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A prospective, comparative study of clinical outcomes following clinic-based versus self-use of medical abortion

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ABSTRACT

Background To determine whether clinical outcomes differ among women accessing a combined medical abortion regimen from a health clinic when compared with those accessing it from a pharmacy.

Methods We conducted a multicentre, prospective, comparative, non-inferiority study of participants aged ≥15 years seeking medical abortion from five clinics and five adjacent pharmacy clusters in three provinces of Cambodia. Participants were recruited in-person at the point of purchase (clinic or pharmacy). Follow-up for self-reported pill use, acceptability, and clinical outcomes occurred by telephone at days 10 and 30 after mifepristone administration.

Results Over 10 months, we enrolled 2083 women with 1847 providing outcome data: 937 from clinics and 910 from pharmacies. Most were early in their pregnancy (mean gestational age of 6.3 and 6.1 weeks, respectively) and almost all took the pills correctly (98% and 96%,). Additional treatment needed to complete the abortion was non-inferior for the pharmacy group (9.3%) compared with the clinic group (12.7%). More from the clinic group received additional care from a provider, such as antibiotics or diagnostics tests, than those from the pharmacy group (11.5% and 3.2%,), and one ectopic pregnancy (pharmacy group) was successfully treated. Most said they felt prepared for what happened after taking the pills (90.9% and 81.3%, respectively, p=0.273).

Conclusions Self-use of a combined medical abortion product resulted in comparable clinical outcomes as use following a clinical visit, consistent with existing literature on its safety and efficacy. Registration and availability of medical abortion as an over-the-counter product would likely increase women's access to safe abortion.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The combination of mifepristone and misoprostol is a safe and effective method of abortion. Although most research to date includes an abortion provider in the process, telemedicine and accompaniment approaches have minimised the role of the provider and demonstrated continued safety and effectiveness. Comparative studies, however, have been uncommon.

WHAT THIS STUDY ADDS

⇒ This study shows that clinical outcomes following either self-use or a clinical appointment before initiating the medical abortion process were comparable; for those who opt for this self-use after sourcing medicines from a pharmacy, clinical outcomes and safety remain.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study supports pathways to medical abortion without a clinical encounter and could contribute to the requirements for over-the-counter regulation of medical abortion commodities.

INTRODUCTION/BACKGROUND

More than 22 million women every year—almost all in lower- and middle-income countries—have an unsafe abortion

because they lack access to safe, high-quality abortion care.[1] Women in the global south are most at risk of injury or death from unsafe abortion, and death from pregnancy-related causes is the second-leading cause of death for adolescent girls.[1–3] Making abortions safer in these contexts is therefore key to decreasing deaths and disability. In addition to decreasing potential harms to health, approaches that decrease the role of the provider are preferable to some and facilitate access to abortion; different models, including self-care, are therefore crucial from a human rights perspective to ensure those who need an abortion have a pathway that meets their needs.

Randomised controlled trials have shown that the combination of mifepristone and misoprostol is an effective abortion regimen with success rates ranging from 95–98% up to 9 weeks' gestation.[4–8] Serious complications are reported rarely.[7 9] Although mifepristone and misoprostol are prescription medicines, women are increasingly obtaining them through online services, pharmacies, and telemedicine,[10–14] especially where abortion services are restricted or difficult to access.[15] Sourcing medicines through these routes may also reflect the way some women prefer to access abortion care.[16] Over the past 20 years the increased availability and use of medical abortion has increased the safety of abortion, particularly in rural or restricted settings, as it allows for a safe process even where providers have not been trained to perform surgical abortion.[17] Additional approaches such as telemedicine provision and accompaniment models of abortion care have demonstrated safety and effectiveness, and a range of self-care approaches has now been strongly recommended by the WHO.[9 18]

Medabon, a combination product containing mifepristone and misoprostol, is used for medical abortion in many countries. Registered in Cambodia in 2012, it is used by public and private facilities and is available at most pharmacies. The Cambodia Demographic and Health Survey 2014 reported that 12% of women have had at least one abortion in their lifetime.[19] Surgical abortions are most common (60%) while 40% used medications. Of the medical abortions, 61% occurred under the care of a healthcare provider and the remainder reported no assistance or no involvement of a provider.

