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Psychological determiners of distincts fatigue trajectories in colorectal patients undergoing chemotherapy

Submission date
30/04/2018

Recruitment status
No longer recruiting

Registration date
27/12/2018

Overall study status
Completed

Last Edited
02/03/2022

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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?
Results article		01/01/2022	02/03/2022	Yes	No