

Speaking books talk about clinical trials

Researchers behind a project using 'speaking books' to improve knowledge of what it means to be involved in a clinical trial amongst those with poor literacy in Uganda presented their research at a conference on medical ethics held in Uppsala this week.

Researchers from the Infectious Diseases Institute, Kampala, Uganda developed a 'speaking book' in partnership with the World Medical Association, the Steve Biko Centre for Bioethics and the South African Medical Association. The book was presented at the conference "Is Medical Ethics Really in the Best Interest of the Patient" held in Uppsala on June 14-16.

The conducted a clinical trial of the use of the speaking book to see how it improved knowledge about clinical trials amongst potential participants with poor literacy skills. It was found that the group of people who used the speaking books for a week had significantly improved knowledge of what is involved in participation in a clinical trial than the group exposed to a standard informed consent discussion. Added to which, every one person who used the book, introduced it to at least 8 other people amongst their family and friends.

The books are colourful picture narratives, which describe what to expect when taking part in a clinical trial and the rights and responsibilities of the participant and the people running the trial. The information is presented in pictures and text but most importantly corresponding audio descriptions can be easily accessed by pressing a button mounted on the right of the book which is identified as corresponding to the relevant page by matching images.

Multi-media educational tool (speaking book) increases knowledge of clinical trials among HIV-positive patients in Kampala, Uganda

By: Gavin Robertson 1; Soeren Rasmussen 2; Richard Hubbard 2; Kevin Newell 3; Margaret Denty 1; Yukari Manabe 1

1Makerere University, Infectious Diseases Institute, Faculty of Medicine, Kampala, Uganda; 2Pfizer, Inc, Medical Division, New York, United States; 3Clinical Monitoring Research Program, SAIC-Frederick, Inc., NCI-Frederick, Frederick, Maryland, United States

[Find out more about this very interesting project > \[http://www.crb.uu.se/symposia/2010/abstract/robertson.html\]](http://www.crb.uu.se/symposia/2010/abstract/robertson.html)



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Background: Sufficient knowledge and the process of obtaining informed consent present specific challenges with low literacy patients. Our objective was to evaluate the improvement in knowledge in low-literacy patients about the process of clinical trials and the rights and responsibilities of clinical trial participants using an educational tool, the ‘Clinical Trials Speaking Book’.

Methods: This was a randomized controlled trial conducted at the Infectious Diseases Institute in Kampala, Uganda. Participants were randomized to 1) a standard informed consent discussion (Control arm), or 2) an informed consent discussion involving instruction on using the Speaking Book with a take home copy (Speaking Book arm). The discussion content covered in both arms was the same. After the discussion, participants completed a multiple choice test on clinical trials and the rights and responsibilities of participants. A week later they completed the same test to assess knowledge retention.

Results: 91 participants completed both the initial and follow-up tests in the Control arm and 100 in the Speaking Book arm. The average age of participants was 38 years, 53% were female and 67% were employed. 20% had previously been invited to participate in a clinical trial and 19% had participated. Regarding Clinical Trial knowledge scores, the change in proportion of correct responses from test 1 to test 2 was 2.7 (95%CI 0.3-5.0) for the Control Group and 11.5 (95%CI 9.3-13.7) for the Speaking Book Group (t-score= -5.3, p-value<0.0001).

Conclusion: Participants who had instruction in the use of the Speaking Book and used it for one week had a statistically significantly larger increase in knowledge assessment score than those who had no access to this tool. With patients of low-literacy, innovative techniques can assist in increasing the knowledge that potential participants acquire to make a more informed choice about participation in Clinical Trials.

Email: grobertson@idi.co.ug [<mailto:grobertson@idi.co.ug>]

This conference is arranged by [Cesagen](http://www.genomicsnetwork.ac.uk/cesagen/) [<http://www.genomicsnetwork.ac.uk/cesagen/>] at the universities of Lancaster and Cardiff and the [Centre for Research Ethics & Bioethics](http://www.cerethics.org/) [[././index.html](http://www.cerethics.org/././index.html)] at Uppsala University.
