consultants as: - a resource for patients who are experiencing or anticipate difficulties linked to returning to work. - Potential use in specific situations requires the expertise of all involved. This study could also make it possible to develop a measure that can be reproduced in different regions in connection with local partners and actors in the world of work. This project is in line with the primary purpose of treatment support: supporting the patient and their family and friends at every stage of their treatment path and afterwards.