Contemporary Clinical Trials Communications 2 (2016) 6–11

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

Patients' knowledge and perceived understanding – Associations with consenting to participate in cancer clinical trials

Yvonne Brandberg [a], Hemming Johansson [a, b], Mia Bergenmar [a, c, *]

[a] Department of Oncology-Pathology, Karolinska Institutet Z1:00, Karolinska University Hospital, SE-17176 Stockholm, Sweden
[b] Department of Oncology, Karolinska University Hospital, SE-17176 Stockholm, Sweden
[c] Center for Digestive Diseases, Karolinska University Hospital, SE-141 86 Stockholm, Sweden

ARTICLE INFO

Article history:
Received 31 August 2015
Received in revised form
5 November 2015
Accepted 7 December 2015
Available online 17 December 2015

Keywords:
Cancer clinical trial
Informed consent
Knowledge
Understanding
Recruitment
Quality of informed consent

ABSTRACT

Recruitment to clinical trials is essential. The aims of the study were to investigate associations between patients' informed consent to participate in a cancer clinical trial and knowledge and perceived understanding of the trial. Furthermore, associations between demographic factors and consent to participate and knowledge and perceived understanding of information about the trial were studied.

Methods: The patients were recruited in connection to a visit at the oncology clinic for information about a drug trial. The Quality of Informed Consent questionnaire was mailed to the patients after they had decided about participation in the trial. The associations of demographic factors and "knowledge" and "perceived understanding" were analysed using linear regression models.

Results: A total of 125 patients were included. Higher levels of "knowledge" and "understanding" were found to be associated with consent to participate in a clinical trial, both in the univariate and multivariate analyses ($p = 0.001$). None of the tested demographic factors were related to consent to participate. No statistically significant associations between any of the demographic factors and knowledge or perceived understanding scores were found.

Conclusion: The results indicate that interventions that increase patients' knowledge and perceived understanding might improve participation rates in clinical trials.

1. Introduction

Clinical trials are of outmost importance in order to find new treatments and improve the existing ones. Low accrual rates may have several clinical, scientific, economic and ethical adverse effects [1–3]. In addition, low recruitment rates might harm the detection of clinically relevant differences, increasing the risk of abandoning an effective intervention. This leads to delay of implementation of new more effective treatments. Furthermore, investigations of novel research questions and the identification of non-effective interventions might be delayed. Clinical trials are costly to conduct, both in terms of human resources and financially. It is therefore important to reach conclusive results as soon as possible.

In order to increase participation in clinical trials, knowledge about factors included in the recruitment process is of importance, i.e. factors related to the protocol, the patient or the physician. Such factors have been investigated in a number of studies [4–9]. One study showed that travel time and physician communication were associated with participation in clinical trials [4]. Another study found concerns about the trial setting, disliking randomization, discomfort with the research process, the study protocol, potential side-effects of participating and the patients' perception of the physician's attitudes towards the trial to be important [5]. Reduced decisional conflict was found to be associated with trial participation by Miller and co-workers [7]. Altruism has also been identified as a factor of importance [6]. In addition, physician related factors have been found to be associated with participation [6,9]. One study showed, for example, that the major reason for non-inclusion in clinical trials was the physician's failure to inform about the trial [9]. Furthermore, socioeconomic and clinical factors might influence participation. In a recent study, low level of education, non-metastatic disease, no previous clinical trial participation and financial burden were reported as barriers for trial participation [8].

* Corresponding author. Department of Digestive Diseases, Karolinska University Hospital, Huddinge K53, SE-141 86 Stockholm, Sweden.
E-mail addresses: yvonne.brandberg@ki.se (Y. Brandberg), hemming.johansson@karolinska.se (H. Johansson), mia.bergenmar@ki.se (M. Bergenmar).

http://dx.doi.org/10.1016/j.conctc.2015.12.001

Informed consent requires, according to the Helsinki Declaration, that the patient has knowledge and perceive that he/she understands all relevant aspects of the trial. Despite these requirements, many studies show insufficient knowledge and understanding among patients participating in clinical trials [10–13]. Trial participants may hold significant misunderstandings, although reporting being well informed [12–14]. A number of studies have been conducted aiming at improving patients' knowledge and understanding in association to the informed consent procedure [3,15,16].

Although there are a number of studies on associations between patients' knowledge and understanding on participation in clinical trials, it is not known whether better knowledge and understanding are related to participation in clinical trials. A possible scenario might be that better knowledge and understanding are associated with lower participation rates, thus constituting a conflict between the interest of improving patients' knowledge and understanding at the time for informed consent, and the pursuit of increasing participation rates in clinical trials.

