Koonrungsesomboon Nut 論文内容の要旨

主　論　文

Improved participants' understanding of research information in real settings using the SIDCER informed consent form: a randomized-controlled informed consent study nested with eight clinical trials

SIDCERインフォームドコンセント書式を用いた研究参加者の内容理解改善：8件の臨床試験を用いたインフォームドコンセントのランダム化比較試験

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緒　　言
An informed consent form (ICF) is a required document in most clinical trials. It is a vehicle to deliver research-related information to prospective subjects for their decision making whether to participate in a trial. However, the ICFs used in contemporary clinical trials have been lengthened over time and many of them are incomprehensible or incomplete. These result in a limited, suboptimal understanding of information among the subjects, thereby affecting the validity of consent obtained. In collaboration with the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), we have developed the methodology for enhancing the quality of ICFs, named “SIDCER ICF”, and first validation was performed in Thai healthy volunteers. In the present study, we tested the applicability and effectiveness of the SIDCER ICF methodology across multiple clinical trials involving Thai research participants with various conditions.

対象と方法
A single-center, randomized-controlled informed consent study nested with eight clinical trials was conducted at Thammasat University Hospital, Thailand. A total of 258 participants from any of the eight clinical trials were enrolled and randomly assigned to read either the SIDCER ICF (n = 130) or the conventional ICF (n = 128) of the respective trial. Their understanding of necessary trial-related information was assessed using the post-test questionnaire. The primary endpoint was the proportion of the participants who had the post-test score of ≥80%. The secondary endpoint was the total score of the post-test.

結　　果
The proportion of the participants in the SIDCER ICF group who achieved the primary endpoint was significantly higher than that of the conventional ICF group (60.8% vs. 41.4%, p = 0.002). The total score of the post-test was also significantly higher among the participants who read the SIDCER ICF than those who read the conventional ICF (83.3% vs. 76.0%, p <0.001).

考　　察
The present study nested with eight clinical trials validated the applicability of the SIDCER ICF methodology in the development of enhanced ICFs for various clinical trials. Significant improvement of the participants’ understanding indicates the effectiveness of the SIDCER ICF in the real informed consent settings among Thai populations with diverse conditions. Using the SIDCER ICF methodology, researchers can improve the quality of ICFs for their clinical trials.