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Through the eyes of the participant: using photovoice to understand the experiences and effects of ivermectin MDA in the context of the BOHEMIA clinical trial in Kwale, Kenya

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Abstract

Background Assessing the acceptability of new malaria control interventions in clinical trials can be complex due to the need for strict ethical standards and specific trial procedures. While in-depth interviews and focus group discussions can provide useful insights, a more participatory method of data collection which complements these methods is photovoice. Photovoice offers a unique approach, empowering participants to share their experiences and perceptions on their own terms. Photovoice was employed alongside the BOHEMIA clinical trial (a trial investigating the safety and efficacy of ivermectin mass-drug administration (MDA) for malaria control) to explore participants' views on the trial and the effects of the intervention on individuals and communities.

Methods Two participants from each of five villages involved in the trial (two intervention, three control) were purposively selected and trained on the ethical and technical use of cameras. During the final round of the intervention, participants photographed their trial experiences and the MDA effects. Two picture-sharing discussions were conducted to explore the picture content and reasons for their inclusion.

Results Both intervention and control groups expressed confidence in the trial procedures, with pictures capturing barcode scanning and health assessments, activities reported to provide reassurance and enhance trust. Photos from both groups showed positive outcomes such as improved appetite and fewer mosquitoes. However, photos from the ivermectin group also showed clearing of jiggers and killing of bed bugs. Images of rashes, described as a negative effect of the MDA, were taken by both groups. Pictures of mosquito breeding sites and sources of intestinal worms were also shared by both groups.

Conclusion Photovoice provided valuable insights into trial experiences, intervention effects, and revealed unexpected outcomes, such as killing of bedbugs, that warrant deeper exploration. It exposed broader community concerns of the source of malaria and intestinal worms not addressed by either the intervention or local health authorities.

Keywords Photovoice, MDA, Randomised control trials, Ivermectin, Malaria, NTDs, Trial experiences, MDA effects

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Background

Malaria remains a significant public health burden in many countries in sub-Saharan Africa, with the 2023 World Malaria Report describing a range of threats which are undermining the progress made against the disease since 2000 [1]. To combat these emerging challenges several complementary malaria control tools are currently under development [2]. To receive a recommendation for use by the World Health Organization (WHO), these tools need to have evidence of their safety and public health efficacy [3, 4]. Since the 1980's the gold standard for the evaluation of therapeutic efficacy is a randomized control trial (RCT) [5, 6] and currently recommended interventions, such as insecticide-treated nets (ITNs), and first-line anti-malarial drugs have all undergone rigorous testing for safety and efficacy through a series of RCTs.

Over recent years, in addition to efficacy, funding bodies and the WHO have become concerned not just with the efficacy of interventions but also their acceptability to local populations and the feasibility of implementation [7, 8]. Consequently, alongside RCTs, funding has been made available for quantitative and qualitative studies on the acceptability of the intervention and the feasibility of implementation. However, assessing acceptability in the context of an RCT can be challenging for two main reasons. First, to ensure their ethical conduct, RCTs require significant levels of inputs and support that are unlikely to be available in routine settings [9, 10]. In low-and-middle income countries this frequently means providing access to services that are not often readily available through the routine health system. The availability of these services can make it challenging for researchers to unpick the extent to which the perceptions and experiences of the participants are associated with the trial inputs (secondary effects) or the intervention itself (primary effects). Secondly, a range of factors including trial-specific procedures may contribute to the increased acceptance or lack thereof of a trial or an intervention [11–13]. These procedures may include consenting and providing information about the study, as well as the relationships that develop between trial participants and trial staff which can engender a sense of a supportive social relationships and generate trust in the research team [14]. Knowing the desired outcomes of the trial, has the potential to influence perceptions and expectations of positive effects[13].

With one or two exceptions [15], to date, most of the studies addressing the acceptability of new malaria control interventions in the context of an RCT have focused on quantitative questionnaire surveys and/or qualitative data collection methods, such as in-depth interviews and focus group discussions [12–20].While these data can provide useful insights, a more participatory method of data collection which complements these methods and has recently been employed to better understand community perceptions and response to malaria is Photovoice (PV) [21–23]. Photovoice is a participatory action research method that has been increasingly used in public health and malaria research [21, 24]. It allows participants to take photos that document specific aspects of their lives or social realities; select particular images to reflect on and discuss with the researchers and to communicate perceptions and experiences to key stakeholders and decision-makers [24]. Participants can use photography to express insights or experiences that may be difficult or uncomfortable for them to share in words alone [21]. When used in a trial or intervention study, this approach enables the researchers to understand issues and experiences from the perspective of participants, gaining more insight into how they experienced the trial or intervention. Photovoice can empower community members to share their experiences and articulate their perceptions of an intervention and the manner of its delivery in their own terms [23]. It allows researchers to access the lived experiences of participants in a way that is meaningful to the participants themselves [23, 25].

In the context of a RCT, photovoice provides the opportunity for the participants to document their experiences of trial participation and their perceptions of the effects of the intervention in real time. The images produced by trial participants are a record of what the trial means to them and provide the potential for discussions about experiences, effects and acceptability from the viewpoint of the participants rather than the researchers. This paper describes the use of photovoice (PV) in the context of a RCT to test the safety and efficacy of a malaria control intervention (the BOHEMIA trial). The aim of the PV study was to understand how participants experienced the trial and their perceptions of the effects of the intervention.

Study setting

The BOHEMIA consortium (Broad One-Health Endectocide-based Malaria Intervention in Africa) is exploring a strategy for malaria control that involves mass drug administration (MDA) with ivermectin once a month for three months during the malaria transmission season [26]. In Kenya the study was conducted in Kwale County, a coastal rural county in southeast Kenya with a population of 866,820 and the highest malaria burden in coastal Kenya [27]. The county is divided into 4 administrative sub-counties, with the trial taking place in two of these sub-counties, Lunga Lunga and Msambweni. The trial was a cluster randomized control trial covering a population of 28,932 eligible participants [28] divided into 84

clusters (42 in the control arm and 42 in the intervention arm) across 69 administrative villages.