The aims of the present study were firstly to investigate associations between consenting to participate in a cancer clinical trial and knowledge and perceived understanding of information about the clinical trial. Secondly, we aimed to evaluate the associations between demographic factors and 1) consenting to participate in a cancer clinical trial and 2) knowledge and perceived understanding of information about the clinical trial.

The Regional Ethical Review Board at Karolinska Institutet approved the study (2005/604-31/3).

2. Methods

2.1. Patients and procedure

Patients in the present paper were recruited for a randomised study of an audio-recorded intervention aiming at improving patients' knowledge and understanding in the informed consent procedure. The study, which has been presented elsewhere, showed no effects of the audio-recorded intervention [17].

The patients planned for information about a cancer clinical trial in phases 2 or 3 between 2008 and 2013. They were included in the intervention study by a study nurse in connection with a visit for information about the drug trial. No other inclusion or exclusion criteria besides those applied in the clinical drug trials were used in the study. The questionnaires were mailed to the patients together with prepaid envelopes when they had decided about participation in the clinical trial. Data on participation in the clinical trial (signed informed consent form) or not was collected from the trial database. One reminder was sent to those who did not respond within two weeks. Clinical data were collected from patients' files.

2.2. The instrument

The questionnaire Quality of Informed Consent (QuIC) was used, consisting of two parts [18]. The first part, “knowledge” includes 20 items, out of which 14 are trial phase independent. The responses are given in three categories (“disagree”, “unsure”, “agree”). The second part, “perceived understanding”, consists of 14 items where patients rate to what extent they perceived that they understood the information about the clinical trial. The response format is a 5-point scale from “I didn't understand this at all” to “I understood this very well”. The English version of the QuIC has been validated [18]. QuIC was translated to Swedish by a forward-backward procedure followed by pilot testing in accordance with the guidelines by the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Group [19], and has been used previously [20]. For patients declining participation in the drug trial, the wording was changed to “the trial you were informed about and asked to consider” instead of “your clinical trial”, as stated in the original questionnaire.

2.3. Statistical methods

The two randomized groups in the intervention study were well balanced with respect to demographic variables [17]. Thus, the data from the two groups were compiled in the present analyses.

The first part of the questionnaire QuIC, “knowledge”, was scored in the following way. Responses categorized as “correct” were assigned the value of 100. Incorrect responses and responses in the category “unsure” were assigned the value of 0. The phase independent questions only were included in the analyses of “knowledge”. In the second part, “perceived understanding”, the response format is a 5-point scale from “I didn't understand this at all” to “I understood this very well”. Correspondingly, the responses were assigned the values 0, 25, 50, 75 and 100. For both parts (knowledge/perceived understanding) respectively, the scores were summated and divided by the number of items.

The following variables were included in the multivariate logistic and linear regressions for “knowledge” and “perceived understanding”: age, gender, education, “cohabitant status”, “randomized study or not”. The two parts were not included in the same multivariate logistic regressions, but were tested separately as they are intended to assess different features. The effects of different factors on “knowledge” and “perceived understanding” were tested and estimated using linear regression models. Results from these analyses are presented as mean differences and 95% confidence intervals. The odds of consenting to participate in a cancer trial were modelled using unconditional logistic regression. The results from these models are presented as odds-ratios. All reported p-values are two-sided and based on the Wald-test. The level of statistical significance was set to ≤ 0.001 to correct for multiple testing.

3. Results

3.1. Patient characteristics

A total of 183 patients were invited to participate in the audio-recording study, 53 (29%) declined, leaving 130 (71%) patients in the study. Out of those, 5 patients were included in the intervention study, but were not asked to participate in a drug trial (“too ill” = 3, “language problems” n = 1, “administrative failure” n = 1). Thus, 125 patients were included in the present analyses. In all, 16 drug trials were represented, out of which 14 were randomized (10 Phase 3 trials). A total of 13 oncologists performed the inclusion in the drug trials. As presented elsewhere, the patients showed relatively high levels of knowledge and understanding [17]. Patients' demographic and clinical characteristics are presented in Table 1. The majority was between 45 and 64 years of age, well educated, co-habitants and the majority (82%) were women.

3.2. Associations between consenting to participate in a drug trial and knowledge, perceived understanding of information about the clinical trial and demographic factors

Table 2 presents the results of the univariate and multivariate analyses of associations between consenting to participate in a drug trial and demographic factors and the knowledge and understanding scores. Higher “knowledge” was associated with consenting to participate in a drug trial in both the univariate and multivariate analyses ($p = 0.001$). In addition, a similar result was