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# Comparing attitudes of younger and older patients towards cancer clinical trials☆

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ABSTRACT

*Objectives:* To determine the attitudes of patients towards cancer clinical trials (CCTs) and assess the differences between older and younger patients.
*Materials and Methods:* Patients with cancer, receiving treatment or in follow-up in University Hospital Waterford, Ireland were eligible. Patients completed a self-administered questionnaire. To determine attitudes towards CCTs, patients indicated their preference if offered participation in three hypothetical studies (cancer prevention/screening trial; CCT comparing standard to new treatment; a trial of new drug where no standard exists). Patients' reasons to or not to participate in CCTs were explored.
*Results:* From May 2014 to March 2015, 219 patients were accrued, 119 <65 years and 100 ≥65 years. Twenty-two (18%) younger and 4 (4%) older patients had been/were actively enrolled on a CCT ($p = 0.0012$). No older patient and 5 (4%) of younger patients had enquired about CCT availability. For the CCT questions, 85 (71%) younger vs 57 (57%) older patients would participate in a prevention/screening CCT ($p = 0.033$); 60 (50%) vs 44 (44%) for standard vs new drug ($p = 0.415$), and 83 (69%) vs 78 (78%) for a CCT where no standard exists ($p = 0.218$). The most common reason to participate in a CCT was a recommendation from the oncologist –98% <65 years vs 87% ≥65 years ($p = 0.001$), with health problems being the leading reason not to participate, 86% vs 72% ($p = 0.01$), respectively.
*Conclusions:* Older and younger patients in this study gave similar importance to reasons for and against participation in CCTs. Most patients did not actively seek out a CCT, which may reflect a lack of awareness and a need for better education.


## 1. Introduction

Population aging is a global phenomenon. Older age is a major determinant of cancer risk with more than 60% of cancers occurring over the age of 65 years.[1] Despite these statistics, cancer in the elderly is surprisingly undertreated and the enrolment of these patients into cancer clinical trials is particularly challenging. While 60%–70% of paediatric patients participate in trials, the numbers decrease dramatically with increasing age, such that as few as 2%–4% of all newly diagnosed adult cancer patients participate.[2,3] Older patients, in particular, are under-represented in clinical trials[4,5]—although 60% of new cases of cancer occur amongst the elderly they comprise only 25% of participants in cancer clinical trials.[6]

A number of studies have examined why patients who have been diagnosed with cancer, agree or refuse to enrol in a cancer

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clinical trial. A review of this literature suggests a combination of altruism and a hope for better treatment motivated most of the patients who enrolled in a cancer clinical trial.[7–10] The major barriers to participation included low levels of understanding about the clinical trial process, concerns about the possibility of additional tests, additional discomfort, increased costs, insurance problems, and additional travel. In a case control study conducted at ten Cancer and Leukaemia Group B institutions, Kemeny et al.[11] reported that older patients with stage II breast cancer (≥65 years) were significantly less likely to be offered a clinical trial compared to younger patients (68% vs 34%, respectively), a finding that remained significant after adjustment for disease stage and physical functioning. In this study,[11] 24 older patients were offered trial, 12 of whom accepted. The most common reasons stated by patients for accepting included the belief that it offered the best treatment available, the expectation of health improvement and the wish to find a cure for cancer. The most common reason to decline participation was the wish to choose their own treatment. Lara et al. reported preference for another treatment, distance from the cancer centre and insurance denial as the most common reasons patients ($n$ = 37) declined participation in a clinical trial.[2] This study included all age groups and all cancer types. Kornblith et al.[12] in their study focussed on the physicians perspective ($n$ = 156). Co-morbidities, protocol requirements, toxicity risks and patients understanding of trial requirements were identified as the factors that physicians considered most important in negatively impacting accrual of older patients with breast cancer to clinical trials.

While these data highlight some of the challenges facing patients offered clinical trial participation, they are not all specific to the older population and the older patients' perspective regarding cancer clinical trials must be further explored.

We thus undertook this study to gain a better understanding of patient's attitudes towards clinical trials and compared the perspectives of older and younger patients.

## 2. Methods

### 2.1. Study Population

From May 2014 to March 2015, patients who were receiving systemic therapy or were in follow-up in the South East Cancer Centre, Waterford, Ireland were eligible for this study. The study was initially restricted to patients with gastrointestinal malignancies but subsequently expanded to include all tumour types.

The participants were divided into younger and older subgroups, defined as <65 years and ≥65 years respectively.

### 2.2. Data Collection

Participants were invited to complete a self-administered questionnaire (Appendix 1) which was distributed in the oncology dayward and outpatient clinic. This questionnaire was previously used in a Canadian population[13] and permission to use this questionnaire and adapt it as necessary was sought from the author (C. Townsley). As reported by Townsley, the questionnaire was developed by first completing a literature review to identify barriers to cancer care for older patients. Four investigators then condensed the survey to the core questions utilising a modified Delphi technique,[14] which was then piloted on 5 older patients to ensure clarity and face validity.

Additional information was obtained, with consent, from patients charts as needed (including current age). Patient information collected included age at cancer diagnosis, gender, health status, living situation, cancer diagnosis, distance to nearest treatment centre and distance to the South East Cancer Centre, Waterford. Data were not collected on non-respondents.

The questionnaire was designed to explore three areas; the attitudes of patients towards clinical trials participation, reasons to participate in a clinical trial and reasons to decline enrolment in a clinical trial.

In order to assess willingness to participate in CCTs, the participants were asked questions regarding three types of clinical trials and were asked to indicate if they would be willing to participate. The three questions related to a cancer screening/prevention trial, a trial where a new drug was being compared to the standard of care and a trial with a drug where there was no existing standard. There were five possible answers to these questions, ranging from strongly disagree to strongly agree. The responses "agree" and "strongly agree" were considered together as a positive response.

Participants were also given several options of reasons that would and would not influence their decision to participate in a clinical trial of a new cancer treatment. They were allowed to select more than one reason. They gave each answer a value on a 5-point scale ranging from extremely unimportant to extremely important.

The South East Cancer Centre in Waterford, Ireland operates a hub and spoke model of care. The centre serves a population of 490,000 people and consists of a central unit with three satellite units, each an average of 55 km away. While patients from all units are given the opportunity to participate in clinical trials, treatment and follow-up is only done in the central unit. Thus we sought to determine if distance was a factor influencing accrual rates.

### 2.3. Statistical Analyses

Summary statistics with medians, percentages and frequency were used to describe the respondents. Differences between the groups were investigated using the Fishers exact test. All tests were two-sided and $p$-values of 0.05 or less were considered statistically significant.

Ethics approval for this study was obtained from the South East Ethics board and all patients provided written informed consent.

## 3. Results

### 3.1. Baseline Demographics

Two hundred and thirty eight questionnaires were distributed, and 219 returned, for a response rate of 92%. Patient demographics are outlined in Table 1. One hundred and nineteen patients (54%) were <65 years. The median age for