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Effects of ivermectin mass drug administration for malaria vector control on ectoparasites and soil-transmitted helminths: a cluster randomized trial

Christian Kositz[1,*], Mariama Drammeh[1], Hristina Vasileva[1], Joanna Houghton[2], James Ashall[2], Umberto D'Alessandro[3,#], Michael Marks[1,#], John Bradley[4,#]

[1] Clinical Research Department, Faculty of Infectious and Tropical Diseases, London School of Hygiene & Tropical Medicine, London, United Kingdom
[2] Department of Infection Biology, London School of Hygiene & Tropical Medicine, London, United Kingdom
[3] Disease Control and Elimination, Medical Research Council Unit Gambia at London School of Hygiene and Tropical Medicine (MRCG at LSHTM), Bakau, The Gambia
[4] Department of Infectious Disease Epidemiology, Faculty of Epidemiology and Population Health, London School of Hygiene & Tropical Medicine, London, United Kingdom

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ABSTRACT

Objectives: Ivermectin, used to control several neglected tropical diseases, may also reduce malaria transmission. Mass drug administration (MDA) for malaria control therefore might have off-target impacts on neglected tropical diseases.

Methods: In The Gambia, nested in a trial of ivermectin MDA, cross-sectional surveys measuring ectoparasites and soil-transmitted helminths in children aged 3 to 14 years took place in June and November 2019 and in November 2021.

Results: After MDA, scabies prevalence was 41.2% (237/576) in the control and 38.2% (182/476) in the intervention arm (odds ratio [OR] 0.89 (95% confidence interval [CI] 0 67-1.2), *P*-value = 0.471) but by 2021, had rebounded to 38.8% (180/464) in the control and 53.2% (245/458) in the intervention arm. After MDA, prevalence of *Strongyloides stercoralis* was 16.8% (87/518) in the control and 9.1% (40/440) in the intervention arm (OR 0.4 (95% CI 0.16-0.94), *P*-value = 0.039). In 2021, it was 9.2% (38/413) in the control and 11.3% (45/399) in the intervention arm (OR 1.31 (95% CI 0.74-2.28), *P*-value = 0.35).

Conclusion: Scabies prevalence was similar between the two study arms. *S. stercoralis* prevalence was reduced. However, this effect did not last long: the prevalence 2 years after MDA was similar between study arms.

Background

Despite substantial progress over the last 20 years, malaria remains an important cause of morbidity and mortality in many endemic countries (World Health Organization. World malaria report, 2021). Ivermectin has been identified as an additional tool for vector control due to its mosquitocidal properties against *Anopheles* spp. (The Ivermectin Roadmappers *et al.*, 2020). Mathematical modeling suggests that mass drug administration (MDA) of ivermectin at a dose of 300 mcg/kg for 3 days or 400 mcg for 1 day and with 70% coverage of those aged over 5 years would reduce malaria transmission (Slater *et al.*, 2020). These dosing regimens have been shown to be both safe and mosquitocidal (Smit *et al.*, 2018).

In addition to its potential for vector control, ivermectin is already established as an effective drug against several neglected tropical diseases, particularly ectoparasites and soil-transmitted helminths (STH), which are a major cause of morbidity in lower- and middle-income countries. Ectoparasites occur at low levels in almost all countries but can be highly prevalent in hyperendemic foci in vulnerable or neglected populations (Feldmeier and Heukelbach, 2009; Gbakima *et al.*, 2002; Heukelbach *et al.*, 2003). STH, including *Strongyloides stercoralis, Ascaris lumbricoides, Trichuris*

* Corresponding author: Christian Kositz, Clinical Research Department, Faculty of Infectious and Tropical Diseases, London School of Hygiene & Tropical Medicine, Keppel Street, London, WC1E 7HT, United Kingdom.
E-mail address: christian.kositz@lshtm.ac.uk (C. Kositz).
Joint last author.

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trichiura, and hookworms, are common intestinal parasites, with up to 3 billion individuals worldwide harboring at least one helminth (Jourdan *et al.*, 2018). Moreover, unlike other STH, *S. stercoralis* is able to sustain itself within the host for life (Gill *et al.*, 2004).

