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.

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. 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 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. JM van Delden, RJ de Haan, and GJE Rinkel supervised and commented on all drafts. All authors approved the manuscript. HB is guarantor.

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