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The Colofight feasibility study protocol

Hypnosis and Cognitive Behavioral Therapy with online sessions to reduce fatigue in patients undergoing chemotherapy for a metastatic colorectal cancer

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To address fatigue in cancer patients, both physical activity and psychosocial interventions are recommended ¹

- ColoRectal Cancer (CRC) patients reported barriers to physical activity programs (such as age, pain, or comorbidities ²
- Thus, psychosocial interventions are of interest. Studies have shown the effectiveness of CBT on fatigue in cancer patients ³⁻⁶ but there is a lack of studies on the effectiveness of hypnosis ⁷
- There is no study proposing CBT or Hypnosis to reduce fatigue in CRC patients, and there is a need to develop standardized interventions for specific populations. Because of the complex implementation in health care center, a feasibility study appears to be the first step



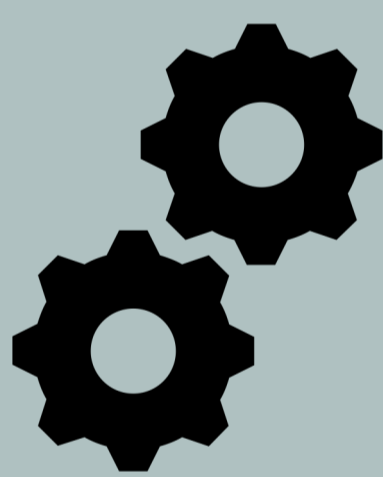
Literature Review

To assess the feasibility of two standardized interventions for fatigue reduction in patients with CCR

1. To assess acceptance to participate in the study and reasons for refusal
2. To identify the reasons for non-adherence to the program
3. To highlight the barriers/facilitators to the implementation of the protocol
4. To evaluate the relevance of the program (adapt to the patients' needs)
5. To assess fatigue (pre- and post-intervention) and its evolution
6. To describe the QoL at baseline and after the intervention

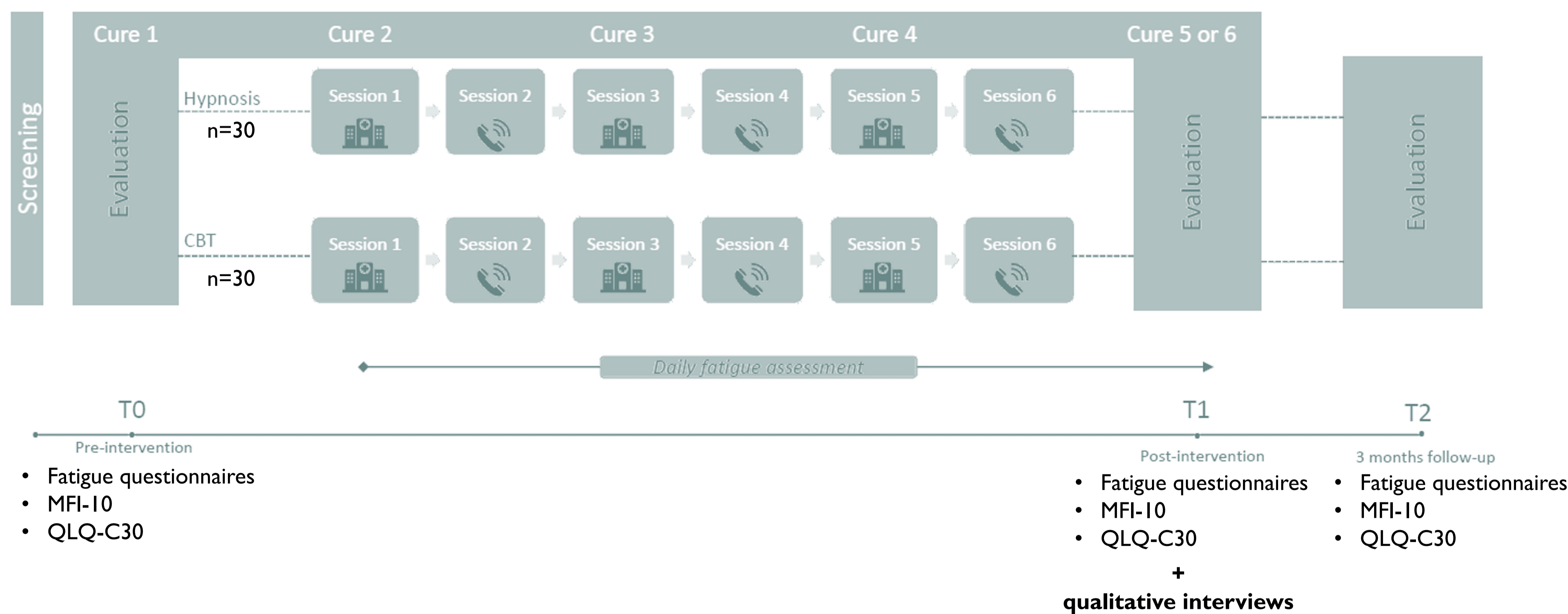


Objectives



Methods & Design

A prospective single-center randomized interventional feasibility study N=60



Description of the programs

- Both programs consist of 6 weekly sessions over a period of 6 weeks (1 session/week)
- They focus on CRF and its psychosocial determinants
 - Session 1: Patient Education about CRF
 - Session 2: Perceived control
 - Session 3: Emotional regulation
 - Session 4: Social support during illness
 - Session 5: Coping strategies
 - Session 6: Synthesis
- ✓ **CBT sessions are easily standardized. Our CBT program are inspired by previous studies ⁸⁻¹¹ and each of the exercises worked on during the session is adapted to the problematic of the session, with specific CBT exercises.**

How to standardized Hypnosis sessions ?

Audio-script ^{12,13} are one way to standardize but we lost patient's singularity and it remains difficult to establish what patients are doing at home

Face-to-face hypnosis sessions ¹⁴⁻¹⁶ based on a written script that each clinician read to the patients and minor wording changes to facilitate verbal flow could be an appropriate solution



Curious ? Flash-me

Development of a specific hypnosis session for fatigue, as in CBT

	CBT	Hypnosis
1 -		
2 -	Exercise on causal attributions (internal, external and hazard) To think about action to implement	Miracle question and search for exception based on Solution-focused therapy
3 -	To identify feelings and associated thoughts To list problematic situations To notice dysfunctional thoughts and searching for alternative thoughts	Safe place and work on emotion observations and rating Anchoring the feeling of well-being
4 -	To identify people resources for each type of support To learn how communicate needs and assertiveness	Rossi's mirroring hands to identify people who are social resources
5 -	To think about patient's behaviors and coping efficacy (Cunji's circle) To consider alternative behaviors	Work on metaphors and reifying the symptom
6 -		



1 NCCN, 2017 ; 2 Fisher et al., 2016 ; 3 Page et al., 2006 ; 4 Berger et al., 2009 ; 5 Morin et al., 2009 ; 6 Heckler et al., 2016 ; 7 Baussard et al., 2020 ; 8 Baussard et al., 2022 ; 9 Gielissen et al., 2006 ; 10 Gielissen et al., 2007 ; 11 Poort et al., 2017 ; 12 Bragard et al., 2017 ; 13 Grégoire et al., 2017 ; 14 Jensen et al., 2006 ; 15 Jensen et al., 2008 ; 16 Jensen et al., 2012