ELSEVIER

A Randomized Trial Assessing the Impact of Written Information on Outpatients' Knowledge About and Attitude Toward Randomized Clinical Trials

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ABSTRACT: To improve the patient education process in clinical research, three information materials describing general aspects of design and conduct of randomized clinical trials were developed. The materials varied in length, reading ability level, and reader appeal. Their influence on knowledge about and attitude toward randomized clinical trials was assessed in a randomized, parallel group, evaluator-blinded trial among 415 outpatients. The patients were randomized to the following groups: control (no intervention), leaflet, brochure, or booklet. Knowledge was assessed by a 17-item multiple-choice questionnaire and attitude was assessed by a 32-item Likert questionnaire at entry and 2 weeks after the intervention. The interventions and the questionnaires were pilot tested and power calculations were performed. At entry, the mean knowledge score was 7.9 points. At follow-up, the knowledge scores increased by 0.5 for the control, 1.0 for the leaflet, 1.6 for the brochure, and 1.4 for the booklet. The brochure and the booklet improved the knowledge score significantly compared with the control. The general attitude was positive at entry (mean 71.5 points). Only the booklet significantly increased the total attitude score (4.8 points) and the randomized clinical trials attitude subscale score (1.8 points). In conclusion, written information significantly improved outpatients' knowledge about and attitude toward randomized clinical trials. Detailed rather than brief

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INTRODUCTION

The information offered to eligible participants in randomized clinical trials (RCTs) usually focuses on the disease, treatment options, study design, and the implications of participation. However, most patients have limited knowledge about general aspects of RCTs and may not understand the rationale [1, 2]. Without sufficient basic knowledge, specific information about a RCT may be difficult to comprehend. Furthermore, RCTs are often conducted in stressful situations, which may impede understanding [1]. Accordingly, studies have shown that patients in RCTs are not always aware of their rights or the consequences of participation [2–6]. In addition, investigators sometimes find it difficult to deal with the education process in RCTs, which may result in physicians' reluctance to accrue patients and a decline in patients' willingness to enter RCTs [7–14].

General information about methodological aspects of RCTs may improve patients' knowledge about why and how clinical trials are performed, their attitude toward RCTs, and possibly their recruitment to RCTs. Most RCT patient education studies have dealt with information about specific trials [5, 15, 16]. However, a booklet about cancer trials has been developed by The National Cancer Institute [17]. This booklet improved cancer patients' knowledge about clinical trials significantly, but did not affect recruitment rates [17].

The objective of the present trial was to examine how three types of written information influence outpatients' knowledge about and attitude toward research and RCTs.

METHODS

The INFO Trial was a randomized, parallel group, observer-blinded trial comparing three types of written information (a leaflet, a brochure and a booklet) to each other and to a no intervention group.

Patient Selection Criteria, Recruitment, Randomization, and Blinding

Participants were recruited from the outpatient clinics at the Departments of Medical Gastroenterology, Gynecology, Orthopedic Surgery, and Urology at H:S Hvidovre University Hospital, from November 5 to December 11, 1996. The inclusion criteria were ability to read and understand Danish and written informed consent. We excluded patients under 18 years of age and patients enrolled in another clinical trial on the same day.

Outpatients entering the waiting room were invited to participate by a study nurse. Recruitment was not consecutive, because it was impossible for the nurse to approach all patients, but no selection criteria were used. Patients were informed verbally and in writing about the trial. Participants gave their

written informed consent and answered two questionnaires, each taking about 15 minutes, in a separate room. The questionnaires assessed knowledge (KN) about and attitude (AT) toward clinical research focusing on RCTs [2].

The parallel group trial was randomized (1:1:1:1) and observer blinded. The four intervention arms were control (no intervention), leaflet, brochure, and booklet. The allocation sequence was generated by a computer using blocks of 12 and stratified for age (< 50 years versus $\geqslant 50$ years), gender, and department. Centralized randomization was accomplished using a press-button phone voice-response system [18]. The nature of the interventions precluded blinding of the patients. Randomization, data management, and statistical analyses were blinded and the code was not broken until after the final analysis.

Participants allocated to the control group left after completing the questionnaires. The participants in the intervention groups read the allocated information material and then returned it. Participants spent 10 to 30 minutes on reading, depending on the length of the information and personal skills. Two weeks later, all participants were mailed questionnaires similar to the entry questionnaires. Participants who did not return the questionnaires were reminded to do so by phone.

