

# Psychological determiners of distincts fatigue trajectories in colorectal patients undergoing chemotherapy

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<b>Registration date</b> 27/12/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/03/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Most studies on tiredness (fatigue) in patients with cancer investigate its factors on a group level. Recent research focuses on the possibility that development of fatigue may differ widely in subgroups of patients.

This study aims to identify these subgroups of patients with clinically different patterns of fatigue, during a 6-month period of chemotherapy for colorectal cancer. Fatigue is a multifactorial concept which can be defined physically as far as psychologically. Our goal is to define the psychosocial determiners of fatigue patterns, based on a theoretical framework in health psychology (Bruchon-Schweitzer, 2002, 2014).

### Who can participate?

Adults aged over 18 years with colorectal cancer

### What does the study involve?

Participants meet a psychologist researcher at the start of the study and indicate their level of fatigue. This is recorded every two weeks for 6 months using a measurement scale from 0 to 10 (visual analog scale). Participants also complete a questionnaire at the start, 2 months, 4 months and 6 months.

### What are the possible benefits and risks of participating?

This study is observational, there are no risks for participants to take part in this study. This study engages patients to be interviewed every two weeks and they are invited to discuss about their symptoms, which is more a benefit than an inconvenience.

### Where is the study run from?

1. Montpellier Cancer Institute (France)
2. Sainte-Catherine Institute (France)
3. Cancer Cancer of Montpellier (France)

When is the study starting and how long is it expected to run for?  
January 2015 to January 2019

Who is funding the study?  
Institut National Du Cancer (France)

Who is the main contact?  
Ms Louise Baussard (Scientific)  
louise.baussard@gmail.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Louise Baussard

**ORCID ID**  
<http://orcid.org/0000-0001-7882-7882>

**Contact details**  
Site Saint-Charles  
Rue du Pr. Henri Serre  
Montpellier  
France  
34000

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
DR-2015-730

## Study information

**Scientific Title**  
Psychological determiners of distincts fatigue trajectories in colorectal patients undergoing chemotherapy: a latent class analysis

**Acronym**  
TR-FATIGUE

**Study objectives**

**Hypothesis 1:**

Three trajectories will be highlighted.

1. Low/moderate initial level of fatigue, stable over time
2. Low to moderate initial level of fatigue increasing over time
3. High initial level of fatigue, mostly stable over time

**Hypothesis 2:**

It is expected that anxiety, depressive symptoms, emotional coping strategies, a causal internal attribution and lack of control over the illness, as well as a low social support, will have an impact on the trajectories of fatigue symptom.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

National Commission for Data Protection and Liberties (CNIL France), 30/12/2015, ref: DR-2015-730.

**Study design**

Observational prospective longitudinal study

**Primary study design**

Observational

**Secondary study design**

Longitudinal study

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Metastatic colorectal cancer

**Interventions**

Participants meet a psychologist-researcher at T0 and indicate their level of fatigue on a visual analog scale (VAS) every two weeks during 6 months. They also fill in questionnaires for psychological variables assessment at T0, but also at 2 months (T1), 4 months (T2) and 6 months (T3).

Demographic and clinical variables (age, gender, level of education, and relationship status are measured. Information regarding clinical variables is retrieved from the hospital registry.

Fatigue is assessed every two weeks using a standardized visual analog scale, developed and published elsewhere (Baussard et al., 2017). The Daily Fatigue Cancer Scale (DFCS) consists of three questions measuring fatigue at time t ('How tired you are?', 'How much you are lacking energy?', 'How weary do you feel?'). Patients indicate their rate using a cursor from "not at all" 0

to "extremely" 10. The sensitivity and diagnostic quality of the DFCS is evidenced by ROC curves, which confirms it as a good diagnostic test and highlights the fact that the best item is "I lack energy". Caregivers have only a 3% chance of misdiagnosing fatigue when the physical item "I lack energy" (VAS) is greater than 5.5 cm (2.16 inches). Additionally, a high VAS did not necessarily correspond to a state of intense fatigue, whereas a less than 5.5 cm (2.16 inches) VAS excluded a state of fatigue at the time of evaluation. Another item allows the assessment of psychological fatigue : "I feel weary".

Latent class analysis is conducted using lcmm Package on R free software, version 3.2.3 (Proust-lima, et al.,) to identify subgroups of patients with similar CRF profiles. Latent class analysis is a data-driven approach that aims to obtain the smallest number of groups with similar profiles based on a categorical latent variable (Magidson and Vemunt, 2004).

