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COMMENTARY

Details about informed consent procedures of randomized controlled trials should be reported transparently

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1. Commentary

Informing potential participants about the aims and procedures of a trial is mandatory when seeking their consent. A description of the potential benefits and harms of the intervention and control conditions is an integral part of the information that should be provided. The World Medical Association's Declaration of Helsinki from 1964 [1] is the most often used guideline when it comes to the content of informed consent. It states that ''the nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.'' In addition, the Declaration of Helsinki explicitly states that consent should, as a rule, be obtained in writing. Research ethics committees are used to check whether the informed consent procedures proposed by researchers adhere to this general guideline. Current practice in obtaining informed consent seems to have been shaped by emphasis on the legal duty of disclosure; consent is seen as an action, concluded by signing a form [2]. In line with this administrative attitude toward informed consent, the procedure is standardly reported in a research article.

However, the exact information that is given to potential participants is often not understood by them [3,4]. At the same time, this information affects their decision to accept or refuse the invitation to take part in a trial [5−7], for example, because of the description of the expected treatment effect [8] or the extent to which pain is emphasized in the provided information [9]. Furthermore, the information may also affect the behavior of participants during the trial (in particular regarding trials where participants cannot be blinded), for example, dissatisfaction with not receiving a potentially beneficial treatment or loyalty to those providing the treatment [10], which might also lead to dropout [11]. It is therefore important to know, when interpreting findings from a trial, how participants were informed about their participation.

Guidelines such as Consolidated Standards of Reporting Trials (CONSORT) [12] have been developed to improve the reporting of trials. Implementation of such guidelines and endorsement by leading medical journal editorial organizations have led to better reporting of trials, although the current reporting is still not optimal [13−17]. Because the first version of CONSORT, which was published in 1996 [18], several updates and extensions have been published (www.consort-statement.org). Until to date, however, these guidelines do not include a statement with regard to the reporting of the informed consent procedure of trials. This may be a reason why details about informed consent procedures of randomized controlled trials are currently poorly reported as our research shows.

We used the data frame of a systematic review including a random sample of 100 medical trials [19] to assess which information on informed consent procedures is commonly reported. Whereas almost all reports (92/100) included a statement that informed consent was sought from participants, only very few (6/100) reports included some details about how exactly participants were informed. However, the given information was often very brief (see examples in Box 1). No report (0/100) referred to a publication with additional detailed information or provided the original participant information as supplementary material (full data from this analysis can be found on the Open Science Framework: https://osf.io/fx3m7/).

We argue that details about informed consent procedures of randomized controlled trials should be reported transparently. We propose that essential features of the information for participants are very briefly summarized in the methods section of

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Box 1 Examples of the reporting of details about the informed consent procedure in trial publications

"Each patient signed a consent form before being included in the study, and all patients were informed about both arms of the trial (CPAP and sham CPAP as placebo—CPAP at a very low pressure (<1 cm H20) without any known therapeutic effect)." [20].

"All eligible mothers were informed by the fieldworkers about the overall aims of the study (advice on feeding of infants and its effects on the child's health) as well as all research procedures, including use of a questionnaire, anthropometric and blood hemoglobin measurement, dental examination, and differences between the intervention and control groups." [21].

"To ensure equipoise, the description of the study to patients and their physicians emphasized the possible benefits and limitations of both the intervention and usual care conditions." [22].

a trial report and that the full, original participant information letter (and ideally also an English translation if necessary) is published alongside the report as supplementary material or using platforms such as the Open Science Framework. This fits with the current move toward a more open research culture in which transparency, openness, and reproducibility are vital features [23−26]. We further recommend including a respective statement in a future version of CONSORT and related guidelines on the reporting of detailed information about the informed consent procedure, in particular how potential benefits and harms of the intervention and control conditions were communicated to participants.

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