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

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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].

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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

Table 1
Patients demographic and clinical characteristics.

Characteristic	N = 125
Age	*N (%)*
<45	20 (16)
45–64	85 (68)
≥65	20 (16)
Mean [SD]	55 [10.6]
Gender	
Females	103 (82)
Males	22 (18)
Education	
Compulsory school (1–9 years)	18 (14)
Senior high school (10–12 years)	20 (16)
University education (13–16 years)	14 (11)
Higher university education (16 years)	48 (39)
Data missing	25 (20)
Marital status	
Married/living with partner	70 (56)
Living alone	30 (24)
Missing	25 (20)
Diagnosis	
Breast	98 (78)
Gastro-intestinal	18 (14)
Prostate	9 (8)
Participation in the clinical drug trial	
Yes	91 (73)
No	34 (27)
Study phase	
Phase III	75 (60)
Phase II (randomized)	25 (20)
Phase II (single-arm)	25 (20)

knowledge and better understanding are associated with consenting to participate in a clinical trial.

3.3. Associations between knowledge score/perceived understanding score and demographic factors

We found no statistically significant associations between any of the demographic factors and knowledge or perceived understanding scores, Tables 3 and 4. Thus, these variables do not seem to be related to knowledge about clinical trials and perceived understanding.

4. Discussion

The present study aimed at identifying factors of importance for consenting to participate in cancer clinical trials. A number of demographic variables, as well as “knowledge” and “perceived understanding” of the specific trial the participant was asked to consider, were entered into the analyses. Higher knowledge and understanding were found to be associated with consent to participate, even after accounting for other factors. None of the demographic factors were, however, related to consenting. In addition, the association between the demographic factors and knowledge and understanding were investigated, but no associations were found.

“Knowledge” and “perceived understanding” were assessed by a questionnaire developed based on the requirements of informed

Table 2
Consent to participate in clinical trials: Uni- and multivariate analyses of associations with demographic factors, knowledge and perceived understanding.

		Univariate analysis		Multivariate analysis knowledge[a]		Multivariate analysis understanding[a]	
Factor	Participating (%)/Not participating	Odds ratio (95% confidence interval)	P	Odds ratio (95% confidence interval)	P	Odds ratio (95% confidence interval)	P
Age							
<45	17 (85)/3	Reference		Reference		Reference	
45–64	60 (71)/25	0.42 (0.11–1.58)		0.41 (0.07–2.42)		0.34 (0.06–2.11)	
≥65	14 (70)/6	0.41 (0.09–1.95)	0.26[d]	1.87 (0.11–32.6)	0.67[d]	2.37 (0.11–49.8)	0.58[d]
Gender							
Male	17 (77)/5	Reference		Reference		Reference	
Female	74 (72)/29	0.75 (0.25–2.22)	0.60	0.46 (0.07–3.08)	0.43	0.26 (0.02–2.92)	0.28
Education[b]							
Elementary school	15 (83)/3	Reference		Reference		Reference	
High school	15 (75)/5	0.60 (0.12–2.97)		0.47 (0.07–3.9)		0.73 (0.10–5.26)	
University	51 (82)/11	0.93 (0.23–3.76)	0.92[d]	1.03 (0.20–5.31)	0.97[d]	1.89 (0.32–11.2)-	0.97[d]
Living alone or not[b]							
Cohabitant	58 (83)/12	Reference		Reference		Reference	
Alone	23 (77)/7	0.68 (0.24–1.94)	0.47	1.15 (0.33–3.94)	0.83	0.65 (0.18–2.38)	0.52
Randomized study or not							
Not randomized	19 (76)/6	Reference		Reference		Reference	
Randomized	72 (72)/28	0.81 (0.29–2.24)	0.69	1.49 (0.39–5.72)	0.56	1.44 (0.33–6.28)	0.63
Knowledge score,[c] mean [SD]	72 [15.1]	1.39[e] (1.15–1.65)	**<0.001**	1.39[e] (1.14–1.69]	**0.001**	–	
Understanding score,[b] mean [SD]	86 [12.4]	1.43[e] (1.16–1.77)	**0.001**	–		1.54[e] (1.20–1.97)	**0.001**
Total	91 (73)/34						