The following criteria are applied to choose the best fitting models: first, the Bayesian information criterion (BIC), the Akaike information criteria (AIC) and the sample-adjusted BIC (sabic) are inspected, with lower values indicating better fit. We also consider the entropy values, where values closer to one indicating good separation of trajectories and accurate classification of individuals within those trajectories (Ram & Grimm, 2009). The probability of belonging to a trajectory (postprob), define the discriminating power of classes. Respondents are assigned to the class for which the posterior probability is highest. The factors that discriminate the identified classes are determined using multinomial logistic regression.

Differences in the psychological variables (mean scores) between identified CRF classes are determined with t test. All tests are two-sided and significant if  $p < 0.05$ .

Demographic and clinical characteristics are analyzed as descriptors of fatigue trajectories using mean values for continuous descriptors and frequencies for categorical descriptors, both weighted by the estimated individual trajectory membership probabilities.

## **Intervention Type**

Other

## **Primary outcome measure**

1. Fatigue is assessed using the Daily Cancer Fatigue Scale (DFCS), a VAS with two single items questions: "I lack energy" and "I feel weary" to assess both physical and psychological Cancer Related Fatigue at baseline and every two weeks for 6 months.

## **Secondary outcome measures**

1. Fatigue measured using the Multidimensional Fatigue Inventory MFI (validated by Gentile et al., 2003)

2. Anxiety and Depression is measured using the Hospital Anxiety and Depression Scale HADS (developed by Zigmond and Snaith, 1983)

3. Coping strategy is measured using the Ways of Coping Checklist WCC-21 (validated by Cousson-Gélie et al., 2010)

4. Perceived control is assessed using the Cancer Locus of Control Scale CLCS (validated by Cousson-Gélie et al., 2005)

5. Social support is measured using the Social Support Questionnaire SSQ (validated by Segrestan, Rascle, Cousson-Gélie, & Trouette, 2007).

All secondary data is collected at baseline, 2 months, 4 months and 6 months.

## **Overall study start date**

01/01/2015

## **Completion date**

01/01/2019

## Eligibility

### Key inclusion criteria

1. Age > 18 years
2. Colorectal cancer with metastasis
3. Chemotherapy intravenous (d1-d14) for at least 2 months

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

200

### Total final enrolment

169

### Key exclusion criteria

1. Younger than 18 years
2. Not able to understand french and those with cognitive impairment
3. Psychiatric disorder

### Date of first enrolment

01/10/2015

### Date of final enrolment

01/12/2017

## Locations

### Countries of recruitment

France

### Study participating centre

Montpellier Cancer Institute

208 Avenue des Apothicaires

34298 Montpellier Cedex

Montpellier

France  
34298

**Study participating centre**  
**Sainte-Catherine Institute**  
250 Chemin de Baigne Pieds  
84918 Avignon  
Avignon  
France  
84918

**Study participating centre**  
**Cancer Cancer of Montpellier**  
25, Rue de Clémentville  
34 000 Montpellier  
Montpellier  
France  
34000

## Sponsor information

**Organisation**  
National Cancer Institute

**Sponsor details**  
52, avenue André Morizet  
92513 Boulogne Billancourt Cedex  
Boulogne Billancourt  
France  
92513

**Sponsor type**  
Research organisation

**Website**  
<http://www.e-cancer.fr/Institut-national-du-cancer/Qui-sommes-nous>

**ROR**  
<https://ror.org/03m8vkq32>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Institut National Du Cancer

**Alternative Name(s)**

The French National Cancer Institute, INCa

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Research institutes and centers

**Location**

France

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high impact peer-reviewed journal. Data analysis will be conducted April to June 2018, the paper will be written in September 2018 with intended publication in December 2018.

**Intention to publish date**

01/12/2018

**Individual participant data (IPD) sharing plan**

The datasets generated during and analysed during the current study will be available upon request from Baussard Louise (louise.baussard@gmail.com). Please note that data are:

- raw data and dataframe
- available in 2019 (for 5 years)
- available for replication or meta-analysis authors

**Additional documentation:**

Protocol and statistical analysis will be available on request, in a french form document (at louise.baussard@gmail.com)

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/01/2022	02/03/2022	Yes	No