A multimedia consent tool for research participants in the Gambia: a randomized controlled trial

Muhammed Olanrewaju Afolabi, Nuala McGrath, Umberto D’Alessandro, Beate Kampmann, Egeruan B Imoukhuede, Raffaella M Ravinetto, Neal Alexander, Heidi J Larson, Daniel Chandramohan & Kalifa Bojang

Objective To assess the effectiveness of a multimedia informed consent tool for adults participating in a clinical trial in the Gambia.

Methods Adults eligible for inclusion in a malaria treatment trial (n = 311) were randomized to receive information needed for informed consent using either a multimedia tool (intervention arm) or a standard procedure (control arm). A computerized, audio questionnaire was used to assess participants’ comprehension of informed consent. This was done immediately after consent had been obtained (at day 0) and at subsequent follow-up visits (days 7, 14, 21 and 28). The acceptability and ease of use of the multimedia tool were assessed in focus groups.

Findings On day 0, the median comprehension score in the intervention arm was 64% compared with 40% in the control arm (P = 0.042). The difference remained significant at all follow-up visits. Poorer comprehension was independently associated with female sex (odds ratio, OR: 0.29; 95% confidence interval, CI: 0.12–0.70) and residing in Jahaly rather than Basse province (OR: 0.33; 95% CI: 0.13–0.82). There was no significant independent association with educational level. The risk that a participant’s comprehension score would drop to half of the initial value was lower in the intervention arm (hazard ratio 0.22, 95% CI: 0.16–0.31). Overall, 70% (42/60) of focus group participants from the intervention arm found the multimedia tool clear and easy to understand.

Conclusion A multimedia informed consent tool significantly improved comprehension and retention of consent information by research participants with low levels of literacy.

Introduction

Clinical trial participants in sub-Saharan Africa often have limited understanding of the study information provided during the informed consent process. Low literacy and the difficulty of presenting information in local languages with no standard written form are contributory factors. Nevertheless, international ethics guidelines require informed consent to be obtained in a manner that can be understood by individuals volunteering for clinical studies. Moreover, the Declaration of Helsinki states that special attention should be given to the specific information needs of participants and to the methods used to deliver that information. Consequently, study information must be provided in a medium and language understood by potential participants. However, informed consent documents are usually written in an official national language, often a common international language. In countries such as the Gambia, where local languages have no standard written form, translating documents into the local language and back-translating into the national language (English, in this case), to check consistency is both impractical and inaccurate.

Comprehension of consent information is essential for protecting study participants’ rights and for complying with the principles of good clinical practice. In sub-Saharan Africa, an increasing number of clinical trials are being conducted in populations that are vulnerable to exploitation because of poverty, illiteracy, social exclusion or poor access to health care. In particular, illiterate participants may not understand research concepts, which could undermine their ability to give truly informed consent. Comprehension could be improved using multimedia consent tools that have been effective for communicating crucial research information in developed countries. Moreover, empirical studies indicate that such tools provide an alternative means of presenting study information to vulnerable groups. The effectiveness of multimedia consent tools among clinical trial participants in low English-language literacy in Africa has not been determined.

Previously in the Gambia, we developed and validated both a multimedia tool for providing study information to clinical trial participants and a computerized, audio questionnaire for assessing their comprehension of informed consent. Here we report on the acceptability, ease of use and effectiveness of the multimedia tool among participants in a malaria treatment trial in the Gambia.

Methods

We conducted a randomized controlled trial in Basse and Jahaly Provinces in the Upper River Region and Central River Region, respectively, of the Gambia from 15 August 2013 to 12 March 2014. The study was nested within a parent study – the PRINOGRAM trial. The aim of this trial was to determine the optimal dosage of primaquine required to clear gametocytes and block disease transmission in asymptomatic malaria carriers. Participants in the PRINOGRAM trial were aged 1 year or older and were seen on the day of inclusion (day 0, the
baseline) and on days 3, 7, 14, 21, 28, 35 and 42. In the study areas, most residents were subsistence farmers and the adult literacy rate was about 50%.15

