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Study protocol for the OPTion randomised controlled trial on the effect of prioritising treatment goals among older patients with cancer in a palliative setting

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ABSTRACT

Purpose: Traditionally, general practitioners (GPs) are not involved in cancer-related treatment decisions, despite their often long relationship with patients, and their unique position to explore patients' values, especially with older patients. Therefore, we designed a randomised controlled trial to study the effect, on self-efficacy related to treatment decisions, of a conversation about treatment goals between GPs and patients with cancer in a palliative setting.
Methods: We aim to include 168 patients aged ≥70 years with a diagnosis of non-curable cancer, due to consult their oncologist about treatment options. In the intervention group, patients will consult their GP using an Outcome Prioritisation Tool (OPT). The control group will receive care as usual. The primary outcome will be the score on a decision self-efficacy scale after the consultation with the oncologist. Secondary outcomes will be symptoms of depression, anxiety, or fatigue. In an embedded observational study of the intervention group, we aim to assess the prioritisation of treatment goals (i.e., OPT scores), and their determinants, over a six-month period.
Conclusions: The OPTion study should provide relevant information about the effect on self-efficacy of a consultation between GPs and older patients with cancer, concerning preferred treatment goals in a palliative setting.
Dutch Trial Register NTR5419

1. Decision making in cancer

1.1. Illustrative case

Consider the case of Mrs. Johnson, a 79-year old widow who valued her independency and loved the outdoor lifestyle, who despite having sold her field, continued to live at her old farm. When she presented to her general practitioner (GP) with persistent dyspnea, this led to a standard sequence of events. She was sent to the pulmonologist for further assessment, at which point an x-ray showed features suggestive of lung cancer. This, in turn, prompted additional diagnostic tests that confirmed stage IV lung cancer and led to medical intervention with chemotherapy. Although her initial response was favorable, fever developed after the second round of chemotherapy. Per the medical care plan, this prompted contact with an oncologist who admitted her to hospital, and she died two days later. In this case, all aspects of her care were appropriate and consistent with current standards of care, and her family was content with the care provided. However, the question was raised: did this patient truly want to receive chemotherapy?

1.2. Healthcare providers in cancer care

Worldwide, an estimated 14.1 million new cancer cases and 8.2 million cancer deaths occurred in 2012, and the incidence is expected to increase as a result of population aging [1]. The percentage of patients with cancer who are aged 65 years or older is, therefore, expected to increase to as high as 70% by 2030 [2].

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The care of patients with cancer is complex and involves many different healthcare providers [3]. At present, GPs are formally involved before referral to specialist oncology services and during end-of-life care [4], while in the other phases the role of the GP is not well defined [3,5]. Nevertheless, it is now increasingly recognised that GP involvement is essential at all stages of cancer treatment to optimise patient outcomes, not only through their role in coordinating care but also through their ability to help when making complex treatment decisions and providing psychological support [5,6].

1.3. Treatment decisions in older people

Complex treatment decisions are often necessary for older patients with cancer because they frequently have multiple comorbidities and shorter life expectancies. These factors may unfavourably influence the risk/benefit assessment before treatment, and could explain why older patients are sometimes not treated according to the recommended standards of care [7]. Multiple studies have shown that reduction of mortality was less important for older patients with cancer than improvement or maintenance of function [8,9].

Medical doctors play a very important role in treatment decisions made by older patients [10]. The process of shared decision making (SDM) involves the patient and a medical doctor coming together, recognising that a decision has to be made, discussing the available options, discussing the patient's preferences, and ultimately, making or deferring a decision [11]. Patients with cancer express a higher preference for active participation in this process than other patient groups [12], especially when decisions are related to quality of life [13].

There is sufficient evidence that SDM improves knowledge of the options and outcomes among patients, and can lead to more accurate expectations [14]. Besides, SDM may improve patient confidence and empowerment, which can be measured by decision self-efficacy [14]. This is, the confidence or belief in one's ability to make decisions, including the ability to participate in SDM [15]. Self-efficacy is increasingly viewed as being central to the way patients with cancer cope with their disease, its treatment, and the decisions they make [16,17].

