Health literacy and digital health in cancer patients
"LICAPA" study

Study type according to French Law : Category 3 Non-Interventional Human Research Study (RIPH 3)

According to the French Law & French regulatory authorities :
this is considered as a Non-Interventional Human Research Study, of category -3 (RIPH-3).
As such, a full study protocol is NOT REQUIRED :
French authorities only require a protocol summary.

Protocol summary

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This research is backed by the elderly and cancer clinical research platform (Plateforme de Recherche Clinique Personnes Agées et Cancer - PACAN)

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ABSTRACT

TITLE	**Health literacy and digital health in cancer patients**
SHORT TITLE	LiCaPa
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JUSTIFICATION / BACKGROUND	Health literacy can be defined as "people's knowledge, motivation and competence to access, understand, appraise, and apply health information to make judgements and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality-of-life during the course of life". In his literacy model, Nutbeam defines 3 skills, namely: i) functional health literacy which is sufficient basic skills in reading and writing to be able to function effectively in everyday situations, ii) communicative literacy which refers to more advanced skills which can be used to extract information and derive meaning from different forms of communication, and to apply new information to changing circumstances, and, iii) critical literacy which refers to more advanced cognitive skills which can be applied to critically analyse information, and to use this information to exert greater control over life events and situations. In a world in which information is delivered more and more via digital tools, digital health literacy is coming to play an increasingly important part. It is based on three skills that are skills in healthcare, information skills and digital skills. Low health literacy, whether digital or not, can represent a loss of chance in terms of health [2]. Several studies have demonstrated an association between health literacy and different events such as hospitalisations, understanding prescriptions, quality-of-life or even death. Given its consequences in terms of health, health literacy represents a determining element of public health, which can be acted on. In effect, taking account of health literacy is likely to improve the patient's engagement, informed decision-making and final impact on health. However, the level of health literacy is preoccupying, especially in Europe and including in France. Whereas cancers represent a high cause of morbidity and mortality worldwide, and especially in France, few studies have looked at health literacy in cancer patients and at its consequences. According to the Institut National du Cancer (INCa), cancer in the over 65s represented 62.4% of estimated cancers among all ages in 2017. As a result, close attention must be paid to information provided to the elderly to empower them to become fully involved in their treatment. Management of cancer in the elderly is specific due to the potential presence of various areas of fragility related to the person's age and the extent of the concomitant diseases. People age 65 and older are therefore considered among the populations likely to find themselves

	in difficulty due to their low level of health literacy, especially digital literacy. A pilot feasibility study was conducted in 2019 in people age 65 and over with cancer and treated in consultation or in the outpatient clinic in 6 volunteer centres in France. Overall, 72% of patients had a low level of health literacy. These results, which demonstrate low health literacy in elderly cancer patients, remain however preliminary. A larger study also including a control population of adults age 18 to 64 years is required. This multicentric transversal study will be the first to our knowledge. Health literacy in this population has never before been evaluated prospectively and the proportion presenting with a low level of health literacy was not known.
OBJECTIVES	**Primary objective:** Evaluate the health literacy of cancer patients using the approved French version of the Functional, Communicative and Critical Health Literacy (FCCHL) scale in 2 populations: - Population A: patients age 65 and over treated in an oncology or oncogeriatric outpatient clinic, or seen in an oncology or oncogeriatric consultation. - Population B: young patients age 18 to 64 treated in an oncology or outpatient clinic, or seen in an oncology consultation. **Secondary objectives** • Describe the digital health literacy of patients per population. • Identify groups with low health literacy and evaluate the related factors (age, sex, lifestyle etc.). • Explore the factors related to the use of the digital.
STUDY ORGANISATION	**Study design** Multicentric, prospective, observational, transversal study. **Study questionnaire methodology** The questionnaire (Annex 1) including: • Approved French version of the FCCHL scale • Questionnaire on the use of digital tools adapted from the questionnaire on digital tools, will be completed once only. It will be completed by the participant during the oncology or oncogeriatric consultation or outpatient clinic appointment, in self-questionnaire mode or face to face, assisted if necessary by a family member or member of the medical team. *There will be no specific interview, and the patient's participation in the study shall not lead to any inconvenience or affect their treatment in any way.*
RESEARCH IMPLEMENTATION	**Expected number of centres** Around 20 participating centres. **Study duration** ○ Inclusion time: 2 weeks between September and October 2021 ○ Participation time for each patient: < 1 hour ○ Total study duration: 2 months