Ivermectin MDA, combined with permethrin, has been used successfully to reduce the prevalence of scabies in several settings (Heukelbach *et al.*, 2004; Romani *et al.*, 2015, Romani et al., 2019). Similar studies also show reductions in other ectoparasites, including lice and bedbugs (Coscione *et al.*, 2018; Sheele *et al.*, 2013). Similarly, ivermectin MDA has led to significant reductions in *S. stercoralis* prevalence in several studies (Barda *et al.*, 2017; Forrer *et al.*, 2016; Kearns *et al.*, 2017; Marks *et al.*, 2020) and is highly effective against *A. lumbricoides.* Efficacy for *Trichuris* and hookworms appears to be lower after a single dose of ivermectin, but the repeated application may be more effective (Heukelbach et al., 2004).

We report the findings of a nested substudy evaluating the potential for the synergistic impact of a large-scale ivermectin MDA conducted for malaria control on the prevalence of ectoparasites and STH.

Methods

Background trial

The MASSIV trial (NCT03576313) was a cluster randomized trial implemented in the Upper River Region (URR), eastern Gambia, with 32 clusters (villages) randomized into control or intervention arms. The URR has a rainy season from July to November, followed by a longer dry season. MDA with ivermectin and dihydroartemisinin-piperaquine was implemented in intervention villages at the beginning of the malaria transmission season for over 2 years (2018 and 2019). Each year, three monthly rounds were implemented, in August-October 2018, and in July-September 2019. Ivermectin was given at a dose of 300-400 mcg/kg body weight and dihydroartemisinin-piperaquine at 320/40 mg and 160/20 mg depending on body weight, daily for 3 days. Control villages received standard malaria control measures. Individuals under 15 kg in weight or 90 cm in height, as well as those who were pregnant and breastfeeding did not receive ivermectin. The full details of the MASSIV trial have been previously reported (Dabira *et al.*, 2022).

Study design

Cross-sectional surveys for scabies were carried out in June 2019 (before the implementation of the 2nd year of MDA) and for both scabies and STH in November 2019 (after the 2019 MDA), and in November 2021 (>2 years after the last MDA). No standardized scabies survey was done before implementing the first MDA in 2018. No STH survey was conducted in June 2019 due to logistical and time constraints. The November 2021 survey was originally planned for 2020 but its implementation was delayed due to the COVID-19 pandemic. The surveys measured the prevalence of ectoparasites and STH in children aged 3-14 years.

Ivermectin was administered by the MASSIV trial field team under direct observation. Women of childbearing age were tested for pregnancy before ivermectin treatment and were excluded if positive. Body weight was measured by the MASSIV trial field team with a scale using kilogram units.

Sample size calculation

Because there was no information on the prevalence of ectoparasites and STH in URR, available data from other areas of The Gambia was used. Assuming a 15% prevalence for each ectoparasite and for all STH, and an intracluster correlation coefficient of 0.5, 30 children per cluster would allow the detection of a 75% decrease of prevalence to 6%, with over 80% power.

Study population

The study population was all children aged 3-14 years, living in the 32 study villages, and whose parents/guardians provided a written informed consent. A simple random selection process was used to select children in each cluster. If a household or compound was not willing to participate, moved away, or was not available for any other reason, new participants were randomly selected.

Study procedures

For the June 2019 survey, there were a total of 1322 children randomly selected from the MASSIV trial database. The same list of participants was used for the November 2019 survey, except for one village, in which two compounds had moved out in the meantime. For this village, there were two new compounds randomly selected from the original dataset, increasing the total number of children to 1331 for the November survey. For the November 2021 survey, a new list of 1378 participants from the MASSIV trial database was established because some previous participants were outside the targeted age group. Because no further interventions took place in the MASSIV trial after 2019, we ensured that the children diagnosed with scabies in 2021 received appropriate treatment with benzyl benzoate cream as part of the survey.

Each village was visited between two to five times, at different times of the day, over the course of 5 weeks to account for public holidays and for children being absent during the day. Children that moved away, died, or were otherwise lost to follow-up, were recorded. Investigators were blinded to which arm the respective village was allocated to and did not participate in the distribution of the MDA. All findings were collected using a standardized electronic case report form using REDCap® software in 2019 and Open Data Kit.