The intervention involved the mass drug administration of ivermectin to eligible participants in the intervention arm and albendazole in the control arm. Ivermectin is a drug effective against intestinal worms and ectoparasites which can kill malaria vectors that feed on treated subjects [29], while albendazole is a well-known and widely used dewormer which is non-mosquitocidal [30]. Albendazole was used in the control arm because just like ivermectin it would provide the deworming benefit and increase comparability given some deworming in both groups [26]. Mass drug administration was carried out once a month for three consecutive months (MDA rounds 1, 2 and 3) during the rainy season. In the intervention arm participants received 400 mcg/kg of ivermectin (tablets per person ranged from 2 to 13 depending on the weight of an individual)) per round while in the control arm participants received a standard dose of 400 mg (one tablet) of albendazole in each round. Trial recruitment, consenting and drug distribution were undertaken by field workers, members of the local community who had been selected and trained in the ethical conduct of trials. This training was provided by members of the KEMRI-Wellcome Trust Research Programme in collaboration with the BOHEMIA research team as per good clinical practice- GCP and clinical trials requirements. Eligible participants within the clusters were recruited and informed consent sought in the first round of the MDA. Apart from consenting, certain inclusion and exclusion criteria were observed including pregnancy testing for women of reproductive age, weight of 15kgs and above, and whether the participants were on any contraindicated drugs [26]. In the subsequent rounds of the MDA, verbal consent was sought to ensure that the participants were still willing to participate in the trial. Pregnancy testing, weight measurement and other inclusion and exclusion criteria were carried out in all three rounds of the MDA.

Alongside the trial, a social science study was undertaken investigating participant perspectives of the implementation and outcomes of the clinical trial. The study involved ethnographic research with social science research assistants (SSRAs) living for periods of time in 5 of the trial villages (2 villages in the intervention and 3 villages in the control arm) covering 6 clusters. The selection of villages was purposive aiming for maximum variation to include representation from the range of village 'types' found in the area. The criteria for the categorizing villages included; malaria prevalence, ethnicity, religion, subsistence activities, village size, proximity to urban centres and access to media. Village selection was undertaken by the social science team with input from the local administrators. A photovoice study (undertaken in the 5 social science study villages) and a post-trial cross-sectional qualitative study involving focus group discussions (FGDs) among intervention and control villages involving high uptake and low uptake participants. This paper reports on the photovoice component of the social science study.

Methods

The initial experiences of participants in round one and two of the MDA were captured using observations and IDIs by the SSRAs. The photovoice study started during the second round of the MDA and ran until a week after the third round of the MDA so that it focused on understanding perceptions and experiences towards the end of the process, allowing for the recording of the effects of having been involved in three rounds of the MDA. During the second round of the MDA the SSRAs identified potential photographers in each of the 5 social science study villages (2 photographers per village: 1 male and 1 female). The criteria for the selection of photographers were being an adult (18 years or older), a participant in the BOHEMIA trial, availability in the village throughout the photovoice activity period, and able to operate a smartphone. Smart phone coverage in this area of Kenya is high with every homestead in the five study villages owning at least one smart phone. The national language is Kiswahili and all the data collected and analysis was done in Kiswahili language. Alongside photographer recruitment, photovoice community sensitization meetings were held in each village to inform the community about the PV activity and introduce the photographers.

Between MDA round 2 and MDA round 3 the photographers attended a one-day training on how to use a simple digital camera, how to take photos, how photographs and narratives may be used in the research project and the ethical use of a camera during the PV activity. As part of the training the photographers were given a test activity to take photos in the vicinity of the training grounds of things that for them represented Kwale County. These pictures were then shared and discussed to help illustrate how to take pictures without compromising anonymity and how to frame photos so that they illustrate the issue that they are wanting to capture. The photographers signed a written informed consent form for participation which included maintaining privacy, confidentiality, and respect for the community members as they took the photos. Following the training the photographers were each provided with a digital camera for 2 weeks, a period which included MDA round 3. During this period, they were asked to take pictures to address the following questions:

1. What are the experiences of the BOHEMIA project in your community?
2. What effects has the MDA had on you and your community?

After 2 weeks, two separate picture sharing discussion groups were conducted. The first discussion group was with photographers from the control arm (PVD1) and the second group discussion was with photographers from the intervention arm (PVD2). These group discussions were organized at a central location that was accessible and convenient for all the photographers. Prior to the meetings, the photographers had been asked to select the 5 pictures that best represented their experiences and the 5 pictures that best represented the effects of the MDA to share during the meeting. At the start of the meeting these photos were uploaded onto a computer for subsequent sharing and discussion. The social science research officer (TO) who facilitated the discussion used a projector to display each of the photographs in turn. The photographers were asked why they took the displayed picture, the meaning of the picture and how the photos described their experiences of the BOHEMIA trial and the effects the MDA had on them and the community. Towards the end of each group discussion the participants were asked to agree which of the pictures best represent their experiences of trial participation and which pictures best represented the effects of the MDA.

All group discussions with the photographers were conducted in Kiswahili and, with the written informed consent of the participants, the discussions were audio recorded. The recordings were transcribed verbatim and any identifiable personal information removed from the transcripts. The data transcripts were subsequently uploaded into Nvivo 12 for management and analysis. A framework approach was used in the analysis of the transcripts using deductive codes from the objectives of the PV activity and inductive codes that emerged from the discussions and transcripts during analysis.

Results

Experiences of the trial

Table 1 summarizes the photos that each photographer took of the experiences of the BOHEMIA trial in their community. Each photographer shared five pictures with the group except for photographers nine and five. Due to a technical malfunction of the camera, photographer nine only had one picture to share while photographer five shared six pictures.

As seen in Table 1, the pictures taken by the intervention and control arm photographers of community experiences of the BOHEMIA trial were very similar. These experiences pictures primarily focused on the trial processes including measuring the weight and height of participants (8/10), checking the location of the study households (7/10), the directly observed treatment of the study drugs (7/10), the informed consenting process (6/10), and the assessment of pregnancy status among girls and women aged between 13 and 49 years (6/10).