	<u>Methods of recruitment of persons questioned</u> Patients seen in an oncology, or oncogeriatric consultation or treated in an oncology or geriatric outpatient clinic (not including full hospitalisation lasting ≥ 24h). **<u>Methods of information and tracing of consent</u>** The information leaflet (Annex 2) will be handed to the patient by the investigator who will state the patient's consent to participate in the study in their medical record.
INCLUSION CRITERIA	1. Man or woman. 2. Age ≥ 18 years. 3. Patient treated for cancer. 4. Patient who can read and understand French. 5. Patient seen in an oncology or oncogeriatric consultation or treated in an outpatient clinic. 6. Patient in treatment or about to start treatment that has been offered to them, from the announcement consultation to 2 years after the start of treatment
EXCLUSION CRITERIA	1. Patient hospitalised for longer than 24 hours. 2. Patient with know cognitive impairment preventing them from answering the questionnaire.
OUTCOME MEASURES	**<u>Primary endpoint</u>:** The primary endpoint is the percentage of participants with an overall score of ≤ 4 on the FCCHL scale, corresponding to a low level of health literacy: • The FCCHL questionnaire includes 14 items, divided into 3 sub-scales, reflecting 3 health literacy skills (functional literacy, interactive literacy and critical literacy). • The FCCHL is validated and a French translation is available. • The scores for the three sub-scales are described for each population, and an overall score will be calculated by determining the mean score for the 3 sub-scales. • An overall score of ≤ 4 points to a low level of literacy. **Secondary endpoints**: The secondary endpoints include: • The questionnaire on the use of digital tools will be described per item: o This questionnaire includes 10 items. o A Likert-type scale with five modalities of response is proposed (never, rarely, sometimes, often, always). o No overall score will be calculated. • The responses to the FCCHL scales and to the questionnaire on the use of the digital will also be described by sub-groups defined according to the patient's characteristics at baseline (age, sex, lifestyle, etc.).
STUDY SIZE	**Total: 840 patients** - Population A: 420 patients - Population B: 420 patients **The primary endpoint is the percentage of participants with an overall score of ≤ 4 on the FCCHL scale, evaluated in 2 populations:**

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- Population A: patients age 65 and over treated in an oncology or oncogeriatric outpatient clinic, or seen in an oncology or oncogeriatric consultation.
- Population B: young patients age 18 to 64 treated in an oncology or outpatient clinic, or seen in an oncology consultation.

We plan to include around 300 eligible and assessable patients (overall score available) for the primary endpoint in each of the two populations (A and B). **A total of 420 patients per population will be included in this study** in order to take account of 40% of non-eligible/non-assessable patients (score not available – 35% of patients had not fully completed the questionnaire in the feasibility study)**.** Inclusion will last 2 whole weeks, **between September and October 2021, in 21 centres which will include at least 40 patients each**.

Our primary objective is to describe the percentage of patients with low health literacy, corresponding to an overall score of ≤ 4 on the FCCHL scale. We found an overall score of ≤ 4 for 72% of the patients in our feasibility study. Also, according to the latest report from the OECD, 60% of French adults have a low level of literacy. Finally, around 88% of the elderly in Canada have a low level of health literacy compared to 60% of adults.
In each of the two populations, presuming 300 subjects are recruited for whom the overall score will be available, below we provide the precision of the estimations according to the expected percentage of subjects with a low level of literacy, between 60% and 90%. This percentage was calculated using the Wald test (normal approximation) (NQuery).

Expected percentage	Precision	CI width	95% confidence interval (95%CI)
60%	5.5%	11%	**[54.5%; 65.5%]**
70%	5.2%	10.4%	**[64.8%; 75.2%]**
80%	4.5%	9%	**[75.5%; 84.5%]**
90%	3.4%	6.8%	**[86.6 %; 93.4%]**

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<tr><td>**DATA STATISTICAL ANALYSIS**</td><td>
Analysis populations:
- Eligible population: all the patients included without major deviation from the eligibility criteria.
- Eligible and assessable population: eligible patients having completed all 14 items on the FCCHL scale to calculate the overall health literacy score.

Primary endpoint analysis:
- The primary end point analysis will cover the eligible, assessable population.
- The analyses will be conducted independently in each of the two populations A and B.
- The percentage of patients with a low level of health literacy will be calculated as follows:
  - Each item on the FCCHL takes a score of 1 to 5 points.
  - For each patient, a literacy score per sub-scale (functional, interactive and critical) will be determined by calculating the
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	number of points divided by the number of items on the sub-scale. The score can range from 1 to 5. ○ An overall literacy score will be calculated for each patient, by determining the mean of the functional, interactive and critical literacy scores. The score can range from 1 to 5. ○ The percentage of patients with a low level of health literacy will be calculated for each population (A, B), by dividing the number of patients with an overall score of ≤ 4 by the number of eligible and assessable patients. The percentage will be reported along with its 95% confidence interval (binomial law). • The responses to the FCCHL scale will be described for each population (A, B) by sub-scale and overall, by calculating the mean and the standard-deviation of the 4 literacy scores (functional, interactive, critical and overall) resulting for each patient. • The quantitative variables will be described based on the mean and standard-deviation if the assumption of normality is followed, otherwise other descriptive statistics will be used (minimum, maximum, median and quartile). • The qualitative variables will be described based on numbers and associated frequencies, given as a percentage (%).
EXPECTED RESULTS	**For patients**: Determining the level of health literacy of cancer patients, with a special focus on the elderly, would make it possible to provide information that is more compatible with the mean level of literacy in this population. Determining the level of digital health literacy in the same population would make it possible to find out whether digital follow-up is feasible. Appropriate education could be implemented to develop their ability to access, understand, appraise, and apply basic health information. **For public health:** Better understanding of health literacy would make it possible to improve and develop prevention actions for cancer patients and elderly patients in particular. This could lead to a decrease in healthcare costs, better treatment compliance, reduction in adverse effects and fewer hospitalisations, emergency department admissions and readmissions.