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# Evaluating the long-term impact of large-scale trainings: An exposure based cross-sectional study on female genital mutilation related knowledge, attitudes, and practices among Sudanese midwives in Khartoum State

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Evaluating the long-term impact of large-scale trainings: An exposure based cross-sectional study on female genital mutilation related knowledge, attitudes, and practices among Sudanese midwives in Khartoum State

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#### **ABSTRACT**

# **Objectives**

To examine the long-term impact of large-scale training to address female genital mutilation (FGM) among midwives with a hypothesis that those trained would have a significantly higher knowledge, non-support for midwives' involvement in this practice and improved clinical practice compared to those not exposed.

# Design

We conducted an exposure based cross-sectional study, using closed and open-ended questions during phone interviews.

# Setting

Khartoum State in Sudan has a high prevalence of FGM (88%) typically involving the severest form performed by midwives.

# **Participants**

Midwives who received (n=127) and did not receive FGM training (n=55).

# Primary and secondary outcome measures

We developed primary outcomes aligned to the three levels (reaction, learning and behavior) of Kirkpatrick's training evaluation model for descriptive and multivariable analyses in Stata.

#### Results

All the midwives interviewed were female, mostly village midwives (92%) and worked in health centers (89%). The mean age and midwifery experience was 51 years (SD=10) and 23 years (SD=12) respectively. Overall, most midwives (>90%) reported being supportive of FGM discontinuation. Midwives who had FGM training were more aware that performing FGM violates code of conduct (P = .001) and reported to always counsel patients to abandon FGM (P <.001) compared to midwives who did not have FGM training. However, these associations were not statistically significant in multivariable logistic regression model adjusting for age. Exploratory analysis of training curricula showed higher knowledge, correct attitude, and practices among those who reported in-service training before 2016.

# Conclusion

Compared to non-trained midwives, trained midwives reported higher frequency of FGM prevention counseling and awareness that performing FGM violated professional code of conduct; however, they identified re-infibulation as a correct procedure during labor management. There is a need to address values and clinical skills in FGM training curricula as well as conduct regular monitoring and evaluation for timely quality improvement.

Key words: female genital mutilation, Sudan, midwifery in-service/induction trainings, knowledge, attitudes, practices

# Strengths and limitations of this study

- The use of a retrospective exposure-based design with multivariable analysis increased rigor
  to frequently used pre-/posttest analyses and a practical and efficient approach to costly
  prospective studies.
- Objective questions which assess actual knowledge and skills to recommended standard generate non-biased data compared to previous studies that assess health workers' perceived changes in knowledge and skills.
- Some of the study questions such as satisfaction rates and practice were affected by respondent bias and would need further improvements, testing and validation.
- The absence of data from midwives' clients limited assessment of impact of their interventions.
- Kirkpatrick evaluation model was a useful framework to assess training outcomes however an
  ecological framework which recognizes the complex interplay between individuals, family,
  community and society including the health systems would need to be included in future
  evaluations.

#### INTRODUCTION

Female genital mutilation (FGM) is a harmful practice that affects 14 million women and girls in Sudan.¹ This practice involves partial or total removal of tissue or other injuries to the external female genitalia². In Sudan specifically, the commonest type affecting 72% of girls and women (15 – 49 years) living with FGM is classified by the World Health Organization (WHO) as Type 3 or "infibulation". This type involves the cutting of the inner and outer vulvar folds with or without removal of the clitoral glans and closing the outer vulvar folds leaving a small opening for urine and menstrual blood flow³. Among girls under 15 years, FGM is mainly reported to be performed by midwives (64%) known as "FGM medicalization"², followed by traditional practitioners (29%)⁴. Furthermore, 24% of girls and women (15 – 49 years) who gave birth in the preceding year report having FGM type 3⁴ repeated or "re-infibulation" performed by midwives. Midwives' involvement not only violates the health professional code of conduct to "do no harm" but also endorses the practice and negatively impacts FGM abandonment efforts.

Midwives constitute about a quarter of the Sudanese health workforce (23%) as either community (83%) or facility-based midwives (17%)<sup>5</sup>. Community-based midwives complete their training in one year, while facility-based midwives complete 2-4 years of training. The FGM sessions in their training curricula have varied in content and training modality over the years and across all midwifery schools. After training, midwives receive a one-day induction training prior to obtaining their midwifery practice license that they renew every three years in the National Medical Council for Health Professionals (NMCHP). Thereafter during their practice, they participate in a 10-12-day in-service training mostly provided by the Federal Ministry of Health (FMoH).

To stop midwives' involvement in FGM practice, the FMoH implemented a large-scale health sector FGM program in 2016. One component of this program was to build midwives' FGM related knowledge and skills during their induction and in-service trainings.

The FGM-related content within these trainings was updated using WHO's 2016 guidelines on management of health complications<sup>6</sup>. The FGM content duration was one hour and two-days for the induction and in-service trainings, respectively. The content covered FGM epidemiology, typology, health complications, non-linkage of FGM practice with religion, midwives' role as change agents and FGM medicalization as a violation of professional code of conduct that carries administrative punitive measures.

In 2018, the in-service FGM training content was adapted to focus mainly on skills for social norm change via communication, community dialogue and advocacy. The training content was adapted from United Nation's Population Fund (UNFPA) and United Nation's Children Fund (UNICEF) manual on social norm change <sup>7,8</sup>.

By the end of 2018, 18% and 31% of all the midwives (*N*=16,183) in Sudan received FGM training based on the 2016 curriculum during induction and in-service trainings respectively<sup>9</sup>. A further 9% of all the midwives received FGM training based on the 2018 curriculum emphasizing social norm change during in-service training.