P-values in bold indicates statistical significance.
[a] Adjusted for all other listed factors.
[b] Data missing for 25 patients.
[c] Data missing for 24 patients.
[d] Test for linear trend.
[e] OR corresponding to an increase in knowledge score with 5 units.

found for “perceived understanding”, where better understanding was predictive of consenting (p = 0.001). None of the other tested demographic factors appeared to be related to consent to participate in a drug trial. In conclusion, the results indicate that higher consent in cancer clinical trials [18]. This is a brief, valid and reliable instrument, and the Swedish translation has been validated [20]. The “knowledge” part can be considered to objectively measure knowledge about the drug trial that the patient is considering to

Table 3
Univariate and multivariate analyses of associations between "Knowledge"[‡] and demographic factors.

			Univariate analysis		Multivariate analysis[a]	
Factor	N [%]	Mean (SD)	Mean difference (95% confidence interval)	P	Mean difference (95% confidence interval)	P
Age						
<45	18 [18]	75 (14.7)	Reference		Reference	
45–64	68 [67]	72 (14.6)	−3 (−10 to 5)	0.67	−2 (−10 to 6)	0.86
≥65	15 [15]	70 (16.0)	−5 (−15 to 5)	0.38[#]	−3 (−14 to 8)	0.60[#]
Gender						
Male	17 [17]	72 (13.7)	Reference		Reference	
Female	84 [83]	73 (15.0)	1 (−7 to 8)	0.88	−1 (−9 to 8)	0.89
Education						
Elementary school	18 [18]	69 (14.5)	Reference		Reference	
High school	20 [20]	76 (17.4)	7 (−3 to 16)	0.37	6 (−4 to 16)	0.50
University	62 [61]	73 (13.5)	4 (−4 to 11)	0.37[#]	3 (−5 to 12)	0.46[#]
Missing	1 [1]	–	–		–	
Living alone or not						
Cohabitant	70 [69]	74 (12.7)	Reference		Reference	
Alone	30 [30]	70 (17.9)	−4 (−11 to 2)	0.17	−4 (−11 to 2)	0.19
Missing	1 [1]	–	–		–	
Randomized study or not						
Not randomized	22 [22]	77 (16.8)	Reference		Reference	
Randomized	79 [78]	71 (14.0)	−6 (−13 to 2)	0.12	−6 (−13 to 1.3)	0.11
Total number of patients in the study with information on knowledge	101	72 (14.7)				

[‡] Part A. Phase specific questions excluded. Total number of questions included 14 (out of 20). For each question, correct answers are assigned a score of 100, unsure and incorrect answers are assigned a score of 0.[#] Test for linear trend. [a] Adjusted for all other listed factors. [a] Adjusted for all listed factors.
Linear regression was used to estimate mean differences and confidence intervals. All reported p-values are two-sided and based on the Wald test.

participate in or not. The "knowledge" items include a correct response alternative. Thus, they are less prone to subjective responses, although there is of course a risk of choosing the right answer by chance. It is encouraging that higher levels of knowledge relate to willingness to consent, thus educational efforts for patients in connection to inclusion in clinical trials might result in a higher proportion of patients consenting to participate. The finding that perceived understanding was related to consent indicates that the patients also perceived themselves as well informed. It must be considered, however, that the patients responded to the questionnaire after the decision to participate or not in a drug trial. Therefore, there is a risk of response bias in that those who consented might have been more prone to express that they understood the information about the trial than those who declined. Knowledge, on the other hand, was not likely to be affected by response bias, as the questions are based on facts about participation in a clinical trial. Previous studies, have however, not found associations between knowledge and participation in clinical trials, using QuIC [4,10]. There were no associations between "knowledge" and educational level in that study, also including a high proportion of well-educated participants.

Physicians' recommendation to patients to participate in a clinical trial increases the likelihood that the patient will take the decision to participate [5,21]. Baseline levels of knowledge could also have contributed to the decision to participate or not, but these were not assessed in the present study. Baseline attitudes toward participation in clinical trials could also have contributed to the association found between consent to participate in a clinical trial and knowledge and understanding [8]. Those who had negative attitudes to participation in clinical trials at the medical consultation might have been less prone to listen to the information and consequently reported lower levels of knowledge and perceived understanding, and decided thereafter not to participate in the clinical trial they were informed about. In addition, those who consented might have been more interested to read and learn more about the trial than those who did not.