We conducted this study to determine whether clinical outcomes differ among women who access a combined medical abortion regimen from a pharmacy when compared with those who access it from a health facility.

METHODS

We conducted a prospective, observational cohort study among two groups of medical abortion clients within 9 weeks of gestation. Medical abortion clients were eligible for participation if they: purchased Medabon independently at a pharmacy or received it from a clinic for a pregnancy at ≤9 weeks since the last menstrual period; were at least 15 years old; were a resident of Cambodia; had no contraindications to medical abortion drugs; were able to give informed consent; and were willing to be followed up by telephone or in person three times over the course of 30 days after taking mifepristone.

Participants were recruited from 21 study sites (12 pharmacies and nine clinics) in three provinces: Siem Reap, Preah Sihanouk, and Phnom Penh. Pharmacies were situated near participating clinics to ensure similar geography and clinic accessibility between the two study groups. Both clinics and pharmacies were selected based on volume of services provided per month and staff willingness to participate in the study. Those seeking care from clinics had a short outpatient visit during which they opted for a medical abortion; after their visit with the provider, they were sent home with Medabon to complete their abortion process at home, as is typical practice for early gestation pregnancies. Pharmacy-recruited participants presented to their pharmacy asking for medical abortion pills directly. Recruitment occurred after clients had received or purchased Medabon from either the clinic or pharmacy; those potentially interested in participating were directed by staff to speak in person with a female research assistant stationed at each study site to conduct recruitment.

Eligible clients who consented to participate agreed to be contacted by the research assistant on three occasions following their baseline interview: on day 3 (survey 1) after completing the baseline survey, day 10 (survey 2), and day 30 (survey 3) after mifepristone intake. The day 3 call verified that the participant had initiated the abortion by taking mifepristone. Only participants who reported taking at least one pill were fully enrolled in the study and followed up on days 10 and 30. Surveys 2 and 3 both assessed abortion outcomes, including the primary outcome.

The primary outcome was additional treatment to complete the abortion (either by uterine aspiration or with repeated misoprostol) following the medical abortion pills within 30 days.[20] Secondary outcomes included the participant's confidence that the abortion was complete, and any visit to a healthcare professional for any other problems. All outcomes were measured based on participant self-report.

The primary outcome was assessed by asking participants 'Did you have additional treatment to complete the abortion, either more medical abortion pills or a surgical procedure like manual vacuum aspiration (MVA)?' at both days 10 and 30 after taking mifepristone. Participants were coded as having had additional treatment if they reported 'yes' on either the 10- or 30-day survey. Participants were coded as not having had additional treatment if they reported 'no' or 'don't know' on both the 10- and 30-day surveys or if they missed the 10-day survey and reported 'no' or 'don't

know' on the 30-day survey. The secondary outcome of confidence in abortion completion was measured by asking participants 'Do you think you are still pregnant?' at the 10-day survey. Those who responded 'yes' or 'don't know' were coded as not feeling confident the abortion was complete. The secondary outcome of visiting a health professional was assessed by asking 'Since taking the medical abortion pills (Medabon), did you get treatment from a healthcare professional for any other problems?' immediately after asking the question about additional treatment to complete the abortion. Participants who responded 'yes' were asked detailed information about the care they received and were coded as having received additional care for reasons other than to complete the abortion. Cases with missing outcome data were excluded from this analysis.

The sample size was calculated based on non-inferiority design, assuming need for additional treatment after medical abortion pills of 6% in the clinic group based on previous studies.[7 8] We considered a difference of 4 percentage points to be a clinically meaningful non-inferiority limit. The calculation assumed 80% power to detect a 4% difference, α of 0.05, intraclass correlation (ICC) of 0.001,[21] and 20% loss to follow-up. The resulting sample size was 2000 participants: 1000 for each group (pharmacy and clinic).