Clinical investigation

Scabies

Clinical examination for scabies was carried out by an experienced clinician familiar with the diagnosis of scabies. If possible, a full body examination was conducted, respecting the communities' cultural and societal norms. The electronic case report form questions were structured according to the International Alliance for the Control of Scabies criteria for scabies (Engelman *et al.*, 2020). Because dermatoscopy and parasitological testing were not available, patients were diagnosed using clinical criteria. For the purpose of the study, we considered the International Alliance for the Control of Scabies categories B1, B2, B3, and C1 to be cases of scabies (Engelman *et al.*, 2020) (Table S1).

Head lice and bedbugs

Examination for head lice consisted of direct visual inspection at the sites predilected for nits located behind the ear, the temples, and the neck using standardized methods used in the previous survey in The Gambia (Lindsay *et al.*, 1989). For bedbugs, the sleeping quarters of participants were physically inspected based on a previous survey conducted in The Gambia (Lindsay *et al.*, 1989).

Sample collection for STH

Participants and/or their caregivers received a 60-ml container and spoons, as well as instructions on how to scoop the feces into

the container and the amount needed. Instructions included storing the sample in a cold, dark place, and preferably taking a morning stool sample to reduce the time between sample production and collection. Samples produced at the time of a study visit were collected the same day. Collected samples were aliquoted into a 7-ml Bijou container containing 98% ethanol to preserve DNA and prevent bacterial overgrowth at a 1 : 2 to 1 : 4 ratio, avoiding larger objects. Samples were then transported into the research facility and aliquoted into 1.8-ml cryotubes for further cold storage at -20C.

STH detection by quantitative polymerase chain reaction (qPCR)

Stool samples in 98% ethanol were thawed at ambient temperature and processed as previously described (Farrant *et al.*, 2020). Due to the potentially low prevalence and therefore, lack of sensitivity, no microscopy was done (Farrant *et al.*, 2020). qPCR was performed on a Rotorgene 3000 platform, using previously evaluated STH qPCR protocols (Farrant *et al.*, 2020). Briefly, *S. stercoralis* was analyzed using a singleplex qPCR (Verweij *et al.*, 2009), whereas *A. lumbricoides, Necator americanus, Ancylostoma duodenale,* and *T. trichiura* were analyzed together using a multiplex qPCR (Basuni *et al.*, 2011; Mejia *et al.*, 2013). For both qPCRs described, 3 µl of target DNA template was used in a total volume of 25 µl reaction. Table S2 in supplementary materials shows primer and probe sequences.

Statistical analysis

The co-primary outcomes were the prevalence of each ectoparasite and a composite end point of overall STH prevalence. For adjusted analyses, age was stratified into three groups, 3-6 years, 7-10 years, and 11-14 years, roughly corresponding to preschool, primary school, and secondary school children, respectively. To compare between arms, a logistic regression model with fixed effects for age and sex, and with random effects for the study cluster was fitted.

The statistical analysis was conducted using STATA 14. Figures containing statistical data were made using R software with R studio version 4.0.2 (June 22, 2020).

Role of the funding source

The Wellcome Trust did not have any involvement in data collection, analysis, or interpretation; trial design; patient recruitment; or any aspect pertinent to the study.

Results

Using the MASSIV trial census, 1342 children were randomly selected in July 2019, 1321 in November 2019, and 1378 in November 2021; 81.7 % (1096/1342) of these children were identified in July 2019, 79.6 % (1052/1321) in November 2019, and 66.9 % (922/1378) in November 2021 (Figs. 1 and 2). Stool samples were provided by 72.5% (957/1321) children in November 2019, and 58.9% (812/1378) in November 2020. Baseline demographic details by the survey are described in Tables 1 and 2.

Head lice and bedbugs

During the June 2019 survey, no bedbugs were found. Only eight (0.7%) individuals, four in each study arm, had nits with no living head lice detected. Therefore, no further search for these ectoparasites was carried out in the following surveys.

Scabies

In June 2019, the overall prevalence of scabies was 43.7% (478/1096); 38.8 % (205/529) in the intervention, and 48.2% (273/567) in the control arm (Table S3). After adjustment for clustering, scabies prevalence was significantly lower in intervention villages (odds ratio [OR]: 0.64; 95% confidence interval [CI]: 0.43-0.95, *P*-value = 0.027).