Of the estimated 2062 possibly eligible patients present during the recruitment period, a total of 722 (35%) were approached by the study nurse [2]. Of these patients, 294 (40%) were not included due to insufficient Danish skills ($n = 36$) or lack of informed consent ($n = 258$). Accordingly, 428 (59%) patients were randomized. Thirteen (3%) patients withdrew before finishing the first questionnaire, four of whom gave no explanation, four found participation too difficult, two lacked Danish skills, two had insufficient time, and one had psychological problems. Accordingly, 415 patients finished the first KN and AT questionnaires at entry. At follow-up, 369 (89%) patients returned a complete KN questionnaire and 313 (75%) returned a completed AT questionnaire. The dropouts were evenly distributed in the four groups. No specific reasons for dropping out were obtained. Figure 1 shows the participant flow through the trial.

Interventions

The information materials were developed with the assistance of communication professionals, physicians, nurses, and psychologists. The process of adjusting the interventions involved pilot tests among healthy volunteers, students, and employees at our institutions.

The information materials explained basic aspects of research and RCTs, covering aim, background, formalities, ethics, informed consent, randomization, blinding, and placebo. In addition, the booklet contained paragraphs describing drug development and financial aspects of research. The three materials varied in the degree of detail and presentation style (see below). All materials were in black and white without illustrations. English translations of the three materials are available at <<http://inet.uni2.dk/~ctucph>>.

The readability level of the information materials was estimated using Flesch's Reading Ease Score (RES) and Human Interest Score (HIS) formulas. The RES formula is $206.84 - 0.85W - 1.02S$, where W = number of syllables per 100 words and S = average sentence length [19]. The HIS formula is 3.63