Weight measurement

The most frequently taken picture by photographers in both trial arms (5 of the 6 in the control arm and 3 of the 4 in the intervention arm) was of participants being weighed or measured before they were given any drugs. In the discussion about why they took the pictures of participants being weighed, the photographers explained that being weighed was necessary to ensure that a person is given the right dosage of the drug according to their weight.

Figure 1a, b: Weight measurement.

Table 1 Images of experiences taken by each photographer

Image	Control arm photographers						Intervention arm photographers			
	P1 (M)	P2 (F)	P3 (M)	P4 (M)	P5 (M)	P6 (F)	P7 (M)	P8 (F)	P9 (M)	P10 (F)
Weight measurement	X	X	X	X		X	X	X		X
Scanning of barcodes/ barcodes	X		X		X	X	X		X	X
DOT	X		X	X		X	X	X		X
Consenting process	X	X			X	X	X			X
Pregnancy testing	X	X			X	X		X		X
Tablet (Gadget)			X	X	X			X		
Empty blister packs		X	X	X	X		X			
Field worker bag		X		X				X		
Broken chair					X					

Fig. 1 Weight measurement: **a** Weight measurement in the control arm; **b** Weight measurement in the intervention arm

Fig. 2 Scanning of barcodes and barcodes; **a** Scanning of barcodes; **b** Barcode on the door

"That is a photo of the weighing scale they were using, so you can ask yourself what the weighing scale was for? So, I thought to take a photo of it to explain that before you took the drugs that were being distributed it was a must for you to be weighed before you are given the drugs." PVD1P2 (Fig. 1a)
"This photo brings a memory of when the exercise was going on that one was being weighed, so when you see it, you remember that during this exercise, when one was being given the drugs, it was a must for his weight to be known" PVD2P7 (Fig. 1b)

Bar codes/scanning of barcodes

The second most frequently occurring picture presented during the discussions were pictures of the bar codes that were fixed to the external doors of each participating households. These pictures occurred in the pictures taken by 4 of the 6 control photographers and 3 of the 4 intervention photographers. Several of the photographers also included a picture of the bar codes being scanned during the MDA. The barcodes had been fixed by the demography field team prior to the MDA during an initial household identification and recruitment process.

Figure 2a, b Scanning of barcodes and barcodes.

"They started by identifying some houses and they put stickers (barcodes) on the doors to show that in that household that they have put the sticker they will pass by to give… to do that research and the research was distributing drugs." PVD1P3 (Fig. 2a)
"That is a sticker (barcode) that is an experience, it shows that those houses within the cluster that were supposed to be given drugs they must have that sticker on the door." PVD2P7 (Fig. 2b)

In discussing the reasons for taking these pictures, the photographers explained that they took these photos because it was a way of identifying the households that would be participating in the trial and that only those houses that had the sticker would participate. To the participants it was a form of evidence that they took the drugs in case of any adverse event and for follow up.

Informed consenting process

Out of the 10 photographers 6 (4 in the control and 2 in the intervention arm) took a photo of the consenting process and, in both groups these pictures were among those chosen to represent the experience of the BOHEMIA trial. For both sets of photographers the process was important and they explained that it was like an agreement between the researchers and the participants. They said that they were also given adequate information regarding the trial, and one had an option to voluntarily decide to participate or not.

Figure 3a, b Informed consenting process.

"So that is an experience in that the process was going on well and they were recording, we were not just being given drugs at least they were recording" PVD1P6. (Fig. 3a)

"This one also talks of that, if you wanted to be enrolled during the third round and was not in the previous two rounds, you had to sign a form where one copy you would remain with, and another one in which the fieldworker would go with it." PVD2P7 (Fig. 3b)

Fig. 3 Informed consenting process; **a** Informed consenting in the control arm; **b** Informed consenting in the intervention arm

Direct observation treatment and empty blister packs

In both arms participants took pictures of the drugs that were dispensed during the MDA. Under the trial requirements the drugs were given to the participants under direct observation in the presence of the field workers. This contrasted with reported past experiences of MDA for lymphatic filariasis which had taken place in the study area. With the display of the photos, the photographers discussed how in the past the drugs had just been left in the household for them to take, whereas during the BOHEMIA trial the drugs were only given out if the participant consumed the drug in the presence of the field worker. Furthermore, the fieldworker would then wait for 30 min after giving out the drug to see if there was any immediate adverse event that occurred. This was reassuring to the participants that the trial team was concerned about their wellbeing. Seven out of the ten photographers took a picture of this process and five out of ten also took a photo of empty blisters packs of the drugs.

Figure 4a, b: Direct observation treatment and empty drugs blister packs.

"This picture shows that this person was being given the drug, it also brings back the memory that when you see it, you remember when this person was being given the drug and he was taking it right there and then." PVD2P7 (Fig. 4a)

"You see that packet (empty drug packets) shows that they accepted and took the drug,."PVD1P3. (Fig. 4b)

Pregnancy testing

Albendazole and ivermectin are both contraindicated in pregnant women as there are no data to ascertain their safety profile in pregnancy. This necessitated pregnancy testing for all women of reproductive age at each of the three visits. All four female photographers took a picture of the pregnancy testing while only 2 out of 6 male photographers took a picture of this process. The two male participants who took a photo of the pregnancy testing said that they had been present when members of their household were asked to take the test for them to be able to participate in the trial.

Figure 5a Pregnancy testing.

"That is a photo of the pregnancy testing kit. So here I experienced that a woman was not to be given the drugs until she is tested for pregnancy, when she is found not pregnant that is when she takes the drugs."