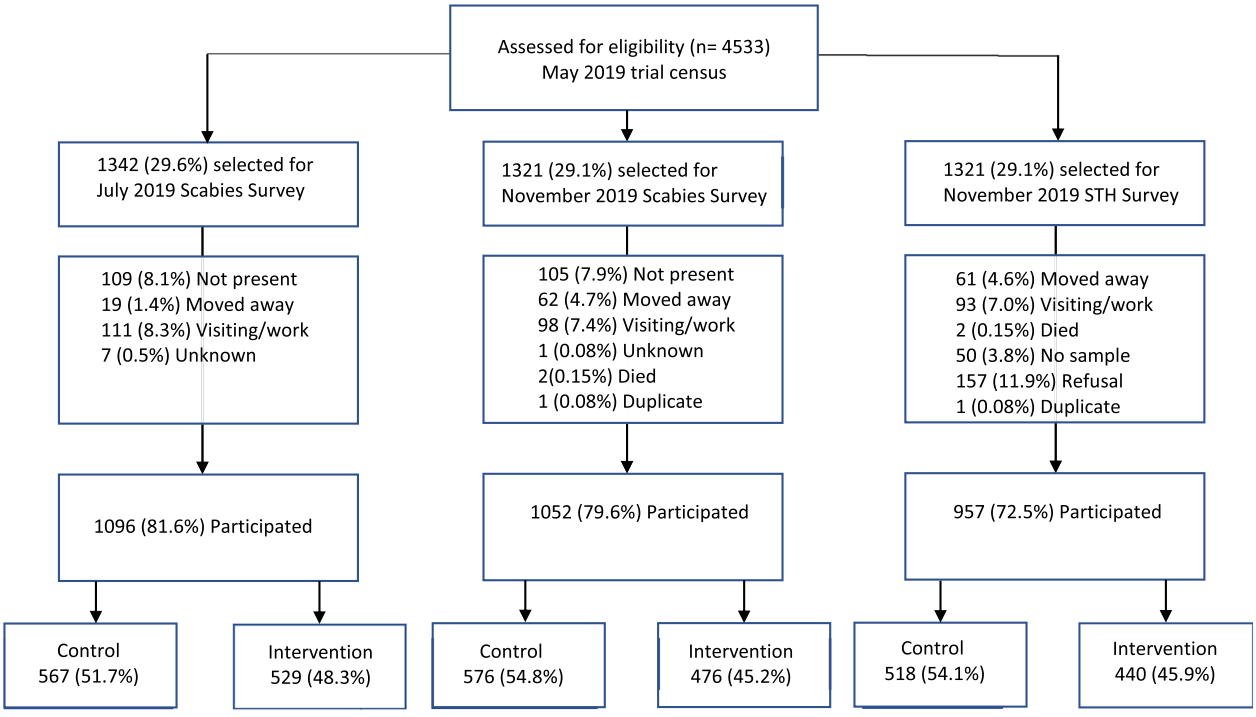

Fig. 1. Participants and their whereabouts in 2019 STH, soil-transmitted helminths.