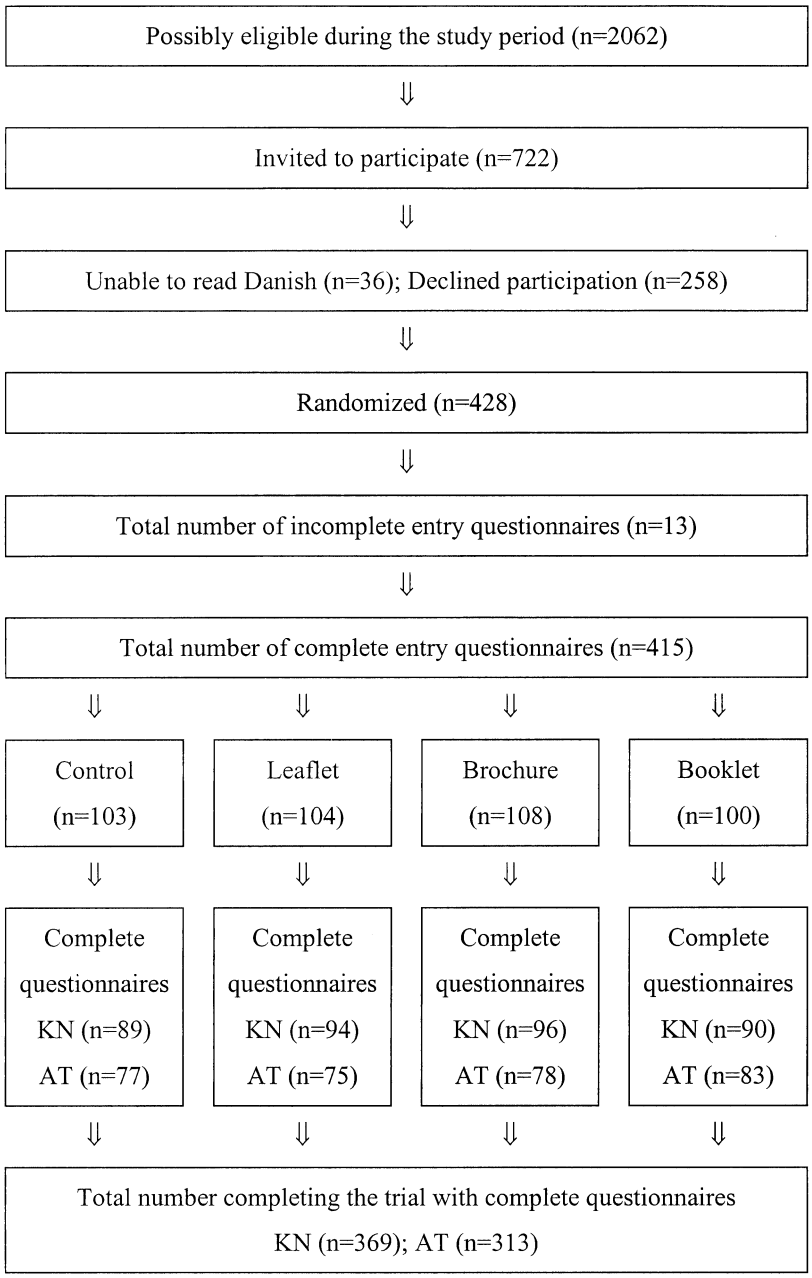

Figure 1 Patient recruitment, randomization to intervention groups and follow-up rates. Abbreviations: KN = knowledge questionnaire; AT = attitude questionnaire.

pw + 0.31 ps, where pw = percentage of 'personal words' and ps = percentage of 'personal sentences' [19]. The higher the RES the easier it is to read the text. The higher the HIS the more interesting it is to read the text. The leaflet was based on information and journalism theories, paying attention primarily to

reader appeal and readability [20, 21]. The length was 1.5 A4 pages (8 1/4 × 11 1/2 inches), RES was 57 (fairly difficult, comparable to a quality magazine), and HIS was 37 (interesting, comparable to a digest magazine). The brochure was based on practical communication experience, focusing primarily on logical composition and presentation of condensed information. The length was 2.5 A4 pages, RES was 43 (difficult, comparable to an academic magazine), and HIS was 25 (interesting, comparable to a digest magazine). The booklet was also based on practical communication experience, but gave more elaborate explanations. The length was 12 A4 pages, RES was 11 (very difficult, comparable to a scientific magazine), and HIS was 22 (mildly interesting, comparable to a trade magazine).

Questionnaires

The KN and AT questionnaires tested the effects of the information materials. The present trial did not evaluate the effect on patients' accrual to specific RCTs. The items in the KN questionnaire focused on basic aspects of the design and conduct of RCTs and research. The items in the AT questionnaire reflected statements about research and RCTs given by patients, lay persons, and health care staff. The wording and composition of the questionnaires were developed in collaboration with a panel of experts including physicians, psychologists, researchers, and communication experts. The objective was to design questionnaires that were generally applicable and not directed toward specific patient groups. The provisional questionnaires were pretested by lay persons, medical students, and employees at our institute to ensure that they were comprehensible and unambiguous. The consistency and reliability of the questionnaires were assessed and adjusted according to standard psychometric methods [2, 22, 23]. English translations appear in the appendix. The patients completed the questionnaires at study entry and again 2 weeks later to assess long-term memory [24].

Knowledge Questionnaire

The initial questionnaire contained 18 questions with eight additive scales about clinical trials: aim, background, formalities, ethics, informed consent, randomization, placebo, and finance. One correct and four alternative answers were given to each question. The internal consistency of the questionnaire was evaluated by Rasch analysis [22]. One question did not fit the model and was excluded. The remaining 17 questions were included in the final version, which comprised a strictly unidimensional test [2]. One point was added to the total score for each correct answer, providing a range of 0 to 17 points.

Attitude Questionnaire

The AT questionnaire comprised 32 statements (st) in Likert-type format (AT (total)). Twenty-eight of the statements were grouped into five subscales describing patients attitude towards RCTs (st 19 to 21; AT (RCTs)), participation in fictive RCTs (st 25 to 30; AT (RCT-participation)), enrollment of children in clinical research (st 22 to 24, 31, 32; AT (children)), role of physicians (st 9, 11,

14, 15, 17; AT (physician)) and clinical research in general (st 1 to 7, 12, 18; AT (general)). The remaining statements (8, 10, 13, 16) did not fit any of the groups mentioned above. Patients expressed their opinion by rating their degree of agreement with each of the 32 statements on a 0 to 4-point scale. Statements 1 to 4, 8, 10 to 12, and 19 to 31 were scored in disagree to agree order (0 to 4), and the remaining in agree to disagree order (4 to 0), providing a range of 0 to 128 points. Higher scores reflected a more positive attitude. The Cronbach's alpha coefficient and the product-moment correlation between the AT scale and the subscales showed high internal consistency [2, 23].