Fig. 4 Direct observation treatment and empty drugs blister packs; **a** Direct observation treatment; **b** Empty blister packs to show DOT

Fig. 5 Pregnancy testing; **a** Woman holding urine cap and pregnancy testing strip; **b** Unopened pregnancy testing kit and urine cap given to women to test for pregnancy

PVD1P5 (Fig. 5a)

In PVD2 the participants described how getting pregnant before marriage was not socially acceptable and a couple of the participants described how some of the field workers had a challenge getting the young girls who were not sure of their pregnancy status to be tested.

"... yeah, there are some who were worried about being tested and turning positive what would happen to them, you had to persuade someone for them to accept to be tested and that was a challenge for those who were doing that work." PVD2P8
"These girls that are not married, and according to the environment if it is known that she is pregnant at that time it is not a good thing, and they are supposed to be given drugs and they have to be tested before being given drugs. So, they were hiding they didn't want it to be known that they are pregnant, maybe it is not known at home and that is her secret so agreeing to the pregnancy testing was a challenge" PVD2P9.

By contrast, during the discussion of the pregnancy testing pictures in PVD1, most of the participants said that the majority of the people were happy to agree to the pregnancy testing.

"I think the pregnancy testing, majority were okay that is they agreed to be tested for pregnancy. It was not a challenge." PVD1P6

However, while the participants in PVD1 agreed that pregnancy testing was a good thing, one of the participants had taken a photograph which suggested that pregnancy testing and trial participation was not without its issues. This picture was of a broken chair (Fig. 6). When asked why he took the photo, the photographer explained that the chair broke due to a disagreement that arose between a wife and her husband due to pregnancy testing requirements. The wife had agreed to take the test so that she could participate in the trial but the husband was against it so there was a pull and push, and the chair broke.

Figure 6 Broken chair

Fig. 6 Broken chair

"The effect of pregnancy testing, there was a husband who didn't want his wife to be tested, he didn't want his wife to take the drug and his wife wanted to be tested and to participate, so it brought a conflict [[M: So, they fought?]] Like not fighting but because of the dispute, the seat was broken." PVD1P5

This picture sparked a discussion in the group around the broader issue of the potential role of gender in decision-making in households. It became clear that there was variation among households in the ability of a wife to decide about trial participation independent from her husband. It was agreed that in some households only the man had the authority to decide what happens within and to his household members, while in others, women had the flexibility to choose what they wanted even if the man was not in support of it.

"Like the husband said I don't want you to take the drug and the wife agreed, okay, I won't take it, but there are others who are independent and are not ordered around...". PVD1P5

Perceived effects of the MDA

A summary of the pictures taken by the photographers to illustrate the effects of the MDA is provided in Table 2. All of the photographers took pictures to illustrate both positive and negative effects of the MDA (control and intervention). Some of the images were common to both arms (increase in appetite, reduction in mosquitoes, development of rashes) while others were unique to the intervention arm (killing bed bugs, clearing jiggers, heavy sleep) or control arm (stomach pains and clearing of ringworms). In addition, the photographers in both arms presented pictures that were not directly linked to the effects of the MDA, but rather illustrated concerns that the MDA was not adequately addressing the sources of mosquitoes and intestinal worms that caused problems in the communities.

Perceived positive effects in both arms

Reduction in number of mosquitoes and not using ITNs

The most common positive effect that was illustrated in images taken by four of the six photographers in the control arm and two of the four photographers in the intervention arm was a reduction in the number of mosquitoes. This effect was illustrated by pictures of mosquito nets which were not fully covering a bed and some pictures of beds which did not have any net at all. In the discussions, the photographers described how some people were no longer using mosquito nets every night due

Table 2 Images of effects taken by each photographer

Image	Control Arm photographers						Intervention arm photographers			
	P1 (M)	P2 (F)	P3 (M)	P4 (M)	P5 (M)	P6 (F)	P7 (M)	P8 (F)	P9 (M)	P10 (F)
Reduction in number of mosquitoes	X		X	X		X			X	X
Increase in appetite	X	X			X	X	X	X		
Development of rashes			X	X	X	X		X		
Clearing of ringworms			X	X	X					
Killing of bedbugs							X	X		X
Heavy sleep							X	X		X
Clearing of jiggers							X	X		
Stomach pains					X					
Clearing of rashes	X									
Malaria prevention methods used		X		X					X	X
Mosquito breeding and resting sites	X	X	X			X	X		X	X
Contaminated water	X	X	X		X	X		X		
Trial challenges		X		X			X		X	X

to the perception that there was a reduction in the number of mosquitoes meaning it was possible to sleep with no net without being disturbed by mosquito bites.

Figure 7a–c: Reduction of mosquitoes.

"So that one is for the ones who used to use nets. So, after taking the drug, they decided to remove the nets outside, that's why you can see it is hanged outside, you see it is not on the bed?" PVD1P3 (Fig. 7a, b)

"...So I asked him, 'have you ever seen a mosquito bite you and then die?' He replied that he had not seen it, but it was impossible to go for two days without seeing a mosquito biting me, but now it has been like three weeks since I felt a mosquito bite me." PVD2P9 (Fig. 7c)

Fig. 7 Photos showing reduction of mosquitoes; **a** A bed without an ITN hanged; **b** An ITN hanged outside; **c** A bed not fully covered by an ITN

Increase in appetite

In both arms the photographers took pictures to illustrate an increase in appetite among the trial participants and a picture illustrating this was included by both groups in their chosen 'effects' pictures. The images included a basket containing a pot that is used for cooking Ugali, the maize meal staple of the area, a picture of the stomach of a girl, and a pot containing pumpkins cut up ready for cooking. In discussing the pictures, the photographers described how after taking the drugs their stomachs felt lighter and there was also a relief from stomach aches. Four out of six photographers in the control arm and 2 out of 4 photographers from the intervention arm took a photo describing an increase in appetite.

Figure 8a–c: photos depicting increase in appetite.