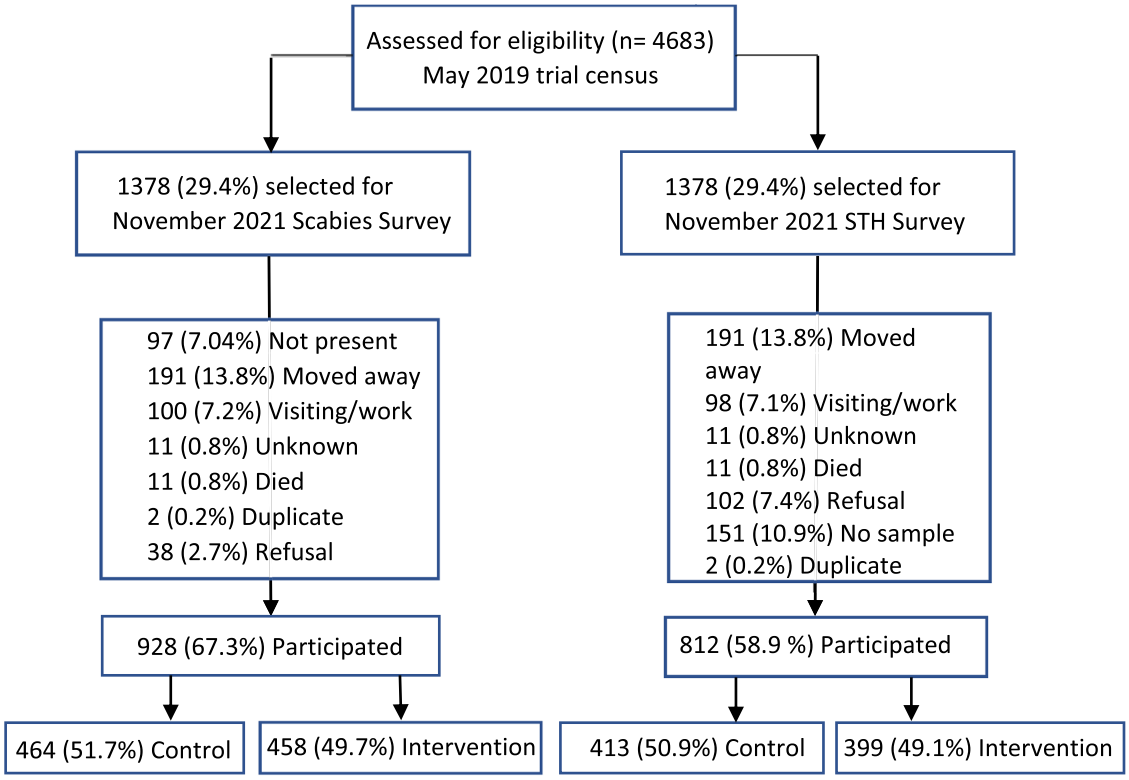

Fig. 2. Participants and their whereabouts in 2021 STH, soil-transmitted helminths.

Table 1
Baseline characteristics of the study participants for scabies surveys.

Demography (scabies)	July-19		November-19		November-21	
	Control	Intervention	Control	Intervention	Control	Intervention
Age group	N (%)		N (%)		N (%)	
3-6 years	244 (22.3)	217 (19.7)	215 (20.4)	172 (16.4)	184 (19.9)	175 (18.9)
7-10 years	210 (19.2)	183 (16.7)	215 (20.4)	172 (16.4)	176 (19.1)	180 (19.5)
11-14 years	113 (10.3)	129 (11.8)	146 (13.9)	132 (12.5)	104 (11.3)	103 (11.2)
Sex						
Female	280 (25.5)	272 (24.8)	278 (26.4)	257 (24.4)	250 (27.1)	206 (19.6)
Male	287 (26.2)	257 (23.5)	298 (28.3)	219 (20.8)	214 (20.3)	252 (23.9)
Arm	567 (51.7)	529 (48.3)	576 (54.8)	476 (45.2)	464 (50.3)	458 (49.7)
Total	1096		1052		922	

Table 2
Baseline characteristics of the study participants for soil-transmitted helminths surveys.

Demography (soil-transmitted helminths)	November-19		November-21	
	Control	Intervention	Control	Intervention
Age group	N (%)		N (%)	
3-6 years	195 (20.4)	161 (16.8)	162 (19.9)	154 (18.9)
7-10 years	207 (21.6)	165 (17.2)	161 (19.8)	162 (19.9)
11-14 years	116 (12.1)	114 (11.9)	90 (11.2)	83 (10.3)
Sex				
Female	254 (26.5)	226 (23.6)	228 (28.1)	166 (20.4)
Male	264 (25.6)	214 (22.3)	185 (22.8)	233 (28.7)
Arm	518 (54.1)	440 (45.9)	413 (50.8)	399 (49.1)
Total	958	812		

In the second survey in November 2019, the overall prevalence was 39.9% (419/1052); 41.2 % (237/576) in the intervention and 38.2 % (182/476) in the control arm (OR: 0.88; 95% CI: 0.66-1 8, *P*-value = 0.406).

In November 2021, 2 years after MDA, the overall prevalence of scabies was 46.5% (425/922); 53.3% (245/458) in the intervention, and 38.7% (180/464) in the control arm (OR: 1.94; 95% CI: 1.1-3.43, *P*-value = 0.022) (Table 3).

Table 3
OR and *P*-values for all three scabies surveys; adjusted for sex and age.

