



Multimedia informed consent for low literacy populations

SUMMARY → Informed consent is vital in clinical research. Achieving adequate comprehension in low literacy settings however is a significant challenge. The present invention is a multimedia tool for obtaining truly informed consent in low to non-literate settings.

Features, benefits & advantages:

- Modular tool with trial specific and generic aspects
- Improves comprehension by >50%
- Greater retention of information
- Clear participant satisfaction

background

Informed consent is a fundamental pre-requisite of clinical research. The process ensures that participants entering into clinical research do so freely and with full knowledge and comprehension of the study process, as well as its risks and benefits.

Full disclosure is easy to achieve; ensuring full comprehension however requires careful consideration and a sensitivity to the cultural and societal requirements of individual study settings. In sub-Saharan Africa for example, empirical evidence has consistently shown that participants demonstrated poor comprehension of even fundamental study concepts, such as placebo, randomisation and blinding.

In award winning research, Dr Muhammed Afolabi (MRC CEO Award – Driving Change) of the MRC Unit The Gambia developed a multimedia consent tool for achieving informed consent in low to non-literate settings, where study participants first language is frequently non-written. The tool has been designed to communicate both trial specific and general concepts in a modular format and is suitable for the communication of this information in multiple languages. In a pilot study, the tool was demonstrated to increase comprehension from 40% to 64%, elicited a statistically significant increase in recall and understanding and led to high levels of participant satisfaction.

the invention

Obtaining informed consent in study populations where literacy levels are low represents a significant challenge. Electronic consent tools are becoming an established part of clinical research; however none are aimed at tackling this specific challenge. The present invention was designed specifically to address this need, providing clear improvements in comprehension and recall.

publications

Afolabi M.O. et al. (2015). A multimedia consent tool for research participants in the Gambia: a randomized controlled trial. *Bull World Health Organ.* 93(5):320-328A. <http://dx.doi.org/10.2471/BLT.14.146159>

Afolabi M.O. et al (2014). Digitised audio questionnaire for assessment of informed consent comprehension in a low literacy African research population: Development and psychometric evaluation. *BMJ Open.* 4 (6): e004817

Afolabi M.O. et al. (2014) Multimedia Informed Consent Tool for a Low Literacy African Research Population: Development and Pilot-Testing. *J Clin Res Bioeth.* 5(3):178. doi:10.4172/2155-9627.1000178

Afolabi M.O. et al (2014). Informed consent comprehension in African settings: A systematic review. *Trop Med & Int Health.* 19(6):625-642

licensing option

We are looking for partners for collaborative development of this technology, which is also available for exclusive or non-exclusive licensing.

If you would like further information about this technology or alternative MRC Technology developments, do not hesitate to contact us.

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