"The effects of these drugs is that after every two hours you feel hungry, that's why he used to eat and put that one on standby (some extra food). He would then go to his farm, arriving at about 9 o'clock, he would cook and eat." PVD1P5 (Fig. 8a)

"Before, you would say that her health was poor, but after using the drug, she regained her appetite and started eating a little more. You can see the belly has grown bigger. If you take this drug, they increase your appetite. PVD2P8 (Fig. 8b)

Similar perceived negative effects

Rashes

In addition to pictures of the positive effects of the MDA, both groups included pictures of a common negative effect following dosing with the drugs. These images were of an arm with a rash. The rashes varied in size, shape and colour, but 4 photographers in the control group and 1 in the intervention group took a picture of an arm with a rash. Both groups also selected one of these images to represent a common effect of taking the drugs. In the discussions of the pictures the photographers in both groups described how after taking the drugs, community members reported that they developed rashes.

Figure 9a Rashes.

Fig. 8 Photos depicting Increase in appetite; **a** A basket carrying extra food to the farm; **b** A healthy young girl; **c** Extra food to be taken in between main meals

"Those were rashes, I think people have talked about that a lot, when they took the drugs, they developed rashes." PVD1P6 (Fig. 9a)
"That's an effect. He says that when he took the drug after a week, he started to get things like those, things like rashes and they became itchy, yeah." PVD2P8 (Fig. 9b)

Fig. 9 Rashes as a negative effect of the MDA; **a** Photo of rashes taken in the control arm; **9** Photo of rashes taken in the intervention arm

Apart from development of rashes there were other perceived negative effects of the MDA that were discussed in both groups, but the photographers didn't know how to take photos to depict the effects. These included stomach pains, diarrhoea, mild headaches, dizziness, nausea and, unique to the treatment group, having deep sleep. However, these effects were described as minor and transient and the photographers said that they did not deter community members from participating in the trial.

Perceived positive effects unique to the intervention group

Three of the four photographers (both women and one of the men) in the intervention group took pictures of a bed or mattress. These photographers explained that the pictures were of beds that were no longer infested with bedbugs.

"This picture that I took shows the benefits experienced by the person who used this drug, it cleared

Fig. 10 A bed that was previously bedbug infested

Fig. 11 Clearing of jiggers

the bed bugs. They were infested with bed bugs and now that he used it, there were no more bed bugs." PVD2P7 (Fig. 10)

In the discussion they described that among the reasons that community members continued to take the drugs in the second and third rounds was to ensure that bedbugs continued to die. They had noticed after the first round of ivermectin MDA that the bedbug menace had reduced, and they were keen to try and remain bedbug free. It was agreed in the group that a picture of a bedbug-free bed was an important image to illustrate the effects of the MDA experienced by their group.

Figure 10 A bed that was previously bedbug infested.

In addition to the positive effect on bed bugs, two of the four participants in the intervention arm took pictures that they described as showing that the ivermectin MDA had been effective in the treatment of jiggers (*Tunga penetrans*). There were no pictures of this effect or discussion of the clearing of jiggers in the control arm.

Figure 11 Clearing of jiggers.

"In this, there was a child who was suffering from Jiggers, he said that after using Ivermectin, it cleared the disease" PVD2P7 (Fig. 11)

Perceived positive effects unique to the control arm

In the control arm there was no mention of bed bugs nor jiggers, but three out of the six photographers took a photo which they described as showing the clearing of '*mashilingi*'. *Mashilingi* is the Kiswahili name for a skin infection that is round in shape and looks like a silver shilling coin. The Kiswahili name was used interchangeably with the English name for this infection, ringworm. In the discussion the photographers described how ringworm was a disease that affected several children in the study area. They said that it was difficult to clear, but after taking the albendazole it was noticed that the skin started to heal. No photos of ringworms appeared in the pictures taken by the ivermectin group.

Figure 12a, b: Clearing of ringworms.

"He says, you see that one, there is another one there, so the worms are clearing. After taking the Albendazole, the ringworm on his head reduced." PVD1P3 (Fig. 12a)

"It's a child who had ringworms, but he says that after taking those drugs in the first round and in the second round, they removed the ringworms and it left small marks, but before that they were the round ones, so he says it is like this drug helped somehow." PVD1P5 (Fig. 12b)

Concerns about effectiveness

Among the pictures that the photographers took that did not directly address the initial questions posed by the research team, were photos that revealed concerns about the ability of the intervention to address the root of the problem of malaria and intestinal worms in their communities. These photographs included pictures of mosquito breeding and resting sites and sources of intestinal worms. In addition, 4 of the photographers included pictures of the obstacles faced by the implementers of the trial which identified potential challenges to the feasibility of implementing the MDA under routine conditions.

Mosquito breeding and resting sites

Four of the six photographers in the control and three of the four in the intervention arm took pictures of mosquito breeding and resting sites. In the discussions

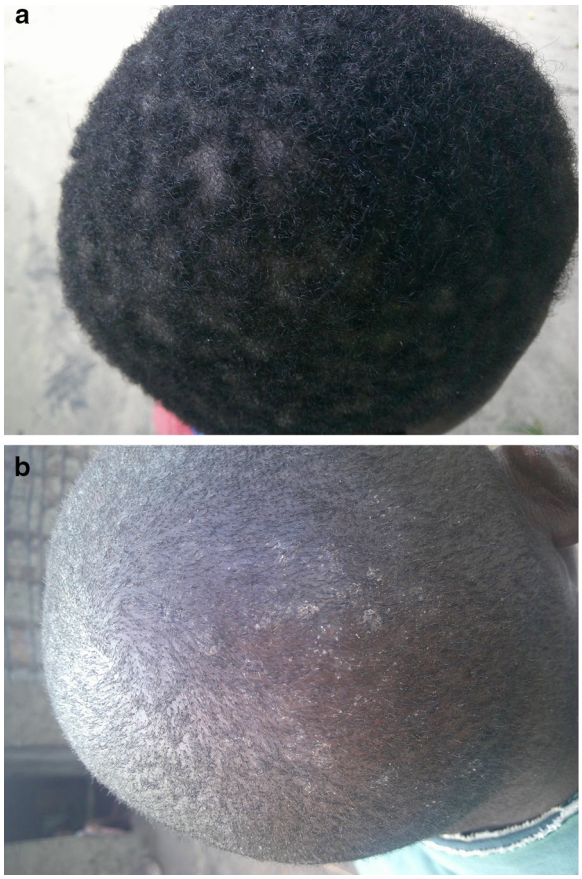

Fig. 12 Clearing of ringworms; **a** Hair growing after ringworms started clearing; **b** Ringworms that have started clearing

around these pictures the photographers expressed concerns that the MDA would be insufficient to reduce mosquitoes and malaria if the mosquito breeding and resting sites still existed. These included swamps, standing water and uncovered water containers as well as long grasses and bushes near houses.