To assess different characteristics by group, we used bivariate mixed effects regression models, including random effects for recruitment site. For the non-inferiority analysis, we computed crude risk differences in outcomes by group using bivariate Poisson generalised estimating equations (GEE) models with identity link to account for clustering by site.[22] This model did not converge using the identity link for the secondary outcome; thus, the log link was used with risk difference calculated from the log relative risk. The adjusted risk difference was calculated by including sociodemographic and reproductive characteristics that were significantly different between groups (age, gravidity, previous abortion, and gestational age). We calculated 95% confidence intervals (95% CIs) on the crude and adjusted risk differences; if the confidence interval did not cross the non-inferiority limit, we considered pharmacies non-inferior to clinics. Finally, we assessed differences in abortion experience by group, including preparedness for the medical abortion process and whether the participant would recommend medical abortion to a friend, using multilevel mixed effects models including random effects for sites. Statistical significance was assessed at $p<0.05$, and all analyses were conducted using Stata/SE version 17.0.

RESULTS

A total of 2199 medical abortion users were approached for participation (1085 at clinics and 1114 at pharmacies): 2114 were eligible and consented (1048 at clinics, 1066 at pharmacies), and 2083 reported taking some or all of the abortion pills by day 3 and were enrolled (1033 at clinics, 1050 at pharmacies). We included 1847 participants (937 at clinics and 910 at pharmacies) who consented, took the pills, and had outcome data in the analyses. See figure 1 for the flow of study participants through the study. The sociodemographic characteristics and reproductive history of participants differed by treatment group (table 1). Participants in the clinic group were younger, less likely to have had a previous pregnancy, less likely to have used medical abortion before, and had later gestations compared with the pharmacy group. Other sociodemographic characteristics were comparable. Of the 640 participants who reported a previous abortion, 83.9% previously used medical abortion and 16.1% had a previous abortion using another method, primarily surgical abortion, but some were unsure (n=13) or used a homemade treatment (n=1). Participants sought care early in pregnancy, on average 6.2 weeks' gestation, and earlier among the pharmacy group (6.1 weeks) when compared with the clinic group (6.3 weeks) (p=0.001). Almost all took the medical abortion regimen correctly: 98.0% of those in the clinic group and 95.7% of those in the pharmacy group (data not shown).

The rates of additional treatment to complete the abortion were 11.0% (n=204); 12.7% (n=119) among the clinic group and 9.3% (n=85) among the pharmacy group for a crude risk difference of −1.6% (95% CI −7.4% to 4.1%) (online supplemental table 1). After adjusting for significant differences between groups, the adjusted risk difference was −2.6% (95% CI −7.6% to 2.4%) indicating non-inferiority of the pharmacy group. Rates of additional treatment to complete the abortion varied across sites from 0% to 20.8%, leading to a higher ICC than anticipated (ICC 0.02749). Confidence that the abortion was complete was greater in the clinic group (88.8%) compared with the pharmacy group (82.0%), but the adjusted risk difference was not significant (aRD −7.4%, 95% CI −15.6% to 0.7%). Visiting a healthcare professional for other problems was rarer in the pharmacy group (3.2%) compared with the clinic group (11.5%); adjusted risk difference was not significant (aRD −4.3%, 95% CI −15.1% to 6.6%).

Women from the clinic group seeking additional care generally returned to the clinic where they had received the Medabon (84%, n=159), with a minority seeking care at different private health clinics (13%, n=24) or public health facility (1%, n=2). Those from the pharmacy group generally sought care at private health facilities (71%, n=64); none returned to the pharmacy of original Medabon purchase. Most participants who sought additional care received a diagnostic test or ultrasound, 18 received antibiotics, and 14 were hospitalised (details of hospitalisations are provided in table 2). One ectopic pregnancy was diagnosed and