Ethical Aspects

Written informed consent was obtained from all participants. The local ethics committee and the Danish Data Protection Agency approved the trial.

Sample Size Calculations

The sample size was estimated using $\alpha = 0.05$, $\beta = 0.20$ and the assumption that 30% of the participants had an acceptable KN score, defined as more than 50% correct answers ($\geqslant 9$ points). Specifying a minimal relevant difference of 20%, i.e., an increase of the proportion of patients with an acceptable KN score from 30% to 50%, 91 patients were to be enrolled per arm. To adjust for the three pair-wise comparisons between the intervention groups and the control group, an additional sample size was estimated [25]. Eighty-eight patients were to be enrolled per arm, using $\alpha(= 0.05/3) = 0.0167$, $\beta = 0.20$, the assumption that 30% of the participants had an acceptable KN score and a minimal clinical difference of 25%.

Statistical Analyses

Intention-to-treat analyses were performed. Incomplete answers were not included. The primary endpoints was the change in KN scores and AT (total) scores between entry and follow-up. The changes in each intervention group were compared with the change in the control group by unpaired *t*-test. To adjust for multiple comparisons, the level of significance was set to $p < 0.0167$ [25]. The proportion of patients with an acceptable KN score at entry and follow-up was calculated. The change in the improvement potential was defined as the change between the score at follow-up and entry divided by the maximum possible score subtracted by the score at entry. The associations between changes in KN and AT (total) scores were analyzed by Spearman's rank correlation coefficient (ρ).

RESULTS

The demographic characteristics of the 369 patients who completed the trial are listed in Table 1. Apart from previous enrollment in RCTs, the intervention arms did not differ significantly regarding demographic and clinical characteristics or KN and AT (total) scores (data not shown).

Table 1 Characteristics of 369 Participants Who Completed the Knowledge Questionnaire According to Intervention Group[a] (Including the 313 Participants Completing the Attitude Questionnaire)

	Control	Leaflet	Brochure	Booklet
Number of completed questionnaires	89	94	96	90
Mean age (SD)	48 (18)	50 (20)	46 (19)	45 (19)
Male	32 (36)	38 (40)	39 (41)	38 (42)
Schooling				
Primary school	16 (18)	19 (20)	22 (23)	19 (21)
Secondary school	48 (54)	43 (46)	42 (44)	50 (56)
Higher education	25 (28)	32 (34)	32 (33)	21 (23)
Disease or condition				
Chronic	44 (49)	42 (45)	47 (49)	41 (46)
Not chronic	45 (51)	52 (55)	49 (51)	49 (54)
Previously enrolled in a trial	29 (33)	25 (27)	30 (32)	31 (34)
Previously enrolled in a randomized trial	11 (12)	3 (3)	5 (5)	18 (20)

[a] Except for age, table entries are frequencies (percents).

Knowledge

At entry, the mean KN score (range 0 to 17) of all participants was 7.9 (SD 3.1). Table 2 shows the mean KN scores by intervention group at entry and 2 weeks later. Compared to the control group, the brochure and the booklet increased the KN score significantly ($p < 0.001$ and $p = 0.007$). The effects of the brochure and the booklet did not differ significantly. The leaflet did not increase the KN score significantly compared to the control. The improvement potential increased by 6% in the control group, 11% in the leaflet group, 17% in the brochure group, and 15% in the booklet group. At entry, 46.3% of the patients obtained an acceptable KN score. At follow-up, the proportion of patients with an acceptable KN score increased by 7% (control), 13% (leaflet), 24% (brochure), and 8% (booklet).

Attitude

At entry, the mean AT (total) score (range 0 to 128) of all patients was 71.5 (SD 14.8). Table 3 shows the AT (total) scores at entry and two weeks later.

Table 2 Change in Knowledge (KN) According to Intervention Group of 369 Participants Who Completed the Questionnaire

	Control	Leaflet	Brochure	Booklet
Number of completed questionnaires	89	94	96	90
KN score at entry	8.2 (2.9)	7.9 (3.1)	7.8 (3.1)	7.9 (3.1)
KN score at 2-week follow-up	8.7 (2.7)	8.8 (3.4)	9.5 (3.3)	9.3 (3.1)
Change in KN score	0.5 (0.2)	1.0 (0.3)	1.6 (0.3)	1.4 (0.3)
Changes compared to the control group	(reference)	$p = 0.15$	$p < 0.001$	$p = 0.007$

Knowledge was assessed by a 17-item multiple-choice questionnaire (score range 0–17) at entry and 2 weeks later.