Thirteen physicians were involved in including patients in drug trials in this study. Thus, it is unlikely that the skills of an individual physician account for the results. It has earlier been recognised that information in connection to inclusion in clinical trials is a difficult and time-consuming task [22,23]. Probably, the physicians involved in our study varied with respect to information skills.

The present study investigates the associations between selected factors related to consent to participate in clinical trials, such as age, gender, education, marital status and whether the drug trial was a randomized study or not, as well as knowledge and understanding. In addition to our results, other studies have found a number of other factors of importance for participation in clinical trials not investigated in the present study [4,6,8,9,24]. These have also to be considered in the informed consent procedure.

We choose to assign 100 point to a correct response to each item in the knowledge questionnaire in the present study, but unlike most other authors, assign 0 for both the incorrect alternative and the "unsure" option [14,18]. The reason was the requirement of

Table 4
Univariate and multivariate analyses of associations between "Perceived understanding"[a] and demographic factors.

			Univariate analysis		Multivariate analysis[c]	
Factor	N [%]	Mean (SD)	Mean difference (95% confidence interval)	P	Mean difference (95% confidence interval)	P
Age						
<45	18 [18]	85 (12.5)	Reference		Reference	
45–64	67 [67]	86 (12.4)	1 (−5 to 8)	0.58	0 (−7 to 7)	0.73
≥65	15 [15]	83 (12.4)	−2 (−11 to 6)	0.60[b]	−3 (−12 to 6)	0.51[b]
Gender						
Male	16 [16]	85 (10.4)	Reference		Reference	
Female	84 [84]	86 (12.7)	1 (−6 to 7)	0.91	−1 (−9 to 6)	0.74
Education						
Elementary school	18 [18]	87 (12.1)	Reference		Reference	
High school	19 [19]	90 (8.7)	3 (−5 to 11)	0.20	3 (−5 to 12)	0.23
University	62 [62]	84 (13.0)	−3 (−9 to 4)	0.36[b]	−2 (−9 to 5)	0.51[b]
Missing	1 [1]	–	–		–	
Living alone or not						
Cohabitant	70 [70]	84 (12.2)	Reference		Reference	
Alone	29 [29]	89 (11.6)	5 (0–10)	0.062	5 (−1 to 10)	0.084
Missing	1 [1]	–	–		–	
Randomized study or not						
Not randomized	21 [21]	89 (11.0)	Reference		Reference	
Randomized	79 [79]	85 (12.6)	−4 (−10 to 2)	0.24	−3 (−9 to 3)	0.32
Total number of patients in the study with information on knowledge	100	86 (12.4)				

Linear regression was used to estimate mean differences and confidence intervals. All reported p-values are two-sided and based on the Wald test.
[a] Part B. Total number of questions included 13 (out of 14). Answer to questions are coded 1,2,3,4,5 and are assigned scores of 0, 25, 50, 75 and 100.
[b] Test for linear trend.
[c] Adjusted for all other listed factors.

informed consent according to the Helsinki Declaration, that individuals who participate in clinical trials should be fully knowledgeable regarding the clinical trial and about the implication of participation. Therefore, we did not consider the "unsure" option to fulfil the requirements of informed consent. Correct responses only were regarded as indicative of actual knowledge. The fact that we have applied this method of scoring makes it difficult to compare the levels of knowledge in our study with other studies using the QuIC. Other studies have assigned the value of 50 to the "unsure" response alternative, probably resulting in higher levels of knowledge reported from those studies. We have, however, used this method in our previous studies, where similar high levels of knowledge were found [17,20].

The high proportion of well educated participants in our study indicates a selection of patients asked to participate in clinical trials in general, not representative of the Swedish general population. A further support for the lack of representativeness of patients asked to participate in drug trials is the finding in our previous study [20]. In that study, including all patients (n = 282) who consented to participate in clinical trials during 1 year at the Department of Oncology, Karolinska University Hospital, we found a high proportion of well-educated patients. Almost half of them reported having a university education. Trialists running these studies should therefore address the selection of patients for inclusion in clinical trials as to also include less educated patients, as this is a matter of equality.