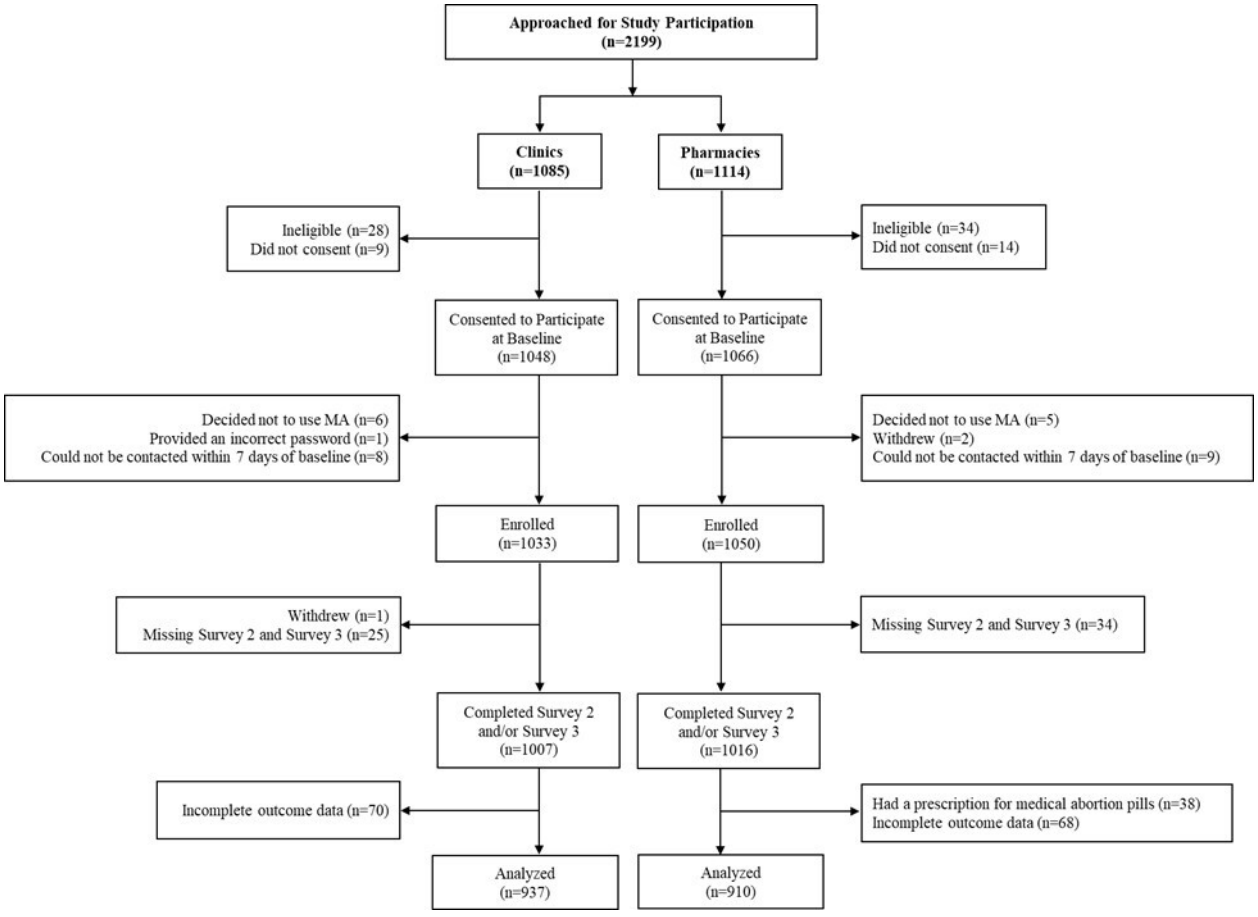

Figure 1 Flow of participants through the study. MA, medical abortion.

treated after a participant from the pharmacy group sought care after having no bleeding following administration of the abortion pills.

Experiences with medical abortion were generally comparable across the two groups (table 3). Participants reported feeling similarly prepared for the process from the clinic and pharmacy groups, 91% (n=852) versus 81% (n=740), respectively (p=0.273). However, some reported unexpected side-effects: seeing clots or tissue, more pain, and heavier or longer bleeding. The participants in the clinic group were significantly more likely than the pharmacy group to report heavier and longer bleeding than expected. Acceptability, as measured by whether the participant would recommend medical abortion to a friend, was comparable between groups at 70.6% (n=637) in the clinic and 66.2% (n=608) in the pharmacy group. Overall, 7.9% (n=144) responded they would not recommend any type of abortion to a friend.

DISCUSSION

Self-use of a combined medical abortion product resulted in clinical outcomes comparable to use following a clinical visit. In a setting where no interventions were conducted to train pharmacists or supplement information or counselling for those seeking abortion, participants successfully managed their abortion process safely and effectively without an interaction with a healthcare provider.