Changes in knowledge scores of the groups receiving written materials were compared with the control group (no intervention) by unpaired *t*-test.

Values at entry and follow-up are means (SD). Changes are means (SE).

Table 3 Change in Attitude (AT) According to Intervention Group of 313 Participants Who Completed the Questionnaire

		Control	Leaflet	Brochure	Booklet
Number of completed questionnaires		77	75	78	83
AT (total) score	Entry	71.1 (14.1)	71.1 (15.0)	73.3 (16.4)	70.4 (13.4)
(range 0–128)	Follow-up	71.7 (13.9)	71.5 (15.6)	74.4 (20.8)	75.1 (15.5)
	Change	0.6 (1.2)	0.5 (1.2)	1.1 (1.4)	4.8 (1.2)
		(reference)	$p = 0.93$	$p = 0.80$	$p = 0.01$
AT (RCTs) score	Entry	6.8 (3.2)	7.3 (3.4)	7.6 (3.3)	6.7 (3.1)
(range 0–12)	Follow-up	6.8 (3.5)	8.2 (3.1)	8.7 (3.5)	7.5 (3.3)
	Change	0.0 (0.4)	0.9 (0.3)	1.2 (0.3)	1.8 (0.4)
		(reference)	$p = 0.06$	$p = 0.02$	$p < 0.001$
AT (RCT-participation) score	Entry	12.0 (5.7)	14.0 (6.4)	13.6 (6.5)	13.6 (6.0)
(range 0–24)	Follow-up	12.4 (5.5)	14.9 (6.1)	14.7 (6.6)	15.3 (6.7)
	Change	0.5 (0.5)	0.9 (0.5)	1.0 (0.5)	1.7 (0.5)
		(reference)	$p = 0.52$	$p = 0.38$	$p = 0.08$

Attitude was assessed by a 32-item scale in Likert format at entry and 2 weeks later. The scale consisted of five subscales of which only two are shown in the table. Intervention groups were compared to the control group (no intervention) by unpaired *t*-test. Values at entry and follow-up are means (SD). Changes are means (SE).

The booklet increased the AT (total) score significantly compared to the control ($p = 0.01$). The other information materials did not change the AT (total) significantly compared to the control. The improvement potential increased by 1% in the control group, 1% in the leaflet group, 1% in the brochure group and 8% in the booklet group. The changes in KN and AT (total) score were not significantly associated ($\rho = 0.08$, $p = 0.19$).

Subscales

Table 3 shows the AT (RCTs) scores and AT (RCT-participation) scores at entry and 2 weeks later. The booklet increased the AT (RCTs) score significantly compared to the control ($p < 0.001$). The other information materials did not change the AT (RCTs) score significantly compared to the control. The improvement potential of the AT (RCTs) subscale increased by 0% in the control group, 19% in the leaflet group, 27% in the brochure group, and 34% in the booklet group. The scores of the subscales AT (RCT-participation) (Table 3), AT (children), AT (physician), and AT (general) (data not shown) did not change significantly in any of the intervention groups compared to the control group.

DISCUSSION

The present randomized trial investigates the effect of written information on outpatients' knowledge about and attitude toward RCTs. The written information focused on research and RCTs and was presented in three formats that differed in length, reading ease, and reader appeal.

The results showed that the written information improved outpatients' knowledge about research and RCTs. The brochure and the booklet, which were the most elaborate, increased the KN score significantly compared to the control. The leaflet was the shortest, easiest, and most interesting to read, but it did not improve knowledge significantly compared to no intervention. All materials improved knowledge by more than 10% of the improvement potential, the elaborate interventions providing the largest improvements. At entry, 46% of the participants obtained what we arbitrarily defined as an acceptable KN score (≥ 9 points). This was more than expected and could explain the moderate improvements. The booklet primarily increased the KN scores of more knowledgeable patients. Conversely, the brochure seems to have more effect on patients with a knowledge score below our definition of an acceptable limit. Previous studies have demonstrated difficulties in improving knowledge [17, 26]. It is therefore noteworthy that the brochure and the booklet increased the KN scores by 17% and 15% of the improvement potential, respectively. These improvements correspond to the difference observed in KN score at entry between patients with less than 7 years of education compared to 8 to 11 years of education [2].