The results of a positive association between participation in clinical trials and knowledge and perceived understanding are promising, as there was a risk of finding a negative association. Such a finding would imply a conflict between the requirements of informed consent and the pursuit of increasing participation rates in clinical trials. Our results, however, indicate that striving for increasing knowledge and understanding, fulfilling the requirements of the Helsinki Declaration, can be performed hand in hand with efforts to improve participation rates in these trials.

The study has some limitations. The sample size is relatively small. In addition, breast cancer studies were overrepresented, making the gender balance skewed. The scoring of "knowledge" used in our study differs from the scoring suggested by the original authors [18]. In the original paper, the authors state that the reason for assigning the "unsure" option 50 is "because we preferred that subjects recognize areas of uncertainty, rather than be certain of false beliefs". We consider our scoring method, where correct responses only were regarded as indicative of actual knowledge, to be more accurate according to the criteria of the Helsinki Declaration. The patient should be knowledgeable of all relevant aspects of the trial, and the QuIC is developed based on these requirements. Thus, in the ideal situation, all patients consenting to participate in a trial should respond correctly to all items in the knowledge part of the QuIC.

The study also has some strengths. Most studies of factors of importance for participation in cancer clinical trials have used

attitudes toward participation as an outcome, whereas the outcome in the present study was actual taking the decision whether to sign informed consent or not. Other strengths include the use of a validated questionnaire, and that as many as 13 oncologists and 16 trials were represented. In addition, the response rate to the questionnaire was high.

5. Conclusion

In summary, higher knowledge and perceived understanding were related with consenting to participate in clinical trials. No association between demographic factors were found, neither to consenting, nor to knowledge or understanding. Our results indicate that interventions aiming at increasing knowledge and perceived understanding might improve participation rates in clinical trials.

Conflict of interest

The authors declare that there is no conflict of interest.