2. The OPTion study

2.1. Rationale

Oncologists often lack prior knowledge of the patient and have only limited time to discuss treatment options, making SDM difficult to implement. The GP, by contrast, is better placed to talk about treatment with patients because they share a longer relationship, with a greater understanding of both the patient and his or her context. We therefore reasoned that the SDM process would benefit from GPs helping to prepare patients for conversations with their oncologist. In palliative settings, we think this might increase patient self-efficacy and facilitate personalised treatment decisions when used in collaboration with routine oncology consultations. Therefore, we aim to develop a randomised controlled trial of the effect on decision self-efficacy of structured conversations between GPs and older patients with cancer in palliative settings. We propose that these conversations will focus on generic treatment goals just before a treatment decision needs to be made, and that they should be performed using a standardised format.

2.2. Setting and study design

As in several other Western countries, Dutch GPs have a long relationship with their patients and they provide 24/7 primary care service. The GP also acts as a care coordinator, being responsible for managing all of their patients' medical data and for liaising with specialists from different services.

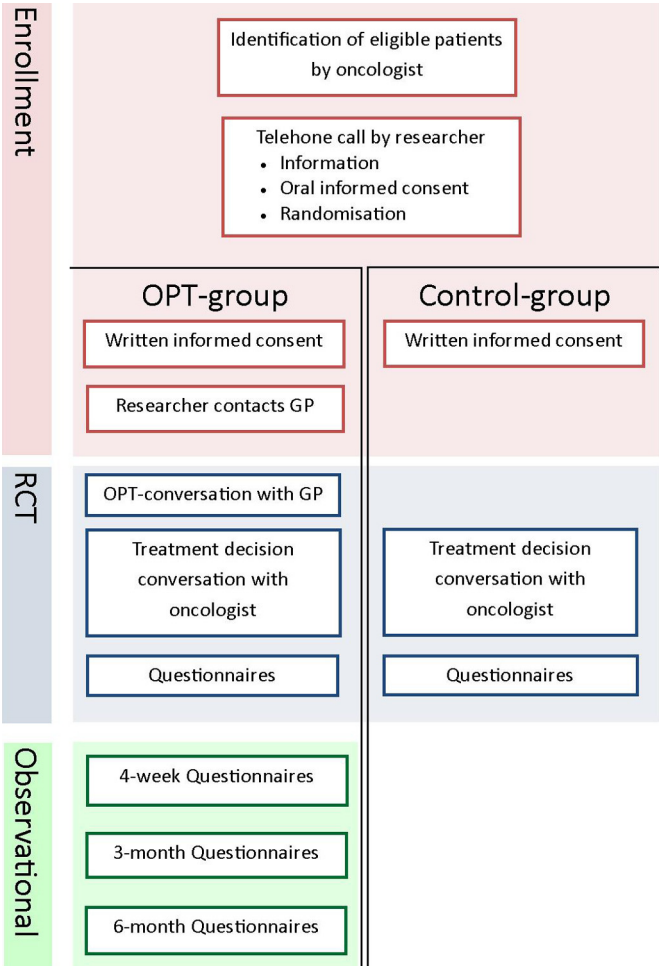

Fig. 1. Graph showing the proposed measurements at the various time points.

This study is designed according to the SPIRIT guidelines [18] and planned to be a two-armed parallel group pragmatic randomised trial [19]. We will study the effects of GPs eliciting preferred treatment goals on patient self-efficacy, among older patients with cancer in a palliative setting, in comparison to care as usual. The primary endpoint is the perceived self-efficacy directly after consultation with an oncologist during which the choice for a specific treatment has been made (Fig. 1).

2.3. Participants

2.3.1. Recruitment

Eligible patients will be recruited by oncologists from eight locations of five hospitals (one academic and four non-academic) in the north of the Netherlands when a new treatment decision is to be made (e.g. at the moment of diagnosis). The oncologist will then check the inclusion and exclusion criteria, and if suitable, will provide interested patients with written information about the study and ask for permission to send their contact details to the researchers.

2.3.2. Inclusion and exclusion criteria

Participants will be required to be aged 70 years or older, have non-curable cancer, and be in a position requiring them to make a new treatment decision.