Only the booklet changed the attitudes significantly compared to the control, by increasing the AT (total) score and the AT (RCTs) score significantly. The increase in the improvement potential of these scores was 8% and 34%, respectively. These changes are notable, because it is well established that attitudes are relatively stable and difficult to change [26]. The booklet included elaborate explanations and background information, which may match the difficult issue

better than the more popular approach of the leaflet. The booklet may appear more reliable and facilitate confidence. In accordance, patients feel more confident when given thorough compared to condensed information in the recruitment phase of specific RCTs [27–31].

Changes indicating a more positive attitude toward RCTs may improve recruitment to specific RCTs. We only studied the effect on recruitment indirectly by assessing attitude toward participation in fictive trials. No significant changes were seen in any of the intervention groups. We did not find it appropriate to apply the present information materials in an RCT with clinical outcome measures, without prior testing of the effects of the materials on knowledge, attitude and potential recruitment rates. Based on the present results, it seems relevant to test the influence of the booklet on accrual rates in RCTs with clinical outcomes.

At entry, knowledge and attitude were significantly, although weakly, associated [2]. However, no significant correlation was observed between the increase in knowledge and the improvement in attitude. This is in accordance with results from health promotions, which demonstrate that knowledge is loosely associated with attitude and behavior [26]. Further, improved knowledge about cancer trials did not increase recruitment into a specific trial [17].

Most information campaigns repeatedly confront the target population. The participants in the present trial were approached only once with abstract and complex information, which was not relevant for the individual at the time. On the other hand, the participants read the information in a separate room and may have felt obliged to read the material more carefully. Due to logistics it was not possible to include patients on a consecutive basis. However, apart from our inclusion and exclusion criteria, no specific selection criteria were applied. The age and gender of the declining patients did not differ significantly from the participants and there were no selective dropouts. The study included outpatients from four departments and they represent a natural target population for future information campaigns. The information materials were not designed for use in specific therapeutic areas and there is no obvious reason why the results should not apply to other patient groups.

In conclusion, written information about general aspects of RCTs improved knowledge about and attitude towards RCTs. Elaborate information rather than brief information was more effective. Detailed written information such as the booklet may improve the information process and recruitment rates of RCTs but needs to be studied directly. Different approaches such as videos, verbal counseling or interactive methods should also be evaluated [31, 32], taking cost-effectiveness issues into consideration.

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APPENDIX (KNOWLEDGE AND ATTITUDE QUESTIONNAIRES)

Knowledge Questionnaire

A multiple choice questionnaire designed to evaluate patients' knowledge about clinical research focusing on randomized clinical trials. The correct answer is italicized.

Why Are Clinical Trials Performed?

1. Because all new drugs must be evaluated in clinical trials with Danish patients before the drugs are allowed to be registered in Denmark.
2. To learn more about disease etiology and natural history.
3. To identify chemical substances that might be used as drugs.
4. *To improve current treatments.*
5. To identify treatments and drugs with fewer adverse events.

When Is a Clinical Trial Conducted?

1. In order to confirm the knowledge that the new drug is superior in effect compared with the conventional.
2. When the drug in question does not have adverse events.
3. In order to confirm that a new cost saving treatment is as good as the conventional more expensive treatment.
4. *When the new treatment is potentially better than the conventional.*
5. When the new treatment is as good as the conventional.

Under Which Circumstances Are Clinical Trials Conducted?

1. Exclusively when there is no established treatment for the disease.
2. In order to examine the adverse events of a new drug.
3. *In order to compare the efficacy of the new and the conventional treatment.*
4. Only in order to compare surgical with medical treatment of the same disease.

5. In order to evaluate whether increased costs of new treatments are balanced by higher efficacy.

Which Legal Requirements Must Be Fulfilled Before Physicians Are Allowed to Launch a Trial?

1. Approval from The National Board of Health and from The Ethics Committee.
2. Approval from the relevant patient organization and The Ethics Committee.
3. *Approval from The Ethics Committee and The Danish Data Protection Agency, and in clinical trials involving drugs from The National Board of Health.*
4. Approval from The National Board of Health.
5. In surgical trials, approval is required from The National Board of Health and The Ethics Committee and in trials involving drugs, approval is required from The Ethics Committee only.