The effectiveness of FGM related content in induction and in-service training was mostly captured in pre- and post-tests which focused on knowledge attainment. There was no long term follow up data on trained midwives' FGM related knowledge, attitudes, or practices. Furthermore, the existent global evidence base on FGM training effectiveness have shown varied levels of success in changing health care providers' knowledge, attitudes, self-efficacy, skills and

patient satisfaction in mostly controlled study settings<sup>10</sup>. Few studies have examined changes in intentions, or actual change in practices from either a study setting or real world interventions<sup>11,12</sup> and we found no study assessing training effects beyond six months of training. From a programmatic perspective, the training costs were substantial (\$296 USD [\$157] per midwife)<sup>9</sup> in Sudan and we felt it was important to assess if these trainings had any lasting impact on midwives' knowledge, attitude, and clinical practices. We conducted an exposure based cross-sectional study to identify associations between current FGM related knowledge, attitudes, and practices among midwives working in Khartoum State, Sudan. We hypothesized that midwives who received FGM related trainings would have a significantly higher knowledge, non-supportive attitudes towards FGM medicalization and improved clinical practice compared to midwives who did not receive FGM related trainings.

# **METHODS**

#### Setting

Khartoum State houses 11% of all midwives in Sudan (*N*=16,183)<sup>13</sup>. Most of girls and women aged 15 – 49 years (88%) living in Khartoum State have experienced FGM mostly type 3 (72%) and 22% of this age group who gave births in the preceding year underwent re-infibulation. Further, Khartoum State has the highest FGM medicalization prevalence (89%) in Sudan, performed mainly by midwives<sup>4</sup>. During the period 2016 – 2018, the FMoH and the NMCHP training records for Khartoum State indicate that 75% and 76% of midwives received training using the 2016 curriculum during in-service and induction trainings respectively while 28% received training using 2018 curriculum.

# Study design and study population

This exposure based, cross-sectional study compared FGM related knowledge, attitudes and practices among midwives who ever received FGM trainings and those who did not.

For the study sample estimation, we used a prevalence of 5% for knowledge on FGM types, 90% for attitudes against FGM practice and 7% for correct knowledge of FGM complications management as a proxy for practice among untrained midwives from previous assessments<sup>14,15</sup>. We anticipated a difference of 20% for FGM related knowledge and practice and 10% for attitude between trained and non-trained arms using 80% for power and 5% alpha error. The sample size generated for these differences ranged between 46 – 71 midwives.

We retrieved records of trained and non-trained midwives in Khartoum State to identify and generate lists of potential trained and non-trained midwives. We used random number generator for sampling. Because of uncertainty about whether records on training status were complete and up to date, we oversampled by 30% and 100% from the lists of trained and non-trained midwives respectively, so that we could re-classify as needed based on self-reported training status. We then obtained the phone contact details of the selected midwives from the FMoH and Khartoum State Ministry of Health.

## **Materials and Methods**

We used Kirkpatrick's four level training evaluation model as a framework to assess training effectiveness. The first level "Reaction" focuses on trainees' perceptions. The second level "Learning" evaluates whether training learning objectives were met. The third level "Behavior" assesses behavioral change while the fourth "Results" evaluates the training impact on the organization, quality, or user of service. For this study, we utilized Kirkpatrick's first three levels since our study included only midwives but not their clients to assess impact.

The primary exposure of interest was any FGM training received and the training outcome variables for each of Kirkpatrick's levels are listed in Table 1.



Table 1. Training outcome variables to assess training effectiveness among midwives who received or did not receive FGM content during induction and in-service trainings in Khartoum State

Kirkpatricks' Levels	Training Outcome Variables	Measurement scale and standards used
Level 1 "Reaction"	Satisfaction levels	Likert Scale
Level 2 "Learning"	WHO's four FGM types	Per WHO's guidance from the clinical handbook
	Four correct FGM health complications	for care of girls and women living with FGM <sup>16</sup>
Level 3 "Behavior"	Agreement to following statements:	Correct responses aligned to zero tolerance on
	FGM practice continuation	FGM and its medicalization and WHO's guidance
	FGM medicalization as a violation of professional code of conduct	on clinical management and role of health workers
	Health workers' influence to change FGM practice	in FGM prevention and care services <sup>3,16–19</sup>
	Health workers to follow social traditions and norms	<b>b</b> /
	Health workers do not have the time to provide FGM related services	
	Correct choice for WHO's recommended surgical steps for de-infibulation	
	procedure during labor out of six	
	Frequency of providing FGM prevention counseling	Likert scale

The study tool had 21 questions which included closed and open-ended questions. The first section had six questions on current demographic data (age, sex, midwifery qualification, midwifery work experience, health facility level) which was used for descriptive data and as potential covariates to be controlled for in the multivariable model.

The second section assessed characteristics of training and satisfaction scale (Kirkpatrick level 1), for midwives who received FGM training. This section had 8 questions on training type (in-service, induction training, other), FGM training year categorized into versions of the training curriculum received (<2016, 2016 – 2018, >), training duration (days), training institution (FMoH, non-governmental, other) and satisfaction levels (Likert scale) with respect to knowledge and skills gained for FGM prevention and complications management.

The third section had 7 questions on current knowledge, attitudes, and practices. Open ended questions focused on describing the FGM types and listing four FGM complications they know of. Closed ended attitudinal questions assessed agreement with statements about their stances on FGM, FGM medicalization, efficacy to change practice, and experiences providing FGM related services (see Table 1).

The co-Principal Investigator (Co-PI), MM, translated the study tool into Arabic that was cross-checked by PI (WA). The co-PI used the Arabic version to develop an online survey administration software (google form survey) with constraints and skip patterns to minimize errors and trained four data collectors with experience in health survey data collection on research ethics and the electronic questionnaire. Data collectors conducted phone interviews during the period October 2022 till January 2023.

# Data analysis

The PI (WA) and co-PI (MM) reviewed, cleaned, and coded the autogenerated data set from google survey into Microsoft Excel (2018). The open-ended responses on FGM types and complications were coded according to WHO definitions and categories<sup>3</sup>. The data set was then imported into StataCorp. 2021. Stata: Release 17. The scale of missing data was less than 5% and randomly missing that did not require any imputation. We conducted descriptive analysis of study population and the trainings. Student t and Chi square tests were conducted for continuous and categorical variables respectively.