To be included in our study, individuals had to be eligible for the PRINOGAM trial, to be aged 18 years or older, to speak and understand one of the three major Gambian languages (i.e. Mandinka, Fula or Wolof) and to have no obvious communication, visual or cognitive impairments. Since a systematic review showed that, on average, 47% of participants in African studies understood basic research concepts,1 we estimated that a study with a 90% power to detect a 20% difference between intervention and control arms at the 5% significance level for a two-sided test would require 137 participants in each arm. On assuming a 10% attrition rate, we estimated that approximately 150 participants would be required in each group. In our study, participants were randomly assigned to the intervention or control arm on day 0 of the PRINOGAM trial, at the time of treatment randomization. An independent statistician used the RANDI2 web-based application (available at: http://dschrimpf.github.io/randi3/) to generate a randomization list for each trial site and participants were allocated to the intervention or control arm at a 1:1 ratio with a block size of four. In addition, participants were stratified by age group and sex.

**Intervention**

The multimedia informed consent tool has been reported in detail elsewhere.12 Briefly, it contained information from the PRINOGAM consent document under the headings: (i) introduction; (ii) reason for the study; (iii) what glucose-6-phosphate dehydrogenase deficiency is; (iv) how to take part; (v) what happens if you take part; (vi) what blood tests are performed; (vii) what the side-effects and possible risks of taking part are; (viii) what the potential benefits are; (ix) how taking part is kept confidential; (x) who carried out an ethical review of the study; and (xi) who to contact if you have questions. The information in each section was presented in a context-specific visual form by members of the clinical trial team acting out various scenes after training. Video recordings were made by a multimedia expert and voice-overs were added separately in the three main Gambian languages. Adverse events of the study drugs that could not be adequately presented in the acted scenes, such as headache, diarrhoea or the passage of dark-coloured urine, were illustrated using animations.12 In addition, the multimedia tool was tailored to the cultural and linguistic diversity of the Gambian population. A digital versatile disc (DVD) incorporating the three language versions was produced and uploaded onto laptop computers. For the intervention arm of our study, a trained field assistant selected the language preferred by each participant and played the DVD using a laptop computer in a quiet room. Individuals consented to participating in the trial by either signing or thumb-printing the consent form in the presence of an impartial witness.

In the control arm, clinical trial information was presented using the
current standard practice accepted by the national ethics committee in the Gambia (chair of the Gambia’s National Ethics Committee, personal communication, 12 October 2010). In the absence of acceptable written versions of the local languages, the study’s principal investigator trained field staff, who were native speakers of the major local languages, on the correct interpretation of the English version of the participants’ information sheet. Subsequently, the study information was presented verbally to prospective participants during discussions on informed consent. Again, consent was given by either signing or thumb-printing the consent form.2,16

**Assessment**

We have previously shown that the computerized, audio, informed consent comprehension questionnaire is a reliable and valid tool for assessing comprehension of informed consent among Gambian trial participants.13 It comprises 26 questions in the three major Gambian languages: nine open-ended, seven closed-ended and 10 multiple-choice questions. The questionnaire was administered using laptop computers by trained interviewers who entered participants’ responses to each question. Responses were automatically recorded in the questionnaire computer database.

Comprehension was assessed on the basis of recall and understanding.17 Recall relates to the participant’s ability to correctly answer closed-ended and multiple-choice questions. Understanding is defined as the participant’s ability to correctly interpret or respond to open-ended questions. Our primary study outcome was comprehension of consent information as indicated by the participant’s questionnaire score, expressed as a percentage, on day 0 at study inclusion. Secondary outcomes were comprehension on days 7, 14, 21 and 28.