What Is a Randomized Clinical Trial?

1. *A trial in which the treatment of the individual patient is decided by lot.*
2. A trial in which physicians choose the treatments to be evaluated by lot.
3. A trial in which it is decided by lot which patients are to be enrolled.
4. Cancer trials in which the treatment of the patient is decided by lot.
5. A trial in which the choice between medical and surgical treatment is decided by lot.

What Is the Reason for Conducting Randomized Trials?

1. To ensure that an equal number of patients will receive the treatment under evaluation.
2. It is the easiest way to plan a trial.
3. Because the physician is unable to determine the best treatment for the individual patient.
4. *To ensure that comparable patient groups receive the treatments undergoing evaluation.*
5. To keep the patients from knowing which treatment they receive.

Is it Possible to 'Draw a Blank' in a Randomized Trial?

1. Yes, if allocated to placebo, one is worse off than those allocated to treatment.
2. Yes, not all patients who agree to participate are included in the trial.
3. No, one can always demand the new treatment.
4. *No, regardless of whether one is to receive placebo, the conventional treatment, or the new treatment as it is uncertain which is superior.*
5. No, although new treatments have more side effects, they are frequently more effective.

What Is Placebo?

1. *Tablets that look like the trial drug but without the active substance.*
2. Tablets with an ineffective substance.
3. Tablets with a substance different from the trial drug.
4. Tablets with minute amounts of the drug, which may cause adverse events without alleviating the disease.
5. Tablets containing a substance which is excreted in the urine to show whether the patient has taken the trial drug.

When Is Placebo Used?

1. *When there is no established treatment to compare with the new treatment.*
2. In order to disclose if the physician exaggerates the effect of a new drug.
3. When the conventional treatment is almost as good as the new one.
4. Primarily in order to study the side effects of a new drug.
5. When it is important to decide whether the participating patients have taken the trial drug as prescribed.

Why Is Placebo Used?

1. Because only the physician is entitled to know whether the patient receives the active drug.
2. To keep nurses and patients ignorant of who receives treatment.
3. Because it is important to keep the patient ignorant of the type of treatment given.
4. *To make sure that the physician and the patient are unbiased in their judgment of efficacy and adverse events of the new treatment.*
5. To avoid that the patient exaggerates the adverse events of a new and effective treatment.

Which Demands Are Patients Required to Fulfill Regarding Trial Participation?

1. Participation is not mandatory provided that a refusal form is signed after receiving information about the trial.
2. Participation is voluntary, but the reasons for refusal must be given.
3. Participation is voluntary apart from a few exceptions within cancer diseases.
4. *There are no demands—participation is voluntary.*
5. One should participate if the physician is of the opinion that it is best for one self to be treated in a trial.

What Are the Requirements for Withdrawal From a Trial?

1. It depends on the design of the individual trial.
2. *None. One can always withdraw irrespective of cause or time.*

3. One can withdraw if adverse events are experienced.
4. One can always withdraw with good cause.
5. Withdrawal is possible after signing that it is at one's own risk.

What Are the Consequences if One Does Not Want to Participate in a Trial?

1. One will have the free choice between the new and the conventional treatment.
2. One will sometimes be transferred to another department where clinical trials are not undertaken.
3. *One will automatically be offered the conventional treatment, but the new treatment can always be requested.*
4. One will be offered the treatment which so far has been considered the established treatment for the disease in question.
5. One will, depending on the disease and the physician's estimate, receive either the conventional or the new treatment.

Which Financial Interests Does the Drug Industry Have in Conducting Trials in Collaboration With Physicians?

1. *Clinical trials are necessary for the approval and subsequent market launch of new drugs.*
2. The drug industry sells new drugs for trials and can accordingly earn money both before and after a new drug is approved.
3. The drug industry primarily tests drugs as part of the marketing of new and approved drugs.
4. Trials with new drugs are conducted to assess adverse events. This is required before a new drug can enter the market.
5. When a new drug has been approved, clinical trials are needed before the authorities allow marketing.

Which Financial Interests do Physicians Have for Conducting Trials in Collaboration With the Drug Industry?