We conducted univariable and multivariable logistic models to examine the association between ever being trained (independent variable) and outcomes on knowledge, attitude, and practices (dependent variables) as primary analysis. For the multivariable models we controlled for age, a characteristic that was significantly different between the two groups and was also related to training exposure, midwifery expertise and training outcomes. Because we conducted multiple testing we used Holm-Sidak corrections for *P*-values. We conducted exploratory analysis to examine associations between training outcomes and training year as a proxy for training curriculum content, as well as number of trainings received.

We obtained ethical approval from the University of Washington Institutional Review Board (STUDY00012584) and Sudan's FMoH National Health Research Ethics Review Committee (P2-3-21). The study was considered as programmatic research not subject to human research protections; nevertheless, we conducted the research following research ethics guidelines.

### **Public Patient Involvement Statement**

This research did not involve patients in the development of research questions and outcomes.

It was not appropriate or possible to involve patients or the public in the design, or conduct, or

reporting, or dissemination plans of our research as we did not conduct the study at health facility level to retrieve patient records or have access to them. We note this limitation in method and discussion section and recommend their involvement in future studies.

#### **RESULTS**

Among the sample of 246 midwives, we interviewed 182 (74%); 74 (30%) were not traceable because of non-valid phone numbers, 5 (2%) were not eligible because they were not midwives, 2 (1%) were dead and 2 (1%) had left Sudan. All the 182 midwives reached agreed to participate and completed phone interviews lasting 10 – 15 minutes.

Most midwives (70%) reported having received an FGM training by the time of data collection (Table 2). All the midwives interviewed were female, most trained as village midwives (92%) and most worked in health centers (89%) (Table 2). The mean age was 51 years (SD=10), and mean years of midwifery experience was 23 years (SD=12). Both study populations had similar demographic and professional characteristics, but the groups differed in mean age. Midwives who did not receive any FGM training were older (M=56 years, standard deviation (SD) = 11) than those who were trained (M=49 years, SD=9) and this difference was statistically significant (P=<0.001).

Table 2: Characteristics of midwives who received and did not receive trainings on female genital mutilation in Khartoum State, Sudan.

Total	Not Trained	Trained
N=182	N=55	N=127
	M (SD)† or n (%)	§

	Total	Not Trained	Trained	
	N=182	N=55	N=127	
Age (years)	51.3 (10.3)	55.7 (11)	49.3 (9)	
Job Title				
Village midwife	168 (92%)	50 (91%)	104 (92%)	
Health visitor	7 (4%)	3 (6%)	4 (4%)	
Assistant health visitor	6 (3%)	1 (2%)	5 (4%)	
Midwifery work experience (years)	23.1 (12.2)	24.5 (13.2)	22.5 (11.7)	
Health facility level				
Hospital	2 (1%)	1(2%)	1 (1%)	
Health center	161 (89%)	41 (75%)	120 (95%)	
Other	19 (10%)	13 (24%)	6 (5%)	

<sup>&</sup>lt;sup>†</sup>Mean (standard deviation) <sup>§</sup> Number (percentage)

The largest group of trained midwives (46%) reported received two trainings (Table 3). There were similar proportions of midwives who received each of the three FGM training curriculum versions i.e., prior to 2016, 2016 - 2018 and after 2018 versions. The mean duration of in-service training was 3 days (SD=1) during 2016 - 2018, 3 days (SD=1) after 2018 and 2 days (SD=1) for trainings prior to 2016. Most of in-service training was conducted by the Ministry of Health (94%) followed by non-governmental organizations (6%).

Table 3: The reported type, year, and number of trainings with female genital mutilation content received by 127 midwives in Khartoum State, Sudan.

FGM training content received	Midwives n (%) §

In-service <2016	72 (48%)
In-service 2016 – 2018*	65 (43%)
Induction 2016 – 2018	27 (21%)
In-service >2018**	79 (53%)

Number of FGM training content received	Midwives n (%) §
One training	46 (25%)
Two trainings	58 (46%)
Three trainings	23 (13%)

§ Number (percentage)

\*FGM training content version was adapted to World Health Organization's 2016 guidelines on the management of health complications

\*\* FGM training content version was adapted to United Nations Population Fund and United Nations Child Fund's manual on social norm change

# FGM training content satisfaction levels (Kirkpatrick Level 1)

Generally, the satisfaction levels on the knowledge and skills gained on FGM prevention and care management were high for in-service or midwifery induction trainings. Overall, most of the trained midwives (89 - 100%) reported being either "very satisfied" or "satisfied" on FGM prevention and health complications management knowledge and skills. A higher proportion (12%) of midwives who received midwifery induction trainings (N=26) reported less satisfaction on skills on FGM complications management compared to midwives (5%) who received in-service

training (N=64). This finding was affirmed by all midwives (N=24) who received both types of trainings.

# Knowledge of FGM types and health complications (Kirkpatrick Level 2)

Overall, less than a third of all midwives knew four FGM types<sup>1</sup> or four health complications. However, 44% and 80% were able to name more than 2 FGM types and health complications respectively. Of the FGM types named, type 3 and type 1 were the most common. While obstetric and chronic complications were the most reported FGM health complications. FGM related acute, psychological, and sexual complications were the least reported.

The difference in knowledge on FGM types and FGM health complications between midwives who reported receiving FGM training to those who did not was not statistically significant.

# FGM related attitudes and practices (Kirkpatrick Level 3)

Most of the midwives who reported ever receiving FGM training (99%) and most of those who did not (96%) were supportive of the abandonment of FGM and its medicalization. A high proportion of midwives thought that FGM is a harmful practice that needs to stop (99%) and not a religious requirement (95%). They also believed that FGM medicalization does not make the practice safer (97%) and is a violation of professional code of conduct (71%).

<sup>&</sup>lt;sup>1</sup> WHO definitions for FGM types: Type 1: "Partial or total removal of the clitoral glans and/or prepuce", Type 2: "Partial or total removal of the clitoral glans and the labia minora, with or without excision of the labia majora", Type 3: "Narrowing of the vaginal opening with the creation of a covering seal by cutting and appositioning the labia minora or labia majora with or without excision of the clitoral prepuce and glans (infibulation)", Type 4 "All other harmful procedures for example pricking, piercing, incising, scraping and cauterization"

With regards to practice related knowledge, 95% of all midwives reported that they always provided FGM counseling. In contrast, only 11% cited the correct de-infibulation surgical procedure during labor.