In addition, 119 randomly selected participants took part in focus group discussions on day 35, to further explore understanding of the PRINOGAM trial and to evaluate the acceptability and ease of use of the multimedia tool. Ten focus group discussion sessions were held in Basse Province; only six were held in Jahaly Province because there were fewer participants. Seven or eight participants were invited to each session and participants were segregated by sex so they could express their views more easily. The sessions were facilitated using a specially designed focus group discussion guide (available from corresponding author). Audio recordings of the sessions were transcribed into English by three translators and the accuracy of the translations was confirmed by independent translators fluent in the local languages and English. The transcribed texts were analysed using NVivo version 10.0 (QSR International Pty. Ltd, Doncaster, Australia) and the main themes that emerged were coded line by line to elucidate their meanings. The themes were subsequently sorted and collated into categories and subcategories and themes from the two sites were compared, integrated and refined. Finally, selected quotations from participants were used to illustrate differences in understanding of consent information between the intervention and control arms.

**Statistical analysis**

Because data on comprehension of consent information were not normally distributed, we compared the median and interquartile range of participants’ comprehension scores at each visit in the two study arms. Associations between participants’ characteristics and baseline comprehension scores were assessed using the Mann–Whitney U test if the characteristic was classified using two categories and the Kruskal–Wallis test if more than two categories were used. We used forward stepwise variable selection in a multivariate logistic regression analysis to identify factors that were associated with comprehension on day 0. For this purpose, we reclassified the comprehension scores as a binary variable equal to 2 (below median) or 1 (median or above). Since participants were recruited at two different sites, we investigated the effect of clustering on comprehension using a mixed-effects model. Survival analysis was used to extrapolate the decline in comprehension scores beyond the end of the study follow-up. A P-value less than 0.05 was regarded as statistically significant. All statistical calculations were performed using Stata version 12.1 (StataCorp., LP, College Station, United States of America).

Approval was obtained from the ethics committee of the London School of Hygiene & Tropical Medicine in the United Kingdom of Great Britain.
Results

Of the 347 participants enrolled in the PRINOGAM trial, 26 refused to take part (7.5%) in the study of the multimedia informed consent tool. Most of those who refused said they did not have time to wait because of domestic demands. In addition, 10 participants (2.9%) insisted on using the multimedia tool without going through randomization, most likely because they had heard about the tool through friends or family already enrolled in the study. After excluding these 36 participants, 311 were enrolled in the study and included in final analysis (Fig. 1). Table 1 (available at: http://www.who.int/bulletin/volumes/93/5-14-146159) shows there was no significant difference in demographic characteristics at baseline between participants in the two study arms. The playing time of the multimedia DVD was 19.4 minutes and the standard consent process took 30 to 35 minutes depending on the communication skills and experience of the research assistant providing the information. On average, question-and-answer sessions after the consent interviews took 32 minutes.

The median consent comprehension score of participants who used the multimedia tool was higher at all times points than those who received information using current standard practice. For example, at day 0 (Fig. 2), the median comprehension score in the intervention arm was 64% compared with 40% in the control arm \( (P = 0.042) \). The corresponding comparisons for days 7, 14, 21 and 28 are shown in Fig. 3, Fig. 4, Fig. 5 and Fig. 6, respectively. Table 2 shows that comprehension of informed consent at baseline in the two study arms combined was significantly greater in male participants, those who resided in Basse province and those who had received formal education based on an English-language curriculum. In addition, multivariate logistic regression analysis found that, after controlling for other covariates, poorer comprehension at baseline was significantly and independently associated with female sex (odds ratio, OR: 0.29; 95% confidence interval, CI: 0.12–0.70) and residing in Jahaly province (OR: 0.33; 95% CI: 0.13–0.82; Table 3). However, on applying the mixed-effects model, place of residence was no longer significantly associated with comprehension at baseline (OR: 0.85; 95% CI: 0.45–1.60; details available from authors). Survival analysis showed that the risk that a participant’s comprehension score would, during follow-up, drop to below 50% of that at day 0 was lower in the intervention arm than the control arm (hazard ratio 0.22, 95% CI: 0.12–0.70) and residing in Jahaly Province. In Basse, 69.6% were female compared with 63.4% in Jahaly.