Scabies					
Survey	Prevalence	Unadjusted OR (95% CI)	*P*-value	Adjusted OR (95% CI)	*P*-value
July-19					
Control	273/567 (48.2%)	1		1	
Intervention	205/529 (38.8%)	0.64 (0.43-0.95)	0.027	0.65 (0.44-0.97)	0.037
November-19					
Control	237/576 (41.2%)	1		1	
Intervention	182/476 (38.2%)	0.88 (0.66-1.8)	0.406	0.89 (0.67-1.2)	0.471
November-21					
Control	180/464 (38.8%)	1		1	
Intervention	245/458 (53.2%)	1.94 (1.1-3.43)	0.022	1.89 (1.07-3.37)	0.029

OR, odds ratio.

Table 4
OR and *P*-values for both STH surveys and *S. stercoralis* surveys; adjusted for sex and age.

Soil-transmitted helminths					
Survey	Prevalence	Unadjusted OR (95% CI)	*P*-value	Adjusted OR (95% CI)	*P*-value
November-19					
Control	121 (23.4%)	1		1	
Intervention	72 (16.4%)	0.63 (0.33-1.19)	0.158	0.63 (0.34-1.21)	0.169
November-21					
Control	57 (13.8%)	1		1	
Intervention	75 (18.7%)	1.47 (0.86-2.52)	0.157	1.51 (0.86-2.63)	0.149
Strongyloides					
Survey	Prevalence	Unadjusted OR (95% CI)	*P*-value	Adjusted OR (95% CI)	*P*-value
November-19					
Control	87 (16.8%)	1		1	
Intervention	40 (9.1%)	0.40 (0.16-0.95)	0.037	0.4 (0.17-0.96)	0.039
November-21					
Control	38 (9.2%)	1		1	
Intervention	45 (11.3%)	1.26 (0.72-2.17)	0.41	1.31 (0.74-2.28)	0.35

OR, odds ratio.

STH 2019 and 2021

In November 2019, the overall prevalence of STH was 20.2% (193/958). *S. stercoralis* was the most prevalent STH (13.3%; 127/958), followed by *N. americanus* (4.8%; 46/958), and *A. lumbricoides* (4.1%; 39/958). No *T. trichiura* or *A. duodenale* were detected (Table S4, supplementary material).

No evidence of an effect of the intervention on the overall STH prevalence was detected (adjusted OR: 0.63; 95% CI 0.34-1.21, *P*-value = 0.169). There was evidence of an effect of the intervention on *S. stercoralis,* with 16.9% in the control and 9.1% in the intervention arm, with an adjusted OR: 0.4 (95% CI 0.17-0.96, *P*-value = 0.039) (Table 4).

In November 2021, the overall STH prevalence was 16.3% (132/812). In 2019, *S. stercoralis* was the most prevalent STH with 10.2% (83/812), followed by *N. americanus* 4.8% (40/812) and *A. lumbricoides* 1.2% (10/812). The prevalence for *A. duodenale* and *T. trichiura* were 0.24 and 0.12%, respectively (Table S4).

No evidence of an effect of the intervention on overall STH prevalence was detected with an unadjusted OR of 1.47 (95% CI 0.86-2.52, *P*-value = 0.15) and an adjusted OR of 0.63 (95% CI 0.34-1.21; *P*-value = 0.169). In the case of *S. stercoralis*, no evidence for a long-term effect was seen, with an OR of 1.26 (95% CI 0.72-2.17, *P*-value = 0.41) and an adjusted OR of 1.31 (95% CI 0.74-2.28; *P*-value =0.35) (Table 4).

Discussion

In this study, we did not show any clear evidence of the impact of ivermectin MDA conducted in the context for malaria control on either scabies or STH prevalence, except for *S. stercoralis*. The prevalence of scabies was relatively high in all three surveys, whereas the STH prevalence varied around 15-20%, most of the infections caused by *S. stercoralis*. The prevalence of other STH was low and comparable to that of a survey carried out in 2015 among Gambian school children; however, this survey did not include *S. stercoralis* (Camara *et al.*, 2021).