We found two statistically significant differences in FGM related attitudes and practice-related knowledge between the two groups. Midwives who received FGM training were more aware that FGM medicalization violates their professional code of conduct (P = .001) and reported always counseling patients to abandon FGM (P < .001) compared to midwives who did not receive FGM training.

See Table 4 provides detailed findings on training outcomes among midwives who received and did not receive FGM content during induction and in-service trainings in Khartoum State.

Table 4: Training outcomes among midwives who received and did not receive female genital mutilation content during induction and in-service trainings in Khartoum State, Sudan

Kirkpatrick Level	Total	Not Trained	Trained	P value
	N=182	<i>N</i> =55	N=127	
Level 2		n (%)		
Midwives who named:				
4 FGM types	33 (18%)	6 (11%)	27 (21%)	0.11
• >2 FGM types	81 (45%)	20 (37%)	61 (48%)	0.17
4 health complications	50 (27%)	14 (26%)	36 (29%)	0.62
<ul><li>&gt; 2 health complications</li></ul>	144 (80%)	45 (82%)	99 (80%)	0.76
Level 3		901		
Midwives who agreed that:		1	>	
FGM is a harmful practice that should stop	176 (98%)	52 (96%)	124 (99%)	0.17
FGM is a religious requirement	12 (7%)	6 (11%)	6 (5%)	0.11
FGM is a meaningful culture and should continue	8 (4%)	5 (9%)	3 (2%)	0.04

Health workers should follow this social norm	19 (11%)	11 (20%)	8 (6%)	0.005
Health workers who conduct FGM make it safer	12 (7%)	7 (13%)	5 (4%)	0.03
Health workers who perform FGM violate professional code of conduct*	134 (74%)	31 (57%)	103 (82%)	0.001*
Health workers do not have any influence to change this practice	63 (35%)	24 (45%)	39 (31%)	0.06
Health workers have no time to provide prevention and care services	29 (16%)	9 (17%)	20 (16%)	0.91
Self-reported to "always" provide counseling against FGM practice*	174 (96%)	47 (86%)	127 (100%)	<0.0001*
Identified the correct de-infibulation <sup>2</sup> surgical procedure during labor	20 (11%)	8 (15%)	12 (10%)	0.29

<sup>\*</sup>P value for Chi square test was statistically significant using Holm-Sidak Correction

<sup>&</sup>lt;sup>2</sup> De-infibulation as defined by WHO refers to the practice of cutting open the sealed vaginal opening of a woman who has been infibulated to allow intercourse or to facilitate childbirth. Infibulation is a type of FGM where vulval folds are opposed leaving a small opening for urine or menstrual flow.

# Univariable, Multivariable and Exploratory Logistic Model Analysis

The univariable logistic model analysis (Table 5) showed that trained midwives were more likely to be aware that FGM medicalization was a violation of professional code of conduct (OR: 3.3, 95% Cl: 1.6 – 6.7, P=.001) compared to non-trained midwives. However, after adjustment for age, this association was no longer statistically significant.

Exploratory analysis for training outcomes by reported training type (induction, in-service), training year (<2016, 2016-2018 and >2018) and training dose (1-3 trainings) showed higher odds ratio in overall knowledge, correct attitude and practice among midwives who reported receiving FGM during in-service training before 2016 (Table 6 in supplemental appendix). In particular, the knowledge on four correct FGM health complications (aOR 5.1, 95% CI: 1.9-13.5, P=.001) and awareness that FGM medicalization as a violation of professional code of conduct (aOR 15.6, 95% CI: 3.7-66.1, P<.0001) was significant after adjustment for age. Similarly, midwives who received one training (aOR 27.0, 95% CI: 3.4-211.8, P=.002) or two trainings (aOR 6.2, 95% CI: 2.1-18.1, P<.0001) were more likely to be aware that FGM medicalization as a violation of professional code of conduct. Interestingly, midwives who received FGM content during induction training in 2016 – 2018 (aOR 13.8, 95% CI: 2.1-88.6, P=.01) and those who reported FGM training before 2016 (aOR 11.9, 95% CI: 2.0-70.5), P=.01) had comparable results on knowledge of four FGM types.

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Table 5. Female genital mutilation related knowledge, attitudes, and practices among trained compared to non-trained midwives in Khartoum State, Sudan.

Cirkpatrick's evaluation model Levels	Crude Estimates <sup>+</sup>				Adjusted Estimates‡		
	OR <sup>¶</sup>	95% CI°	P value	aOR <sup>†</sup>	95% CI°	P value	
earning Outcomes (Kirkpatrick Level 2)							
nowledge of four health complications	1.2	0.6 – 2.5	0.62	1.0	0.5 – 2.0	0.92	
nowledge of four FGM types	2.2	0.8 – 5.6	0.11	3.4	1.2 – 9.9	0.02	
ehavior Outcomes (Kirkpatrick Level 3)							
elieve that health workers should follow FGM as soc	cial 0.3	0.1 – 0.7	0.01	0.3	0.1 – 0.9	0.03	
orm							
ware that performing FGM violates professional co	de 3.3	1.6 – 6.7	0.001*	2.4	1.1 – 5.1	0.03	
f conduct							
Correct de-infibulation <sup>3</sup> surgical procedure	0.6	0.2-1.6	0.30	0.6	0.2 – 1.7	0.34	

<sup>&</sup>lt;sup>3</sup> De-infibulation as defined by WHO refers to the practice of cutting open the sealed vaginal opening of a woman who has been infibulated to allow intercourse or to facilitate childbirth. Infibulation is a type of FGM where vulval folds are opposed leaving a small opening for urine or menstrual flow.