Informed consent

There was general consensus that signing or thumb-printing the consent form implied a commitment to participate in the research. One participant from Basse said, “When you put your hand in that paper, then you have promised to be part of the study.” However, there were divergent opinions on the right to withdraw. Whereas most participants in the control arm felt strongly that it was morally wrong to stop participating before the end of the study, the majority in the intervention arm stated that participants were free to leave at any time. One participant in the intervention arm said, “What we always think is that our doctors will be angry if we leave before the end of the study, but I now know after watching the ’film’ that we have freedom to leave at any time, without telling them the reason for this...”

Participants were unequivocal that incentives were needed to motivate them to join and stay in the trial. Whereas

![Informed consent comprehension questionnaire scores in intervention and control arms](image-url)
One said, “We appreciate all the good things you have done to care for us and our children, but the real help that we expect and will never be forgotten is to give us fertilizers for our crops and train our children to be like you...” Most participants in the control arm could not describe the risks involved, whereas participants in the intervention arm could often name the adverse events associated with the study medications, such as headache, abdominal pain, vomiting and diarrhoea. A male participant in the intervention arm described the passage of dark-coloured urine associated with haemolysis caused by primaquine in individuals with glucose-6-phosphate dehydrogenase deficiency, as urinating “wonjo”. “Wonjo” is a popular, local, dark-red coloured, hibiscus drink. Most participants in the intervention arm described the randomization procedure graphically and some participants in the control arm said randomization was done to ensure all participants had an equal chance of participating.

Multimedia informed consent tool

Overall, 70% (42/60) of focus group participants from the intervention arm thought the visual and verbal information presented through the DVD was clear and easy to understand. However, a few expressed reservations. One said, “Although I like the (computer) pictures and sounds, I prefer face-to-face talking. I can easily ask questions that are not clear to me and this will make me understand better.” Another said, “The Fula man (interpreter) on the computer (video) repeated the same information over and over, and this made everything boring to me.”

Discussion

Our study’s findings confirm that use of a multimedia informed consent tool results in significantly better understanding of clinical trial information than the current standard method for obtaining consent. Participants using the multimedia tool achieved significantly higher consent comprehension scores at all study assessments. Moreover, results indicated that those who used the multimedia tool retained the study information significantly longer.
Although education, place of residence and sex were associated with participants’ comprehension scores at baseline, multivariate analysis found that the associations were significant only for place of residence and sex. This contrasts with findings of previous studies, which reported that educational level was an independent predictor of comprehension. The difference may have arisen because the large majority of our study participants had no formal education, which further strengthens the case for using multimedia tools to provide information to participants with low levels of literacy. Moreover, the multimedia tool was well received: in fact, during recruitment some participants insisted on being allocated to the intervention arm without undergoing formal randomization. Also, in focus group discussions, participants said they liked the way the study information was presented visually and verbally through the multimedia tool.

Our study adds to the emerging body of evidence that multimedia tools can increase trial participants’ comprehension of informed consent in Africa, particularly in areas where low literacy is common. In our study, research concepts that are known to be difficult to understand were clearly illustrated.
A multimedia informed consent tool, the Gambia

Muhammed Olanrewaju Afolabi et al.

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Competing interests: None declared.

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Competing interests: None declared.
**Resumen**

**Outil multimédia de consentement pour les participants à des recherches en Gambie : un essai contrôlé randomisé**

**Objetivo** Evaluar la eficacia de un outil multimedia de consentimiento declarado para los adultos participantes a un ensayo clínico en Gambia.

**Métodos** Los adultos elegibles a la participación a un ensayo de tratamiento du paludisme (n = 311) fueron probados para el reciclaje de las informaciones necesarias al consentimiento declarado, al modo de un outil multimedia (branche d'intervention) o incluso de la procedura standard (branche témoin). Un questionaire audio informatisé a été utilisé pour évaluer la comprensión del consentimiento declarado por los participantes, immédiatement après l'obtention de ce consentement (jour 0) ainsi que lors des visites de suivi ultérieures (jours 7, 14, 21 et 28). L'acceptabilité y la facilité d'utilisation de cet outil multimedia ont été évaluées dans des groupes de discussions.

