Patients' evaluation of informed consent to postponed information: cohort study

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Fundamental bias can be introduced in randomised trials if patients cannot be masked for the allocated strategy and assess subjective outcomes. In such a trial, on the effectiveness of outreach stroke care in addition to standard care, we masked patients by modifying the informed consent procedure. Before discharge home we informed patients that we were studying their needs six months after discharge; we could not inform about an additional research question because that would affect the results; this question entailed no risk and would be clarified after follow up; and the ethics committee approved this study.[1] After we got consent we randomised patients.

We informed patients in the intervention group about the outreach care programme and asked them to participate, but we kept them ignorant that we were studying the programme for effectiveness. Controls received no further information. After follow up, we sent all participants a letter with the postponed information on the additional research question, randomisation, and the reasons why patients did not receive this information during recruitment.

Several arguments can be raised against this modification.[2–5] Firstly, it would lead to a high rate of patients who decline to participate. Secondly, it would lead to a decreased trust of patients in their treating doctors; thirdly, it would lead to less willingness to participate in future studies. Fourthly, this modified procedure would not treat patients with respect. The first three arguments contain empirical claims that were studied.

Participants, methods, and results

Of 123 eligible patients, five declined to participate in the trial. Four declined because of their high age, and the fifth said she had filled in questionnaires in the past, which was a great burden to her.

After six months, we send the letter with the postponed information to all recruited patients. Two weeks later, we interviewed patients. Of the 118 patients recruited, six had died before the time of the interview. Of the 112 patients who were alive, we successfully contacted 102. Of the 102 respondents, 79 had read the letter; seven had forgotten if they had read it; and six indicated that they had no time to read it or that a relative handled their mail. None of the patients answered that their trust in doctors had decreased after reading the letter; one said his trust had increased. One patient said the willingness to participate in future studies had decreased. Two patients categorised their feelings after reading the letter as negative, 71 as non-negative, and six did not understand the letter's content. The negative feelings were raised by one intervention patient, who felt that it was strange that she did not receive the information during recruitment, and one control patient, who did not wish to have the information because her health was satisfactory. Frequently mentioned non-negative feelings were that the information was unimportant (n = 16), that the patient understood why the information was withheld (n = 16); and that the patient found it acceptable that the information was withheld (n = 9).

Comment

The data from patients who had declined recruitment in our trial and from those who had participated do not support the critique that the modified informed consent procedure would reduce patient recruitment, or induce a diminishing trust in doctors or less willingness to participate in future studies. However, a substantial group of recruited patients could not be interviewed, and it could still be argued that this modified procedure fails to treat patients with enough respect. The modified procedure with postponed information deserves consideration when patients cannot be masked and assess subjective outcomes, when the additional treatment entails no risk, and when this treatment seems attractive to patients.

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Contributors: All authors participated in designing the study and developing the questionnaire that was used during the interviews. H Boter collected the data, performed the analyses, and wrote the successive drafts of the paper. JJMvanD, RJdeH, and GJER supervised and commented on all drafts. All authors approved the manuscript. HB is guarantor.

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Competing interests: None declared.

Ethical approval: Ethics committees of the participating centres approved the procedures followed.

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Commentary: Methodological reasons for not gaining prior informed consent are sometimes justified

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Informed consent is generally required before medical research interventions.[1–3] Despite this, good reasons not to seek such consent often exist. Examples might include research with incompetent patients, research using anonymised tissue samples, and certain types of epidemiological research.[4] Another reason, often forgotten, is where there are methodological reasons not to seek consent in advance of the intervention. Boter et al's study represents such an occasion.[1] Informed consent could not be given before the research as the methodology involved the patients assessing their own quality of life. Requiring prior consent would have led to potentially biased results.[5]

Is this study unethical because informed consent was not gained in advance? Leaving aside the fact that the research could not have been accomplished if such consent were required, such a claim raises an important ethical issue. Arguably, no ethical principle should be absolute in this way. Situations are complex, and minor changes can make a significant difference to the way that we assess them. Different ethical and methodological issues need to be weighed against each other and a defensible judgment made on the basis of all of the relevant factors.

In this case, the procedure for consenting was ethically justified because the study considers an important issue; the results could be achieved with blinding to the issue to be investigated; and any possible harm to the participants was negligible.

Even if we agree that the alternative of not doing the study would have treated the patients with more respect,[6] it is not clear it would have been more ethical, as the results of the study will improve the quality of life of stroke victims.[5] Blindly applying absolute principles such as "always gain prior informed consent" does not guarantee ethical outcomes. Such an approach might well be harmful, as potentially beneficial studies will not be done.

One concern about the study's approach might be that it still places too much emphasis upon consent.[7] Informing the participants in advance that some information about the research was withheld could have caused anxiety. As a result, participants might have imagined themselves in all sorts of distressing scenarios. An alternative would have been to say nothing about the consent issue until after the study was completed. It is not clear that the "modified" informed consent procedure is preferable. However, it is important that this research found that most participants could, retrospectively, appreciate the methodological reasons for not seeking prior consent, and they generally seemed happy to be involved in such research.

Researchers, journals, and the members of research ethics committees should all take note of these findings and should be more willing to weigh up the appropriateness of seeking prior informed consent given the methodology employed in a study. An absolute requirement to gain always an informed consent may do more harm than good.

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Comparison of reporting of ethnicity in US and European randomised controlled trials

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Increasing evidence shows that different ethnic groups respond differently to educational, psychosocial, and pharmacological interventions. If diverse communities are to benefit from the implementation of appropriately derived evidence then it is imperative that the ethnic diversity of populations under study are reflected in clinical trials. In the United States, since 1993, the National Institutes of Health have instituted policy insisting that minority groups are represented in study samples unless there is a compelling reason not to do so.[1] However, no comparable legislation exists in Europe. We sought to compare reporting of ethnicity in published reports of US and European randomised controlled studies.

Methods and results

We searched Medline for reports of trials published in 2002 using the Cochrane optimal search strategy.[2] We

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