We found higher intervention rates than expected from the literature; however, it is not uncommon to find lower effectiveness in real life than in clinical trials.[23] Interestingly, we observed that intervention rates were higher among the clinic group, which may indicate a greater acceptance of medical intervention and treatment, or familiarity and comfort with the clinic or provider. As prior experience with an aspiration abortion was correlated with additional treatment to complete the abortion, these participants may have had different expectations about the length of time a medical abortion takes or may have felt more comfortable seeking an aspiration than awaiting completion of the process. Additionally, many providers recommend aspiration as treatment when clients seek care for problematic bleeding.[24 25] Finally, participants who faced barriers to care-seeking from clinics may have faced similar barriers in seeking additional treatment. Although rates of complications requiring hospitalisation were low overall, both groups appeared to access care when needed, including for early treatment of an ectopic pregnancy.[7 9] An important limitation of our data is that all outcomes were by self-report, without confirmation of provider's diagnoses and treatment; indeed, we chose the primary outcome purposely to

Table 1 Participant sociodemographic and reproductive characteristics by group (n=1847)

Characteristic	Total (n=1847)		Pharmacies (n=910)		Clinics (n=937)		P value
	n	%	n	%	n	%	
Age							**<0.001**
16–24 years	465	25.2%	184	20.2%	281	30.0%	
>24 years	1382	74.8%	726	79.8%	656	70.0%	
Education*							0.132
No education or less than secondary	1214	65.7%	737	81.0%	477	50.9%	
Completed secondary (grade 12) or higher	633	34.3%	173	19.0%	460	49.1%	
Residence							0.141
City/town	1736	94.0%	844	92.7%	892	95.2%	
Countryside	111	6.0%	66	7.3%	45	4.8%	
Employment							0.104
Currently working	1448	78.4%	698	76.7%	750	80.0%	
Not currently working	399	21.6%	212	23.3%	187	20.0%	
Marital status*							0.957
Currently married	1566	84.8%	775	85.2%	791	84.4%	
Not currently married	281	15.2%	135	14.8%	146	15.6%	
Parity							0.932
0	528	28.6%	191	21.0%	337	36.0%	
1–2	993	53.8%	538	59.1%	455	48.5%	
3+	326	17.6%	181	19.9%	145	15.5%	
Gravidity*							**0.017**
0	414	22.4%	137	15.1%	277	29.6%	
1–2	822	44.5%	388	42.6%	434	46.3%	
3+	611	33.1%	385	42.3%	226	24.1%	
Previous induced abortion*							**<0.001**
None	1207	65.3%	462	50.8%	745	79.5%	
Previous abortion with medicines	537	29.1%	408	44.8%	129	13.8%	
Previous abortion with other methods	103	5.6%	40	4.4%	63	6.7%	
Gestational age in weeks, mean (SD)	6.2 (1.13)		6.1 (1.11)		6.3 (1.13)		**0.001**

*Imputed to the mean for missing data. The percentage of missing data were <0.25% of the total sample for each variable.
MA, medical abortion.

capture a meaningful, objective outcome not reliant on medical records. An additional limitation was that although most participants in both groups reported feeling their abortion was complete at the 10-day interview, we did not repeat this question at 30 days, while the question about additional treatment was asked at both times.

As we conducted an observational study, we expected that the demographics between groups might differ. Indeed, we found that those seeking care from pharmacies were older, more parous and more experienced with medical abortion than those from clinics. These demographic differences may partially explain their low rate of additional care-seeking, as they may have been more tolerant of the expected effects of a medical abortion. Younger and less parous women may have needed instructions and counselling from a provider and self-selected more frequently from clinics.

Results may be biased by having only one product available—Medabon—in Cambodia, which is registered and distributed for abortion. In countries without a quality-assured combipack or where misoprostol of varying quality is used alone for abortion, efficacy rates among those seeking treatment from a pharmacy may differ from our data. A strength of our study is our low loss-to-follow-up; our study team reported establishing good relationships with the participants during initial in-person recruitment extended to their willingness to answer phone calls for follow-up surveys. We intentionally created short surveys, under 10–15 min, to facilitate the willingness of participants to answer subsequent calls and to enhance the quality

Table 2 Symptoms and care details for hospitalisations/stays in a health facility overnight for 14 participants who received additional care to complete the abortion and/or care for any other problems (n=15 hospitalisations)