1. *None. Possible payment is given for research purposes only and not to the individual physician.*
2. The individual physician does not usually receive payment, but sometimes the physician receives a fee per patient enrolled in the study.
3. Possible settlement is received by the hospital administration, which may pay a bonus to physicians who are especially active in research.
4. Possible payment is administered by the individual department, which can provide remuneration to physicians who participate in research.
5. None. Possible payment for the work is directed to the general running of the hospital.

Which Influence Does the Drug Industry Have on Tests With New Drugs Performed by Physicians?

1. None. The physicians alone decide how to plan trials with new drugs.
2. The drug industry and a group of physicians normally suggest specific trials for a new drug. Other physicians may subsequently decide whether they agree to collaborate.
3. The drug company decides which trials take place. The physicians only have influence on the conduct.
4. None. The physicians have the right to be supplied with new drugs and the sole responsibility for the planning.
5. *The drug industry decides whether new drugs should be supplied to the physicians, who alone decide whether the trial is performed.*

What Is Written Informed Consent?

1. *The patient's written consent to participate in a trial after having received verbal and written information.*
2. The patient's verbal consent to participate in a trial after having received written information.
3. The patient's written consent to participate in a trial after having received verbal information.
4. The patient's written consent to read written information and then decide upon participation in a trial.
5. The patient's consent to participate in a trial outlined in a written information.

Attitude Questionnaire

Statements reflecting attitude towards clinical research focusing on randomized clinical trials. The questions are answered by ticking off one of five boxes to indicate the degree of agreement (from "completely disagree" to "completely agree").

1. Clinical research should be given high priority in order to ensure the current standards of the health care system.
2. Ensuring a high level of service is more important than conducting research.
3. Research should be prioritized in order to improve current treatments.
4. Presently, we have quite good treatments for most diseases. Expenses for research should be kept at a minimum.
5. It is a waste of resources to do research in Denmark, as it is done better abroad.
6. Too much research is performed at Danish hospitals.
7. Current treatment offers are inadequate, more research should be performed.
8. Research should be performed, but only at the university hospitals.
9. Young physicians should learn their craft and not spend so much time on research.

10. Research in prevalent diseases, e.g., atherosclerosis, is most important.
11. It is important that as many physicians as possible do research.
12. Inadequate monetary support is given to research.
13. Research on diseases caused by e.g., alcohol and smoking should not be performed.
14. Physicians focus more upon research and career than on their patients.
15. Physicians should concentrate on treating patients and spend less time on research.
16. It is most important to do research on serious diseases such as cancer.
17. Physicians spend too much time doing research and this is one of the reasons for the long waiting lists for operations.
18. Quality of care and service would probably be better if less time was spent on research.
19. It is acceptable to plan trials in which patients are allocated by lot to different treatments.
20. It is acceptable that some trials are planned in a way that ensures that neither patient nor physician or nurse is aware of the treatment given to the individual patients.
21. It is acceptable that the physicians sometimes compare new drugs with inactive tablets (placebo).
22. I find it acceptable that children participate in trials evaluating new treatments.
23. I find it acceptable that children participate in trials evaluating new treatments of serious diseases.
24. I find it acceptable that children participate in trials in which the treatment given is decided by lot.

What Would You Do if Given the Choice?

In each of the following statements please indicate whether or not it is likely or unlikely that you will act as indicated. Answers are given by ticking off one of five boxes, indicating the degree of agreement from 'highly unlikely' to 'probable'.

25. If you had a protracted, but less serious disease would you participate in a trial with a new drug?
26. If you had a protracted, but less serious disease would you participate in a trial in which it was decided by lot whether you were to receive the usual medical treatment or a new kind of drug?
27. If you had cancer, would you participate in a trial in which the physicians were testing a new treatment with cell toxin (chemotherapy)?
28. If you had cancer, would you participate in a trial if it was decided by lot whether you were to receive the conventional treatment with cell toxin (chemotherapy) or a new kind of treatment with cell toxin (chemotherapy)?
29. If you had a heart disease, would you participate in a trial in which it was decided by lot whether you were to receive one or the other kind of heart medication—and in which neither you nor anyone else knew which medication you were receiving until the end of the trial?

30. If you had a protracted disease with no conventional treatment, would you participate in a trial in which lot decided whether or not you were to receive a new drug or ineffective tablets?
31. I would let my own child participate in a trial with a new treatment.
32. I would let my own child participate in a trial in which lot decided which of two treatments were to be given.