Figure 13a–d Mosquito breeding and resting places.

One of the photographers in PVD1 was concerned that providing people with the MDA would distract attention from other mosquito control measures which would run the risk of an increase in malaria.

> *".. when these people were taking these drugs, they just assume that they will be okay……They think it is just for malaria and thus malaria rate will be very high because people are very comfortable." PVD1P6. (Fig. 13a)*

The trial was initially designed to have both animal and human arms, and this information was in the initial community engagement message to the community members. However, due to lack of information on livestock movement, the animal arm was dropped. One of the photographers in PVD1 took a photo of an animal pen near a house saying that mosquitoes bite both humans and animals and treating humans only may not yield the desired results.

Figure 14 Animal pen.

> *"Here we see a house and a livestock pen. Now looking at the house and a livestock pen, the drug has been brought for trial in humans and mosquitos bite both animals and humans; why was this drug not brought for trial to both domestic animals and humans? PVD1P1(Fig. 14)*

Concerns about intestinal worms

Both drugs used in the trial are dewormers and this information was given in the consent forms and in the community engagement meetings. Five of six photographers in the control and one of four in the intervention arm took pictures illustrating continued domestic use of untreated water from ponds and streams which they said were contaminated and considered a source of intestinal worms.

Figure 15a–c: Contaminated sources of water.

They discussed concerns that if the source of the intestinal worms was not addressed, they would continue to be a problem in the community even with the drugs being distributed.

> *"…Water, people are taking that water for everything, drinking, I don't know what. Even if one has taken the dewormer, those diseases will continue to persist." PVD1P6. (Fig. 15a)*

Trial challenges

In addition to concerns about the effectiveness of the intervention, 2 out of 6 photographers in the control and 3 of 4 in the intervention arm took photographs of the challenges that they saw the fieldworkers experiencing as they were distributing the drugs for the MDA. These included pictures of closed doors (not finding people at home), houses destroyed by rain and floods leading to short term movements out of the study area, and photos of impassable roads and floods due to the heavy rains that were going on during the implementation.

Figure 16a–c: Trial challenges.

> *"…That photo (Fig. 16a) shows a challenge faced by the field worker, maybe on reaching a household and finds the door is locked and is (the owner) at work, so it is that challenge of not getting people" PVD2P8.*
> *"…. This photo (Fig. 16c) shows that the house has fallen/ is destroyed, so it was a real challenge this*

Fig. 13 Mosquito breeding and resting places; **a** Bushy compound; **b** Stagnant water near the house; **c** Stagnant water near homesteads; **d** Open water containers in the home

Fig. 14 Animal pen within the homestead

person whose house had fallen, and he had been recruited, so when the field workers arrive, there they find that he has moved to another house that is maybe outside the cluster or within but it will be still problematic during drug distribution." PVD2P7

The fieldworkers employed for the distribution of the drugs for the MDA were all from the local communities and in the discussion of these images, it was clear that the photographers were concerned about the feasibility of reaching all eligible participants in each round of the MDA within the stipulated timeframe during the rainy season.

Discussion

This photovoice study, undertaken in the context of the BOHEMIA clinical trial, explored the experiences of the trial and perceived effects of the mass drug administration among selected trial participants. The focus was on providing participants with the opportunity to record their experiences of trial participation and of the effects of the drugs they took through the medium of photography. The photos of experiences of the BOHEMIA trial shared by the photographers were primarily images of the trial processes such as measuring of weight and height, recording the presence of a bar code to verify identity of the household, the taking of informed consent,

Fig. 15 Contaminated sources of water; **a** Open well; **b** Flowing rainwater used domestically; **c** Unprotected spring