\*Logistic regression model

¶Odds Ratio †Adjusted Odds Ratio \*P value was statistically significant using Holm-Sidak Correction

#### DISCUSSION

This exposure-based cross-sectional study found the majority of midwives in Khartoum State reported non-supportive attitudes towards FGM practice and its medicalization irrespective of their reported FGM training status. Nearly all midwives who received FGM training reported high satisfaction on their knowledge but slightly less for their skills to manage FGM health complications. Though trained midwives were more likely to be aware of FGM medicalization as a violation of professional code of conduct and to report higher counseling frequency on FGM abandonment, this association was not statistically significant in multivariable logistic model. The low correct knowledge on de-infibulation procedure during labor management for the most prevalent FGM type (infibulation) is concerning because midwives considered re-infibulation a correct step. Re-infibulation increases genital tissue scarification and ensuing wide range of FGM related health risks and complications on women's health including the baby during delivery. Though we recognize that reported knowledge does not necessarily translate to actual practice, we believe that incorrect knowledge is likely to lead to incorrect practice. We believe there was a low possibility that the midwives misunderstood the question because terminologies familiar to their routine midwifery practice was used. Furthermore, their knowledge on re-infibulation as a correct procedural step is incongruent with their high knowledge of FGM health complications, awareness that FGM medicalization is a violation of professional code of conduct and reported high frequency of counseling on FGM abandonment. This inconsistency in findings could be explained possibly by training gaps demonstrated by their lower satisfaction levels on FGM health complications management skills as well as the exploratory analysis findings suggesting weaknesses in training curricula content after 2016. In addition, midwives may not consider reinfibulation as FGM practice for women who are already infibulated. Further, the mean age of trained midwives in our study was 51 years and their ingrained values may be more challenging to change and not in tandem to knowledge change. Future trainings may need to address their values around FGM, FGM medicalization and re-infibulation through value clarification exercises <sup>20</sup> as build their clinical skills for de-infibulation procedure. Midwives may also feel pressured to perform re-infibulation as demonstrated by their perception that health workers have low influence in changing FGM practice. One study found trained Somali midwives were not able to provide interventions because it challenged culture and religion<sup>21</sup>. Finally, the financial incentive to perform re-infibulation<sup>21</sup> may supersede professional code of conduct and their moral compass with the current high unemployment rates and low pay if employed<sup>9,23</sup>.

Most midwives reported FGM content format received was during in-service trainings. In-service trainings have been shown in a systematic review to improve health workers practice in low income settings <sup>24</sup>. Our exploratory analysis showed a similar finding exemplified by a stronger association between in-service trainings and training outcomes compared to induction trainings. However, the comparisons between the different versions of in-service training curricula suggest gaps after 2016 which was affirmed by the absence of training content on de-infibulation procedure in the actual training modules developed after 2016<sup>7,25</sup>. The global low knowledge on practical skills for de-infibulation procedure among all midwives in the study indicate training gaps in midwifery schools that would need to be investigated further and addressed.

Studies have shown that monitoring and evaluation (M&E) is an effective strategy in improving health care providers' practice in low income setting<sup>26,27</sup>. Our previous research found no FGM

related data at facility level,<sup>9</sup> suggesting limited M&E as well as low accountability of trainees to translate their acquired knowledge and skills into practice.

Our study brings in new evidence on the long-term FGM training outcomes among health workers involved in the practice or working in a high FGM prevalent setting. Though our study design was cross-sectional, the use of comparative arms and multivariable analyses strengthened rigor which was noted to be absent from previous FGM related training studies<sup>10</sup>. Another study strength was the use of a retrospective, exposure-based design which was more practical and efficient than carrying out a costly prospective study<sup>28</sup>. Finally, we used objective questions which assess actual knowledge instead of midwives' perceptions as was done previously <sup>12</sup> to generate non-biased data for decision makers involved in training programs and quality of care.

One of our study limitations was the absence of qualitative data to complement our survey data as well data from midwives' clients to determine impact (Kirkpatrick Level 4). The use of qualitative data from midwives could have strengthened data triangulation and provided contextual depth and additional understanding on factors related to the training outcomes. Future evaluation of FGM related trainings may need to use in addition to Kirkpatrick evaluation model, an ecological framework which recognizes the complex interplay between individuals, family, community and society<sup>29</sup> including the health system they operate under. Some of the study questions would need further improvements, testing and validation. For instance, midwives' high response rate in providing FGM abandonment counseling did not align with their belief that health workers have no time to provide FGM prevention services or influence to change FGM practice. Their high response may have been due to social desirability bias to meet the Ministry of Health expectation.

In conclusion, our study findings highlight the need to review all FGM training curricula and focus on addressing midwives' values, self-efficacy in changing practice and practical skills in deinfibulation and managing FGM health complications in trainings. Appropriate evaluation tools will need to be developed and used during M&E. Finally, the influence of health system and societal factors on midwives' practices should not be ignored during evaluations to identify on areas to enc. modifiable intervention areas to enable midwives to translate their knowledge and skills into practice.

#### **DECLARATIONS**

# Ethics approval and consent to participate

The study was approved by the University of Washington Institutional Review Board (STUDY00012584) and Sudan's FMoH National Health Research Ethics Review Committee (P2-3-21). The study was considered as programmatic research not subject to human research protections, nevertheless, we conducted the research following research ethics guidelines.

# **Competing Interests**

The authors have no conflict of interest.

# **Consent for publication**

Not applicable

# Availability of data and materials

The datasets generated and/or analyzed are available from the corresponding author on reasonable request.

# **Competing interests**

The authors declare no competing interests.

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#### **Authors' contributions**

WA conceptualized the study design, conducted analysis and interpretation and manuscript write up. MM translated study tool into Arabic, designed its electronic format, coordinated, and supervised data collection, cleaned and coded data set as well as reviewed manuscript. CF, SG and NP supervised WA and provided guidance in the whole process from conceptualization to substantive input in manuscript write up. All authors read and approved the final manuscript.