**Résultats** Au jour 0, le score médian de compréhension dans la branche d'intervention était de 64 % contre 40 % dans la branche témoin (P = 0,042). La différence est restée significative lors de toutes les visitas de suivi. Las dificultades de comprensión estaban asociadas independidamente al sexo feminí (rapport des cotes, RC : 0,29 ; intervalle de confiance de 95 %, IC : 0,12-0,70) y al tener que residir en la zona de Jahaly más que en la de Basse (RC : 0,33 ; IC de 95 % : 0,13-0,82). Aucune association indépendante significative avec le nivel d'éducation n’a été observée. Le risque de voir le score de comprensión de un participante baisser de moitié par rapport à sa valeur initiale était plus faible dans la branche d'intervention (ratio de risque 0,22, IC de 95 % : 0,16-0,31). Globalement, 70 % (42/60) des participants du groupe de discussion de la branche d'intervention ont trouvé l'outil multimedia clair et facile à comprendre.

**Conclusion** L'outil multimédia de consentement déclaré a sensiblement amélioré la comprensión et la memorización des informations sur le consentement par los participantes a des recherches ayant un faible niveau d’alphabétisation.

**Резюме**

Использование мультимедийного инструмента для получения согласия от участников исследований в Гамбии: рандомизированное контролируемое исследование

**Цель** Оценить эффективность мультимедийного инструмента, предназначенного для получения информированного согласия взрослых на участие в клиническом исследовании в Гамбии.

**Методы** Взрослые, соответствующие критериям для включения в исследование на участие в клиническом исследовании в Гамбии. Оценка проводилась сразу после получения согласия (день 0) и во время последующих визитов. Более низкий уровень понимания отмечался среди женщин (отношение шансов, ОШ: 0,29; 95% доверительный интервал, ДИ: 0,12-0,70) и проживающих в Джаял в сравнении с провинцией Бассе (ОШ: 0,33; 95% ДИ: 0,13-0,82). Существенная зависимость от уровня образования не наблюдалась. Риск того, что уровень понимания участником сократится в два раза в сравнении с первоначальной оценкой, в экспериментальной группе был ниже (отношение рисков, 0,22, 95% ДИ: 0,16-0,31). В целом 70 % (42/60) участников фокус-группы из экспериментальной группы заявили, что мультимедийный инструмент является понятным и простым в использовании.

**Вывод** Мультимедийный инструмент для получения информированного согласия значительно улучшил понимание и запоминание условий согласия среди участников с низким уровнем грамотности.

**Resumen**

Una herramienta multimedia para el consentimiento para los participantes en la investigación en Gambia: un ensayo controlado aleatorizado

**Objetivo** Evaluar la eficacia de una herramienta multimedia para el consentimiento informado para los adultos que participan en un ensayo clínico en Gambia.

**Métodos** Los adultos elegibles para ser incluidos en un ensayo de los tratamientos de la malaria (n = 311) fueron aleatorizados para recibir la información necesaria para el consentimiento informado mediante una herramienta multimedia (brazo de intervención) o un procedimiento estándar (brazo de control). Se utilizó un cuestionario de audio electrónico para evaluar la comprensión de los participantes del consentimiento informado. Esto se realizó 0,22, 95% IC: 0,16–0,31). En términos generales, el 70% (42/60) de los participantes del grupo muestral del brazo de intervención consideraron que la herramienta multimedia era clara y fácil de entender.

**Conclusion** Una herramienta multimedia para el consentimiento informado mejoró considerablemente la comprensión y retención de la información consentida por los participantes en la investigación con bajos niveles de alfabetización.

References

Table 1. Sociodemographic characteristics of study participants in randomized controlled trial of a multimedia consent tool, the Gambia, 2013–2014

<table>
<thead>
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<th>Characteristic</th>
<th>Intervention arm* (n = 155)</th>
<th>Control arm* (n = 156)</th>
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NA: not applicable.

* In the intervention arm, study participants were informed about the clinical trial using a multimedia informed consent tool; in the control arm, information was provided using the current standard method for informed consent.

\* For the purposes of this study, the term “formal education” was defined as education based on an English-language curriculum that involved the completion of primary school, with or without 3 years of junior secondary school.