Symptoms	Pharmacies (n=12)	Clinics (n=3)	Treatment	Length of stay (days)
Incomplete abortion, prolonged bleeding*	1	1	MVA	1
Severe pain, little bleeding*	1	0	MVA	1
Heavy bleeding, loss of consciousness	1	0	MVA, IV fluids and medicine (unknown)	1
Signs of infection, prolonged bleeding	0	1	MVA and medicine (vitamin)	3
Signs of infection, retained blood clots/incomplete	2	0	MVA and medicine (unknown)	1–2
Signs of infection (high fever, chills, sick)	4	0	Antibiotics, IV fluids and medicines (unknown)	2–7
Signs of infection (readmission with heavy bleeding)†	1	0	MVA	1
Ectopic pregnancy	1	0	Surgery	6
Non-abortion related reasons (dengue, heart disease)	1	1	IV fluids, medicines (related to disease)	1–4

*Reason for hospitalisation was not clear.
†This participant was first hospitalised for 7 days for signs of infection (high fever, chills, sick). After discharge, she experienced continued bleeding, so returned to the hospital for additional care.
IV, intravenous; MVA, manual vacuum aspiration.

of data. The overwhelming challenge in this study was recruiting women from pharmacies, which has been attempted in previous studies and the methodologic challenges reported.[15 26] We addressed this challenge by posting enumerators at each pharmacy or pharmacy cluster—all relatively high-volume to ensure sufficient recruitment—which may limit the generalisability of our findings.

Worldwide, the self-use of medical abortion is rising, even in high resource settings with ready access to facility-based care,[16 25 27 28] and an interest in an over-the-counter product has been documented in a recent study among the general US population.[29] During the COVID-19 pandemic, provision of telemedicine medical abortion increased dramatically in the UK and USA.[28–31] Recent publications of accompaniment models compared to clinical care in Argentina and Nigeria, and self-use through drug sellers in Nigeria, have also demonstrated safe, effective and acceptable use among participants.[19 32] Further experiences and research will continue to confirm

Table 3 Participant experiences with medical abortion by site type (n=1847)

	Total (n=1847)		Pharmacies (n=910)		Clinics (n=937)		
	n	%	n	%	n	%	P value
Felt prepared for what happened after taking the medical abortion pills							0.273
Yes	1592	86.2%	852	90.9%	740	81.3%	
No or don't know	255	13.8%	85	9.1%	170	18.7%	
Experienced but not expected							
Saw clots/tissue	101	5.5%	35	7.3%	66	3.7%	0.657
More pain	98	5.3%	64	6.8%	34	3.7%	0.293
Heavier bleeding	87	4.7%	13	1.4%	74	8.1%	**0.005**
Longer bleeding	72	3.9%	15	1.6%	57	6.3%	**0.002**
Higher or longer fever	29	1.6%	16	1.7%	13	1.4%	0.880
More gastrointestinal symptoms (nausea, vomiting, diarrhoea)	16	0.9%	4	0.4%	12	1.3%	0.128
Incomplete abortion	2	0.1%	0	0.0%	2	0.2%	0.994
Other	20	1.1%	5	0.5%	15	1.7%	0.156
Would recommend MA pills to a friend							0.953
Yes	1245	68.4%	608	66.2%	637	70.6%	
No	255	14.0%	109	11.9%	146	16.2%	
Would not recommend any type of abortion	144	7.9%	111	12.1%	33	3.7%	
Don't know	176	9.7%	90	9.8%	86	9.5%	

MA, medical abortion.

the range of safe and effective self-use of medical abortion and expand its generalisability. Beyond investigating different country and legal settings, future research should include misoprostol alone in settings without mifepristone, effectiveness of misoprostol alone in self-use settings, and use at higher gestational ages, all of which have been thought to decrease expected effectiveness.

Given the safety and effectiveness demonstrated by self-use of medical abortion outside of a clinic setting, the increasing availability of medical abortion has the potential to expand choices for care and may facilitate earlier treatment. Registration and availability of medical abortion as an over-the-counter product would increase women's access to this method of safe abortion.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants and received ethical approval from the National Ethics Committee for Health Research in Cambodia (#296NECHR), and was registered with ClinicalTrials.gov (NCT03727308). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

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