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Table 6: Exploratory analysis between training outcomes and female genital mutilation training curriculum type and number of trainings received among midwives in Khartoum, Sudan

	4 FGM types	4 correct FGM health	FGM violates health	Correct de-
		complications	professionals code of	infibulation <sup>1</sup> steps ir
Training			conduct	labor management
Profile			conduct	iaboi illallageillelli
		OR <sup>1</sup> (95%	CI°) P value	
	0/	aOR <sup>‡†</sup> (95%	GCI°) P value	
2016 – 2018 induction	13.8 (2.1 – 88.6) P=0.01	4.0 (0.8 – 19.3) P=0.08	0.2 (0.02 – 2.9) P=0.27	0.7 (0.1 – 7.0) P=0.7
	13.8 (2.1 – 88.6) P=0.01	3.7 (0.8 – 17.7) P=0.10	0.3 (0.03 – 3.0) P=0.32	0.7 (0.1 – 6.9) P=0.7
<2016 in-service	11.9 (2.0 – 70.5) P=0.01	5.0 (1.9 – 13.1)P=0.001*	19.4 (4.7 – 80.6) P<0.0001*	1.7 (0.5 – 5.5) P=0.34
	11.9 (2.0 – 70.5) P=0.01	5.1 (1.9 – 13.5) P=0.001*	15.6 (3.7 – 66.1) P<0.0001*	1.8 (0.6 – 6.0) P=0.31
2016 – 2018 in-service	1.0 (0.2 – 4.0) P=0.97	0.9 (0.3 – 2.2) P=0.76	5.7 (1.1 – 28.6) P=0.04	1.0 (0.3 – 3.3)P=0.94
	1.0 (0.2 – 4.0) P=0.97	0.9 (0.3 – 2.3) P=0.79	4.0 (0.8 – 19.8) P=0.09	1.0 (0.3 – 3.5) P=0.97
>2018 in-service	0.3 (0.1 – 1.2) P=0.09	1.1 (0.5 – 2.6) P=0.75	13.2 (3.8 – 46.6) P<0.0001*	0.2 (0.1 – 0.8) P=0.02
	0.3 (0.1 – 1.2) P=0.09	1.0 (0.4 – 2.4) P=0.95	6.2 (1.6 – 24.2) P=0.01	0.3 (0.1 – 0.9) P=0.04
One training received	0.3 (0.1 – 1.0) P=0.04	0.6 (0.2 – 1.5) P=0.27	37.7 (4.9 – 290.2) P<0.0001*	0.5(0.1 – 2.0) P=0.35
	0.4 (0.1 – 1.4) P=0.13	0.5 (0.2 – 1.3) P=0.15	27.0 (3.4 – 211.8) P=0.002	0.5 (0.1 – 2.1) P=0.37
Two trainings received	0.7 (0.3 – 1.8) P=0.48	1.0 (0.5 – 2.3) P=0.92	7.7 (2.7 – 21.9) P<0.0001*	1.2 (0.4 – 3.5) P=0.72

<sup>&</sup>lt;sup>1</sup> De-infibulation as defined by WHO refers to the practice of cutting open the sealed vaginal opening of a woman who has been infibulated to allow intercourse or to facilitate childbirth. Infibulation is a type of FGM where vulval folds are opposed leaving a small opening for urine or menstrual flow.

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	4 FGM types	4 correct FGM health	FGM violates health	Correct de-			
		complications	professionals code of	infibulation <sup>1</sup> steps in			
Training Profile			conduct	labor management			
Frome	OR¹ (95% CI°) P value						
	aOR <sup>‡†</sup> (95% CI°) P value						
	0.9 (0.3 – 2.5) P=0.89	1.0 (0.4 – 2.2) P=0.96	6.2 (2.1 – 18.1) P<0.0001*	1.2 (0.4 – 3.7) P=0.69			
Three trainings received	1.2 (0.4 – 3.5) P=0.75	1.1 (0.4 – 3.1) P=0.84	2.7 (0.9 – 7.6) P=0.06	0.3 (0.04 – 2.6) P=0.28			
	1.5 (0.5 – 4.5) P=0.51	1.0 (0.4 – 3.0) P=0.96	2.4 (0.8 – 7.3) P=0.12	0.3 (0.04 – 2.6) P=0.28			

<sup>¶</sup> Odds Ratio

<sup>‡</sup> Logistic regression model adjusted for age

<sup>&</sup>lt;sup>†</sup> Adjusted Odds Ratio

<sup>° 95%</sup> Confidence Interval

<sup>\*</sup> P value is statistically significant using Holm-Sidak Correction

STROBE Statement—Checklist of items that should be included in reports of cross-sectional studies

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what	3-4
		was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6-8
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	9
Setting	5	Describe the setting, locations, and relevant dates, including periods of	8
		recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection	8-9
1		of participants	
Variables	7	Clearly define all outcomes, exposures, predictors, potential	10-12
		confounders, and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of methods	11-12
measurement		of assessment (measurement). Describe comparability of assessment	
		methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	13
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If	12-13
		applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	13
		(b) Describe any methods used to examine subgroups and interactions	13
		(c) Explain how missing data were addressed	13
		(d) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(e) Describe any sensitivity analyses	13
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers	14
-		potentially eligible, examined for eligibility, confirmed eligible, included	
		in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	14
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical,	14-10
-		social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of	
		interest	
Outcome data	15*	Report numbers of outcome events or summary measures	16-20
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted	21 –
		estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	23, 3

		(b) Report category boundaries when continuous variables were	35
		categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute	n/a
		risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions,	21, 35
		and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	24
Limitations	19	Discuss limitations of the study, taking into account sources of potential	26
		bias or imprecision. Discuss both direction and magnitude of any	
		potential bias	
26Interpretation	20	Give a cautious overall interpretation of results considering objectives,	24-27
		limitations, multiplicity of analyses, results from similar studies, and	
		other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	26
Other information			
Funding	22	Give the source of funding and the role of the funders for the present	32-33
		study and, if applicable, for the original study on which the present	
		article is based	

<sup>\*</sup>Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

# **BMJ Open**

# Evaluating the long-term impact of large-scale trainings: An exposure based cross-sectional study on female genital mutilation related knowledge, attitudes, and practices among Sudanese midwives in Khartoum State

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Evaluating the long-term impact of large-scale trainings: An exposure based cross-sectional study on female genital mutilation related knowledge, attitudes, and practices among Sudanese midwives in Khartoum State

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#### **ABSTRACT**

# **Objectives**

To examine the long-term impact of large-scale training targeting midwives in a setting where they are the main FGM practitioners. We hypothesized that trained midwives would have significantly higher knowledge, greater opposition to midwives' involvement in this practice, and improved clinical practice in FGM prevention and care compared to non-trained midwives.