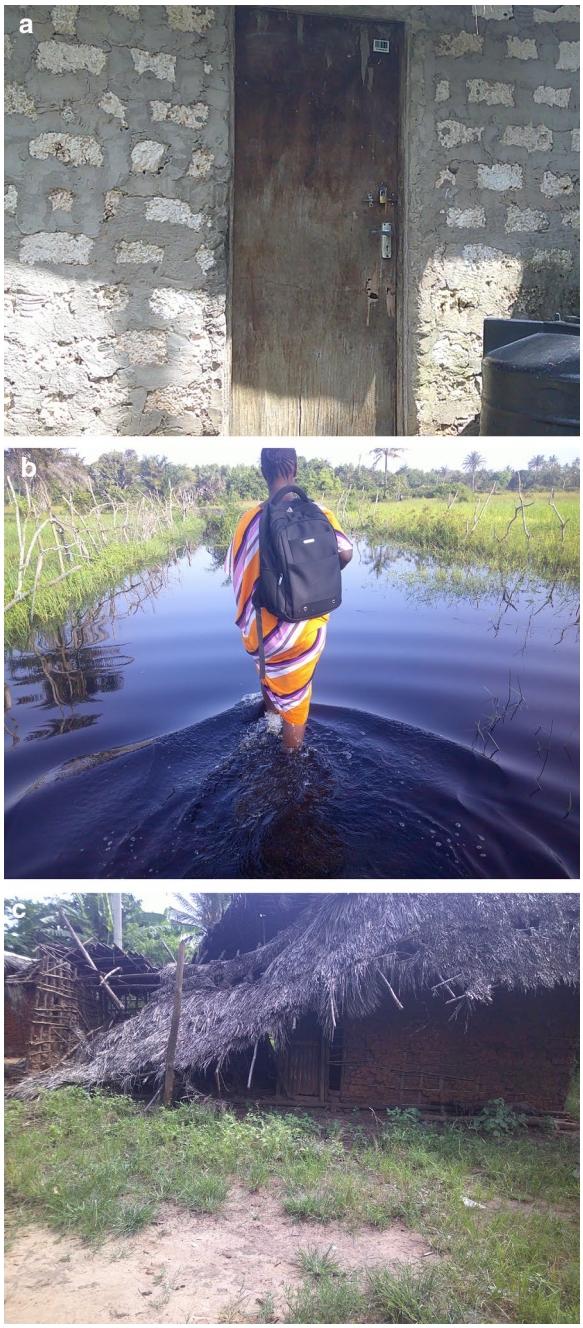

Fig. 16 Trial challenges; **a** Closed door depicting members absent; **b** Flooded roads and paths in the study area; **c** Destroyed house causing the residents to migrate

confirmation that the drugs were taken and there were no immediate adverse effects and pregnancy testing to ensure that women who were pregnant did not take the drugs.

The pictures of experiences taken by the photographers and the discussions surrounding those images suggest that confidence in the trial was fostered by the measurement of weight before the drugs were dispensed. The majority of the photographers had taken pictures of this experience, and they said that it gave them the confidence to take the drugs knowing that there was no possibility of being over or underdosed. In addition, the direct observation therapy where the participants had to

take the drugs on the spot and, as per the trial requirement, the field worker had to wait for at least 30 min before leaving the household, provided reassurance that the researchers were being vigilant. These findings are similar to those in a study undertaken during a malaria vaccine trial in northeast Tanzania which found that the secondary health benefits of trial participation enhanced trust and participation and provided participants with a sense that they were being cared for [12]. However outside of trials under routine conditions DOT has been found to be more challenging both for participants due to their perception on the need to take treatment before bed or the need to eat before swallowing pills as well as the drug distributors themselves [31].

Over the past 20 years several studies have investigated individual and community understandings of the informed consent process in health trials in sub-Saharan Africa [32]. Concerns have been raised around the extent to which participants fully understand the nature and purpose of a trial [33, 34] and the extent to which participation is truly voluntary [34]. The pictures of the informed consent process taken by the photographers in this study suggest that the signing of the consent forms was viewed as an important part of the trial experience. In describing why they took these pictures, the photographers explained how signing a consent form and being left with a copy demonstrated that there was a formal agreement between the participant and the researcher. This provided reassurance of the legitimacy of the trial and placed responsibilities on the researchers as well as the participants. It wasn't clear if the action of the MDA was fully understood by participants and the photographers, but they were clear about the voluntary nature of participation. The focus on obtaining informed consent was also perceived as enhancing trust in the trial process. In addition to photovoice the social science work package included in-depth interviews participant observation and focus group discussions with participants from the five villages and with participants from 8 additional villages. The data from these aligned with these findings from the photovoice study [paper in preparation].

In other trials of mass drug administration for malaria control pregnancy testing has proven to be a barrier to participation [15]. In general, in this photovoice study pregnancy testing was not discussed as a major concern, but rather as an important process which enhanced the view that the researchers were being vigilant and cared about the health of the participants. However, concerns especially among teenage girls were reported. The participating photographers described how some fieldworkers experienced challenges in recruiting unmarried young women and girls due to their concerns about revealing their pregnancy status. In these communities, becoming pregnant before marriage is considered socially unacceptable. Similar concerns about pregnancy testing have been found in other clinical trials, including the study on MDA with ivermectin for malaria elimination in the Gambia [15]. However, in that study the age for pregnancy testing started at 15 years rather than the 13 years of age in the BOHEMIA trial and the authors reported that the major concern for the women was the lack of privacy for providing the urine sample rather than the potential revelation of a pregnancy. Due to clinical trials regulatory requirements pregnancy testing is required when testing the safety and efficacy of a new tool and trialists need to take local views into account when designing studies that require women to undergo pregnancy testing, particularly if such testing involves adolescent girls [26]. However, the necessity for pregnancy testing in any future implementation of ivermectin MDA will be informed primarily by the proven benefits of the intervention and the growing body of evidence on the lack of pregnancy related adverse events after exposure to ivermectin. As in onchocerciasis endemic areas, pregnant women at high risk of blindness are not excluded from ivermectin treatment given a proven benefit (prevent blindness) and limited evidence of harm in women inadvertently exposed to ivermectin during pregnancy [35].

While pregnancy testing necessarily involves the women it was clear from the picture of the broken chair that the decisions around pregnancy testing and MDA trial participation sometimes required the involvement of men. In the local communities in Kwale, as in other coastal Kenyan communities, male heads of households usually have final say whether household members will participate in health interventions or not [36, 37]. That is, authoritative power or power over others [38] in the study community was largely held by male household heads. However, women do not always agree with decisions that their husbands make and, as the picture of the broken chair demonstrated, this could lead to arguments about trial participation. It was also noted that in some households in the study area, women had autonomy, and they could make the decisions of whether to participate or not irrespective of what the male household heads thought.

As has been shown in other studies [11–13], information provided to participants in a trial as part of community engagement activities and informed consenting processes, has the potential to influence perceptions of intervention effects. It is likely that this was the case in the BOHEMIA trial with participating photographers in both control and intervention arms taking pictures illustrating a perceived reduction in mosquito numbers. Entomological studies have shown that albendazole has no effect on mosquitoes [30, 39] and the preliminary

entomological results from the BOHEMIA trial do not support a large effect size on the mosquito biting rate in the six clusters targeted by the entomology team. In view of this perception, should ivermectin with MDA be adopted as a new malaria control tool, it is paramount that the implementors make it clear to the community members that it is a complementary tool. It should therefore not replace the already existing tools like IRS and ITNs but used alongside the tools.