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References

[1] R.B. Gul, P.A. Ali, Clinical trials: the challenge of recruitment and retention of participants, J. Clin. Nurs. 19 (2010) 227–233.
[2] G. Kaur, R.L. Smyth, P. Williamson, Developing a survey of barriers and facilitators to recruitment in randomized controlled trials, Trials 21 (2012) 218.
[3] S. Treweek, P. Lockhart, M. Pitkethly, J.A. Cook, M. Kjeldstrøm, M. Johansen, T.K. Taskila, F.M. Sullivan, S. Wilson, C. Jackson, R. Jones, E.D. Mitchell, Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis, Br. Med. J. Open 3 (2013) e002360.
[4] N.E. Avis, K.W. Smith, C.L. Link, G.N. Hortobagyi, E. Rivera, Factors associated with participation in breast cancer treatment clinical trials, J. Clin. Oncol. 24 (2006) 1860–1867.
[5] E.J. Mills, D. Seely, B. Rachlis, L. Griffith, P. Wu, K. Wilson, P. Ellis, J.R. Wright, Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors, Lancet Oncol. 7 (2006) 141–148.
[6] V. Jenkins, V. Farewell, D. Farewell, J. Darmanin, J. Wagstaff, C. Langridge, L. Fallowfield, Drivers and barriers to patient participation in RCTs, Br. J. Cancer 108 (2013) 1402–1407.
[7] S.M. Miller, S.V. Hudson, B.L. Egleston, S. Manne, J.S. Buzaglo, K. Dervarajan, L. Fleisher, J. Millard, N. Solarino, J. Trinastic, N.J. Meropol, The relationships among knowledge, self-efficacy, preparedness, decisional conflict, and decisions to participate in a cancer clinical trial, Psych. Oncol. 22 (2013) 481–489.
[8] S. Manne, D. Kashy, T. Albrecht, Y.N. Wong, A. Lederman Flamm, A.B. Benson, S.M. Miller, L. Fleisher, J. Buzaglo, N. Roach, M. Katz, E. Ross, M. Collins, D. Poole, S. Raivitch, D.M. Miller, T.G. Kinzy, T. Liu, N.J. Meropol, Attitudinal barriers to participation in oncology clinical trials: factor analysis and correlates of barriers, Eur. J. Cancer Care 24 (2015) 28–38.
[9] C. Mazouni, J. Deneuve, M. Arnedos, F. Prenois, M. Saghatchian, F. Andre, C. Bourgier, S. Delaloge, Decision-making from multidisciplinary team meetings to the bedside: factors influencing the recruitment of breast cancer patients into clinical trials, Breast 23 (2014) 170–174.
[10] N.K. Aaronson, E. Visser-Pol, G.H. Leenhouts, M.J. Muller, A.C. van der Schot, F.S. van Dam, R.B. Keus, C.C. Koning, W.W. ten Bokkel Huinink, J.A. van Dongen, R. Dubbelman, Telephone-based nursing intervention improves the effectiveness of the informed consent process in cancer clinical trials, J. Clin. Oncol. 14 (1996) 984–996.
[11] R.F. Brown, P.N. Butow, P. Ellis, F. Boyle, M.H.N. Tattersall, Seeking informed consent to cancer clinical trials: describing current practice, Soc. Sci. Med. 58 (2004) 2445–2457.
[12] P.S. Hietanen, A.R. Aro, K.A. Holli, P. Absetz, Information and communication in the context of a clinical trial, Eur. J. Cancer 36 (2000) 2096–2104.
[13] V. Jenkins, L. Fallowfield, A. Souhami, M. Satwell, How do doctors explain randomised clinical trials to their patients, Eur. J. Cancer 35 (1999) 1187–1193.
[14] S. Joffe, E.F. Cook, P.D. Cleary, J.W. Clark, J.W. Weeks, Quality of informed consent in cancer clinical trials: A cross-sectional survey, Lancet 358 (2001) 1772–1777.
[15] J. Flory, E. Emanuel, Interventions to improve research participants' understanding in informed consent for research: a systematic review, JAMA 292 (2004) 1593–1601.
[16] A. Nishimura, J. Carey, P.J. Erwin, J.C. Tilburt, M.H. Murad, J.B. McCormick, Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials, BMC Med. Ethics 14 (2013) 28.
[17] M. Bergenmar, H. Johansson, N. Wilking, T. Hatschek, Y. Brandberg, Audio-recorded information to patients considering participation in cancer clinical trials – a randomized study, Acta Oncol. 53 (2014) 1197–1204.
[18] S. Joffe, E.F. Cook, P.D. Cleary, J.W. Clark, J.C. Weeks, Quality of informed consent: a new measure of understanding among research subjects, J. Natl. Cancer Inst. 93 (2001) 139–147.
[19] A. Cull, M. Sprangers, K. Bjordal, N. Aaronson, K. West, A. Bottomley, EORTC Quality of Life Study Group Translation Procedure, second ed., EORTC, Brussels, 2002.
[20] M. Bergenmar, C. Molin, N. Wilking, Y. Brandberg, Knowledge and understanding among cancer patients consenting to participate in clinical trials, Eur. J. Cancer 44 (2008) 2627–2633.
[21] S. Eggly, T.L. Albrecht, F.W.K. Harper, T. Foster, M.M. Franks, J.C. Ruckdeschel, Oncologists' recommendation of clinical participation to patients, Pat. Educ. Couns. 70 (2008) 143–148.
[22] T.L. Albrecht, S.S. Eggly, M.E.J. Gleason, F.W.K. Harper, T.S. Foster, A.M. Peterson, H. Orom, L.A. Penner, J.C. Ruckdeschel, Influence of clinical communication on patients' decision making on participation in clinical trials, J. Clin. Oncol. 26 (2008) 2666–2673.
[23] V. Jenkins, I. Solis-Trapala, C. Langridge, S. Catt, D.C. Talbot, L.J. Fallowfield, What oncologists believe they said and what patients believe they heard: an analysis of phase I trial discussions, J. Clin. Oncol. 29 (2011) 61–68.
[24] V. Jenkins, D. Farewell, L. Batt, T. Maughan, L. Branston, C. Langridge, L. Parlour, V. Farewell, L. Fallowfield, The attitudes of 1066 patients with cancer towards participation in randomized clinical trials, Br. J. Cancer 103 (2010) 1801–1807.