# Design

We conducted an exposure based cross-sectional study, using closed and open-ended questions during phone interviews.

# Setting

Khartoum State in Sudan has a high prevalence of FGM (88%) mainly performed by midwives.

# **Participants**

Midwives who received (n=127) and did not receive FGM training (n=55).

# Primary and secondary outcome measures

We developed primary outcomes aligned to the three levels (reaction, learning and behavior) of Kirkpatrick's training evaluation model for descriptive and multivariable analyses in Stata.

#### **Results**

All the midwives interviewed were female, mostly village midwives (92%) and worked in health centers (89%). The mean age and midwifery experience was 51 years (SD=10) and 23 years (SD=12) respectively. Overall, most midwives (>90%) reported being supportive of FGM discontinuation. Midwives who had FGM training were more aware that performing FGM violates code of conduct (P = .001) and reported to always counsel patients to abandon FGM (P <.001) compared to midwives who did not report training. However, these associations were not statistically significant in multivariable logistic regression model adjusting for age. Exploratory analysis of training curricula showed higher knowledge, correct attitude, and practices among those who reported in-service training before 2016.

#### Conclusion

Though past trainings were associated with higher knowledge and greater opposition to midwives' involvement in FGM, this was not translated into appropriate corrective clinical procedures among affected women during labor. The Sudan Ministry of Health invested heavily in training midwives and it would be important to investigate why trained midwives do not implement recommended FGM-related clinical management.

Key words: female genital mutilation, female genital mutilation type 3, medicalization, midwives, Sudan, trainings, knowledge, attitudes, practices

# Strengths and limitations of this study

- The retrospective exposure-based study design with adjustment for potential confounders using multivariable analysis had higher rigor compared to commonly used simple pre/posttest analysis and provides timely results at lower cost for policy makers, compared to prospective study designs which have stronger rigor.
- The use of objective questions which assessed changes towards the expected training goals in health workers' knowledge, attitudes and skills generated non-biased data compared to previous studies that used health workers' personal perspectives.
- Some of the study questions such as satisfaction rates and practice patterns were affected by respondent bias and would need further refinement, testing and validation.
- The absence of data from midwives' clients limited insights into their perspectives and limited our ability to assess impact of trained midwives' interventions.
- Kirkpatrick's evaluation model was a useful framework to assess training outcomes; however, an ecological framework which recognizes the complex interplay between individuals, families, communities, and society including the health system would need to be included in future evaluations.

#### INTRODUCTION

Female genital mutilation (FGM) is a harmful practice that affects 14 million women and girls in Sudan.(1) This practice involves partial or total removal of tissue or other injuries to the external female genitalia.(2) In Sudan specifically, the commonest type affecting 72% of girls and women (15 – 49 years) living with FGM is classified by the World Health Organization (WHO) as Type 3 or "infibulation". This type involves the cutting of the inner and outer vulvar folds with or without removal of the clitoral glans and closing the outer vulvar folds leaving a small opening for urine and menstrual blood flow.(3) Among girls under 15 years, FGM is mainly reported to be performed by midwives (64%) known as "FGM medicalisation",(2) followed by traditional practitioners (29%).(4) Furthermore, 24% of girls and women (15 – 49 years) who gave birth in the preceding year report having FGM type 3 repeated or "re-infibulation" performed by midwives.(4) Midwives' involvement not only violates the health professional code of conduct to "do no harm" but also endorses the practice and negatively impacts FGM abandonment efforts. The high FGM prevalence and the involvement of midwives who make up 23% of the health workforce (5) prompted the Ministry of Health (MoH) to introduce FGM-related content into preand in-service trainings in efforts improve the quality care to FGM survivors and stop FGM medicalisation. Further, midwives upon graduation are required to make an oath not to perform FGM in midwifery schools. This is followed by receiving sensitization session on FGM medicalisation being a violation of professional code of conduct during the one-day induction sessions for professional licensure in the National Medical Council for Health Professionals (NMCHP).

The FGM training in pre- and in-service training covers content on FGM epidemiology, typology, health complications, non-linkage of FGM practice with religion, midwives' role as change agents and FGM medicalisation as a violation of professional code of conduct that carries administrative punitive measures. The FGM-related content emphasis, training methodology and duration varies by the training modality, training institutions and over time. The FGM content is spread across harmful practices/community health and/or clinical modules within the one year or 2 – 4 years pre-service curricula in midwifery schools for community or facility-based midwives respectively. In comparison, the FGM related sessions are provided in 1-2 days during a 10-12-day in-service training by the Federal Ministry of Health (FMoH) and sessions less than one hour during the pre-license one-day induction training. Further, the 1-2 in-service training content emphasis changed over time. Curriculum versions after 2016 were adapted to the first World Health Organization's (WHO) guidelines on FGM (2016) with content mostly on clinical management of FGM related health complications. In 2018, the in-service training version was revised to focus more on skills for social norm change via communication, community dialogue and advocacy adapted from the United Nations Population Fund and United Nations Child Fund's manual on social norm change (2017).

Not all midwives receive the same exposure of FGM training content, MoH records indicate that 18%, 31% and 9% of all the midwives (*N*=16,183) in Sudan received FGM content during prelicence, 2016 – 2018 version of in-service trainings, and 2018 version of in-service training respectively.(6) The effectiveness of the different trainings received by midwives in Sudan was mostly captured in pre- and post-tests which focused on knowledge attainment only. There was no long term follow up data on trained midwives' FGM related knowledge, attitudes, or practices.

To our knowledge, there is no current global literature on the effectiveness of FGM-related trainings implemented at large scale. Much of the existing literature examining the effectiveness for FGM-related training on health workers' knowledge, attitudes, self-efficacy, skills and patient satisfaction is generated from small scale training interventions in controlled study settings.(7) In addition, the study populations in the literature comprised mostly of health workers in settings where either FGM prevalence or FGM medicalisation is low. As such, the training intervention effectiveness might not be replicable in settings where FGM medicalization and FGM prevalence are high.