The second most commonly taken pictures of the positive effects of the MDA were of increases in appetite. A review of the literature focusing on the factors that influence compliance with the lymphatic filariasis MDA campaigns reported that the deworming effect (elimination of intestinal helminths) was perceived to be a positive effect of the MDA with this effect impacting appetite [40]. Both ivermectin and albendazole have anti-helminthic actions and are used as de-wormers and it is possible that the deworming effect of the drugs led to an increase in appetite among trial participants.

Although the primary objective of the trial was to test if there is a reduction of malaria transmission, interestingly other perceived effects of ivermectin MDA emerged through the photovoice activity. Photographers in the ivermectin arm took pictures of the killing of bedbugs and clearing of jiggers, pictures that were not present in the photos from the control arm. Ivermectin is an endectocide that has been used in the treatment and control of filariasis and other neglected tropical diseases [41]. However, the effects on bedbugs and jiggers are yet to be verified. It appears from the discussion that the effects of ivermectin on bedbugs was a key motivator for on-going trial participation and a much-appreciated effect of the drug. This is because bedbugs were a major problem in the community and anything that provided relief was highly welcome. Interestingly, these findings are similar to those in early studies of the use of ITNs, where participants were more enthusiastic about the effects of the ITNs on killing bed bugs than in reducing malaria [42, 43]. Unfortunately, bedbugs rapidly developed resistance to permethrin and the effects on bedbugs are no longer apparent [43] which is a relevant lesson should ivermectin be recommended as a novel vector control measure.

Photovoice is a participatory research methodology that uses photography and narrative to prioritize the perspectives of community members [21]. In this study, the value of this approach was demonstrated through the pictures taken by the photographers of mosquito breeding and resting sites and sources of intestinal helminths. These images were able to illustrate the concerns of the participants regarding the ability of the intervention to address their perceptions of the root causes of the malaria and intestinal worm infections that plagued the community. The discussions made it clear that participants were aware that this intervention would be only part of the solution, and their fears were that if community members and health authorities perceived the intervention as a 'silver bullet' then other key interventions such as tackling mosquito breeding and resting sites and the provision of clean water would be overlooked and if not addressed the problems would persist.

The value of photovoice was further demonstrated in the images of the challenges faced by the fieldworkers in the distribution of the MDA. This was not part of the researcher focus but it was clear that the photographers were concerned about the strains that distributing the drugs to all eligible participants within the specified timeframe and during the rainy season had placed on the fieldworkers. This has the potential to affect future planning for the routine delivery of MDA, however, the results of the clinical trial demonstrate that with a trail coverage of 62.4% of the eligible population there was a significant effect with a 26% reduction in malaria infection incidence among children 5–15 living in the intervention compared to the control clusters [28].

Limitations of the study

The photovoice activity was conducted in only five of the BOHEMIA trial villages which covered six clusters out of a total of 84 clusters. Although the selection of villages was undertaken to ensure maximum variation, by design the sample size was small. The photovoice data was however triangulated in phase three data collection where the photos agreed upon were used to conduct FGDs in 8 other villages the results will be published in another paper on the acceptability of the intervention. Another limitation of the study was that even though the community photographers were trained on the technical and ethical use of the camera, one of the participants encountered technical problems which weren't reported and so she ended up with very few photos that could be shared. Some of the participants ended up taking photos that depicted malaria and how it is spread, mosquito breeding grounds and malaria prevention which were not directly answering the research questions about the trial and the MDA. However, these pictures did reveal what was important to them and their view of the trial and whether it was meeting their expected need and what can be done to make the trial more successful. Finally, it was difficult for the photographers to take photos of some of the effects of the MDA like diarrhoea, nausea, mild headaches, and stomach aches.

Conclusion

Photovoice can play an important role in clinical trials, helping to understand experiences and intervention effects from the perspective of participants. In the BOHEMIA trial, the photovoice activity revealed activities and processes that encouraged community participation, painting a picture of both positive and negative experiences. The variation by gender in some of the pictures taken and chosen for sharing points to the importance of a gender lens both in trial planning and in the interpretation of uptake and acceptability data. Interestingly, the key differences in the pictures shared by the intervention and control groups did not always align with the differences expected by the study team. Rather some of these pictures reflected unexpected perceived effects on jiggers and bed bugs in the intervention arm which require further investigation. Apart from the experiences of the trial and the effects of the MDA, the shared pictures revealed other emerging issues that reflected the on-going concerns of the community. According to the photographers, these pictures illustrate the root causes of the health problems plaguing the community, mosquito breeding grounds and a lack of clean water which is a source of intestinal worms.

Abbreviations

BOHEMIA	Broad One-Health Endectocide-based Malaria Intervention in Africa
FGD	Focus group discussion
IRS	Indoor residual spraying
ITN	Insecticide-treated nets
MDA	Mass Drug Administration
PV	Photovoice
PVD	Photovoice discussion
RCT	Randomized control trial
WHO	World Health Organization

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Author contributions

CJ conceptualised the study. CJ, TO, KN, KK, WW designed the study. TO, KN, KK, WW collected and analysed the data with supervision provided by CJ. TO drafted the manuscript with guidance from CJ and assistance from KN, KK, WW. MM & JM were the co-PIs of the Kenya arm of the BOHEMIA project, provided input to the overall study design and offered guidance and supervision. CC & NRR conceptualised the BOHEMIA project and its overall study design and offered oversight of the study. All authors read and approved the final manuscript.

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Data availability

The dataset analysed for the current study is not publicly available due to confidentiality concerns. The data can be made available on reasonable request under the legal use permissions following the KEMRI-Wellcome Trust Research Programme and donor procedures.

Declarations

Ethics approval and consent to participate

All participants were explained the purpose of the study by the social science research assistants and gave written informed consent before being included. The study was approved by the WHO Research Ethics Review Committee (ERC 0003264) the Oxford Tropical Research Ethics Committee (OxTREC Ref 511-30), and the KEMRI Scientific and Ethics Review Unit (KEMRI/SERU/CGMR-C/251/4464). Approval was also provided by the Kwale County Health management Team.

Competing interests

The authors declare no competing interests.

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