**Time to practice what we preach? Appreciating the autonomy of cancer patients on deciding whether they want to be informed about interventional studies for fatigue**

**Short title: Informing cancer patients about fatigue interventional studies**

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**Background**

Fatigue is a prevalent and burdensome symptom for patients with advanced cancer. The long-term use of pharmacological interventions for fatigue is not supported by evidence (1); though, non pharmacological and behavioural interventions are promising approaches to reducing fatigue based on their effectiveness in early-stage cancer patients (2). Behavioural factors, like sleeping problems and being less physically active, can also contribute to fatigue in advanced cancer patients (3). Interventional studies for the management of fatigue in advanced cancer patients are needed. However, it is a notorious challenge to identify patients for interventional studies aimed at fatigue or symptom control while patients are undergoing cancer treatment with palliative intent. One of the barriers to successful identification of these patients is professional gatekeeping, due to the care professionals’ perception that study participation might be too burdensome for the patient (4, 5). Although gatekeeping is done in order to prevent additional burden for patients who are seriously ill, it also limits access for patients to potentially effective interventions for fatigue and makes it difficult to develop evidence-based interventions for fatigue in advanced cancer patients. More importantly, gatekeeping assumes that patients are either not capable to decide for themselves if they want to be informed about an intervention study or do not want to be informed. We aimed to investigate to what extent patients receiving cancer treatment with curative or palliative intent would be willing to be contacted by a researcher about possible interventional studies aimed at fatigue once they were screened for the presence of fatigue in routine clinical practice. An ongoing interventional study addressing fatigue in patients receiving treatment with palliative intent for breast or colon cancer was available at the time of this quality project (TIRED study, Netherlands Trial Registry, NTR3812).

**Methods**

At the Radboud university medical center, we conducted a quality project aimed at screening for the presence of severe fatigue in cancer patients prior to starting (a new line of) systemic treatment. Oncology nurses were instructed to introduce the assessment of fatigue to all patients via handing out a pre-printed information letter together with a multi-dimensional fatigue questionnaire. Patients completed the Checklist Individual Strength (CIS) questionnaire directly at the outpatient clinic or at home. The subscale fatigue severity (8 items, 7-point Likert scale) of the CIS was used as a measure of fatigue, a validated cut-off score of ≥ 35 points indicates the presence of severe fatigue (6). In addition, patients were asked the following question: *“Fatigue is an important symptom that influences quality of life during cancer treatment. If this questionnaire shows that fatigue is also an important symptom for you and a treatment is available, do you agree that a researcher contacts you?”* Possible answers were ‘yes’ or ‘no’ and in case of an affirmative answer patients had to provide their contact information. Eligible patients for an ongoing interventional study addressing fatigue in advanced cancer patients receiving treatment with palliative intent for breast or colon cancer were then contacted by a researcher. Oncology nurses provided data on age of the patient, gender, type of cancer, and treatment intent (curative vs. palliative).

**Results**

A total of 229 patients completed the fatigue-screening questionnaire between January and December 2013. In all, 53% (n=121) were female, mean patient age was 58 years (range=25-78). The most common types of cancer were gastro-intestinal cancer (32%) and breast cancer (19%). Other diagnoses included gynecological cancer, skin cancer, head-neck cancer, urogenital cancer, sarcoma, brain tumors, or other. Information about treatment intent was available for 214 patients, 49.5% (n=108) received curative treatment and 50.5% (n=106) received palliative treatment.

In all, 93% (n=212) of patients agreed with being approached by a researcher to be informed about interventional studies for severe fatigue. Of interest, agreement did not differ significantly between patients receiving treatment with curative (91%) versus palliative intent (93%). The prevalence of severe fatigue in patients receiving treatment with palliative intent was 36% (n=38) and 90% (n=34) of those severely fatigued advanced cancer patients agreed to being contacted by a researcher.

**Conclusions**

Overall, cancer patients who completed a fatigue-screening questionnaire also wanted to be informed by a researcher about available interventional studies for fatigue, regardless of treatment intent. Even in severely fatigued advanced cancer patients, 90% of patients wanted to be informed. Our findings accord with a survey study performed in advanced cancer patients, in which almost 90% of patients were interested in studies of symptom control, though the concept of randomization was a deterrent in 40% of patients (7). In light of the new era of patient participation in health care, advanced cancer patients should not only be involved in decisions about medical treatment, but also in deciding whether they want to be informed about studies targeting symptoms and quality of life. Thus, there is no need for well-meant protection of patients receiving treatment with palliative intent by withholding from them information about fatigue interventional studies. Researchers developing evidence-based interventions for fatigue in advanced cancer patients may use our findings to convince health care professionals to actively refer these patients for information about interventional studies, including randomized controlled trials.

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