The study results initially suggested a change in scabies prevalence in July 2019. However, this effect was not seen again after the second MDA in 2019, and the effect appeared to be reversed in the following survey in 2021. This is probably explained by the lack of substantial impact of the MDA on scabies combined with local fluctuations in prevalence (see Fig. S1) because the survey, a few months after the MDA, showed no change in prevalence. Our results differ from most of the previous studies. A lack of impact on scabies has been shown in a study in an area with high population movement (Kearns *et al.*, 2015; Lake *et al.*, 2022). One of the strongest contributors to our results is probably the presence of a substantial untreated reservoir of study participants, including individuals with >15 kg body weight and pregnant and breastfeeding women. The MDA conducted for MASSIV differed importantly from most of the previous studies, where MDA was conducted for scabies. In studies conducted specifically for scabies, individuals who remained untreated due to ineligibility for ivermectin would have been offered treatment with permethrin. In addition, there is a potential of children who were treated being reinfected in schools or while visiting other villages outside the study area or due to contamination between clusters. Using larger clusters might have avoided this risk but is not as statistically robust, and cluster randomized trials have been successfully used for scabies control programs elsewhere. Furthermore, it may be that the coverage reported by the MASSIV trial is enough to impact malaria, but not enough to impact scabies.

The lack of detection for head lice is probably caused by the local habit of shaving the boys' heads, as well as braiding of girl's hair, thus denying lice the necessary living space. In the case of bedbugs, it is possible that, based on temperature data, the climate is too hot in the URR to establish a perennial presence (How and Lee, 2010).

The intervention did not have any effect on the overall STH prevalence. In the 2019 survey, we did detect an impact on *S. stercoralis*, which represented more than half of all STH infections. Of note, only three of 16 intervention villages had two-thirds of all individuals infected with *Strongyloides* (see Fig. S2). Whether this clustered higher burden was due to differences in coverage in these villages is unknown. Despite this initial impact, the effect of ivermectin was not detectable 2 years after MDA. This absence of effect may be due to reinfection from individuals who were untreated within MASSIV or from environmental sources.

This study faced several limitations. The STH survey in 2021 had less than the expected number of participants. Secondly, the prevalence of *A. lumbricoides, N. americanus, A. duodenale,* and *T. trichiura* were much lower than anticipated, resulting in reduced statistical power to detect differences between arms. Unfortunately, this negated the opportunity to shine more light on the potential effect of this repeated ivermectin MDA on *T. trichiura* and hookworm species. Also, not every selected individual provided a stool sample, which may have introduced a bias into the data. In addition, we observed a high level of population movement, either by people moving away to different areas for better job opportunities or seasonal workers migration, which may have impacted the observed efficacy of the intervention (see Figs. 1 and 2).

Finally, although study clusters are all from within the same region of The Gambia and we are not aware of any other factors outside the trial itself that could have influenced scabies prevalence in the control clusters but not the intervention clusters, we cannot completely exclude the possibility that an unidentified external factor influenced the prevalence of scabies in the control villages. Because routine socioeconomic and health interventions are not typically delivered to some villages, we believe that external secular changes are unlikely to account for the lack of effect seen.

Overall, the results of the study were mixed with no effect shown for scabies and only *S. stercoralis* being significantly impacted. Further work is required to investigate the effect of MDA with ivermectin when implemented for malaria control on ectoparasites and STH because this may depend on both the intensity of the MDA coverage and local parasite prevalence.

Funding

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Ethical approval

This study was nested within the MASSIV trial, and all participants were consented for the main study. The communities and local authorities were informed about these surveys and only consented participants were included. Parents consented for their children and additional written assent was obtained for children aged ≥12 years. Ethical clearance was given by the ethics board of the London School of Hygiene and Tropical Medicine and the Gambian government/Medical Research Council Unit Gambia Joint Ethics Committee (Ethics Ref. Nr. 17123).

Author contributions

Conceptualization: CK, JB, MM, JH; review & editing: JB, HV, AL, UD, MM; methodology: HV, JH, JA; original draft: CK; analysis and interpretation of data: CK, JB, HV, JH, JA, UD, MM; read and approved final version: CK, MD, JB, HV, JH, JA, UD, MM.

Data sharing

After publication, trial data will be made available on reasonable request to the corresponding author. A proposal with a detailed description of study objectives and a statistical analysis plan is needed for assessment of requests. Additional materials might also be required during the process. Deidentified participant data will be provided after approval by the sponsor and trial management group.

Declaration of competing interest

The authors have no competing interests to declare.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ijid.2022.10.043.

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