Furthermore, there is a literature gap on trainings' effectiveness on intentions to change clinical practice or actual changes in clinical practice in either a study setting or for real world training interventions.(8,9) We also found no study assessing training effects beyond six months of training. Large scale trainings are costly, (mean of \$296 USD [median: \$157] per midwife)(6) and when implemented alone and over long periods of time, this type of intervention raises costeffectiveness questions for governmental and donor spending among decision makers. It is therefore important to assess long-term effectiveness of scaled FGM training on midwives' knowledge, attitude, and clinical practices.

Our study aims to fill some of the identified gaps in evidence with regards to the long-term effectiveness of a large-scale training program on knowledge, attitudes and on clinical practice of health workers who are also involved in FGM practice and who work in FGM-prevalent settings. We conducted an exposure based cross-sectional study in Khartoum State, Sudan to identify associations between current FGM related knowledge, attitudes, and practices among midwives who received or did not receive past FGM related trainings. We hypothesized that

midwives who reported having received past FGM related trainings would have a significantly higher knowledge, greater opposition towards FGM medicalisation and improved clinical practice compared to those who have not.

#### **METHODS**

# Setting

Khartoum State houses 11% of all midwives in Sudan (*N*=16,183).(10) Most of girls and women aged 15 – 49 years (88%) living in Khartoum State have experienced FGM mostly type 3 (72%) and 22% of this age group who gave births in the preceding year underwent re-infibulation. Further, Khartoum State has the highest FGM medicalisation prevalence (89%) in Sudan, performed mainly by midwives.(4) During the period 2016 – 2018, the FMoH and the NMCHP training records for Khartoum State indicate that 75%, 76% and 28% of midwives received 2016 version of FGM related curriculum in-service training, FGM content during pre-license induction training and 2018 version of FGM related curriculum in-service training respectively.

# Study design and study population

This exposure based, cross-sectional study compared current FGM related knowledge, attitudes and practices among midwives who reported to have ever received FGM trainings to those who reported no training.

For the study sample estimation, we used a prevalence of 5% for knowledge on FGM types, 90% for attitudes against FGM practice and 7% for correct knowledge of FGM complications management as a proxy for practice among untrained midwives from previous assessments.(11,12) We anticipated a difference of 20% for FGM related knowledge and practice

and 10% for attitude between trained and non-trained arms using 80% for power and 5% alpha error. The sample size generated for these differences ranged between 46 – 71 midwives.

We retrieved registration and training records of midwives in Khartoum State to identify and generate lists of potential trained and non-trained midwives. We used random number generator for sampling. Because of uncertainty about whether records on training status on FGM were complete and up to date, we oversampled by 30% and 100% from the lists of trained and non-trained midwives respectively, so that we could re-classify as needed based on self-reported training status. We then obtained the phone contact details of the selected midwives from the FMoH and Khartoum State Ministry of Health.

#### **Materials and Methods**

We used Kirkpatrick's four level training evaluation model as a framework to assess long-term training effectiveness. The first level "Reaction" focuses on trainees' perceptions. The second level "Learning" evaluates whether the trainings' learning objectives were met. The third level "Behavior" assesses behavioral change while the fourth "Results" evaluates the training impact on the organization, quality, or user of service. For this study, we utilized Kirkpatrick's first three levels since our study included only midwives but not their clients to assess impact.

The primary exposure in the study was any reported previous FGM-related training received by midwives and the training outcome variables for each of Kirkpatrick's levels are listed in Table 1.

Table 1. Training outcome variables to assess training effectiveness among midwives who received or did not receive FGM content during induction and in-service trainings in Khartoum State

Kirkpatricks' Levels	Training Outcome Variables	Measurement scale and standards used
Level 1 "Reaction"	Satisfaction levels	Likert Scale
Level 2 "Learning"	WHO's four FGM types	Per WHO's guidance from the clinical handbook
	Four correct FGM health complications	for care of girls and women living with FGM(13)
Level 3 "Behavior"	Agreement to following statements:	Correct responses aligned to zero tolerance on
	FGM practice continuation	FGM and its medicalisation and WHO's guidance
	FGM medicalisation as a violation of professional code of conduct	on clinical management and role of health workers
	Health workers' influence to change FGM practice	in FGM prevention and care services(3,13–16)
	Health workers to follow social traditions and norms	61
	Health workers do not have the time to provide FGM related services	
	Correct choice for WHO's recommended surgical steps for de-infibulation	
	procedure during labor out of six options	
	Frequency of providing FGM prevention counseling	Likert scale

The study tool had 21 questions which included closed and open-ended questions. The first section had six questions on current demographic data (age, sex, midwifery qualification, midwifery work experience, health facility level) which was used for descriptive data and as potential covariates to be controlled for in the multivariable model.

The second section assessed characteristics of training and satisfaction scale (Kirkpatrick level 1), for midwives who received FGM training. This section had 8 questions on training type (in-service, induction training, other), FGM training year categorized into versions of the training curriculum received (<2016, 2016 – 2018, >2018), training duration (days), training institution (FMoH, non-governmental, other) and satisfaction levels (Likert scale) with respect to knowledge and skills gained for FGM prevention and complications management.

The third section had 7 questions on current knowledge, attitudes, and practices. Open ended questions focused on describing the FGM types and listing four FGM complications they know of. Closed ended attitudinal questions assessed agreement with statements about their stances on FGM, FGM medicalisation, efficacy to change practice, and experiences providing FGM related services (see Table 1).

The co-Principal Investigator (Co-PI), MM, translated the study tool into Arabic that was cross-checked by PI (WA). The co-PI used the Arabic version to develop an online survey administration software (google form survey) with constraints and skip patterns to minimize errors and trained four data collectors with experience in health survey data collection on research ethics and the electronic questionnaire. We used phone interviews because of the high network coverage in Khartoum state. Secondly, midwives are community-based (83%)(5) and own cellphones as a means to be accessed by their clientele who are dispersed in large geographical areas. Thirdly,

because of the nature of their clinical practice we anticipated difficulties for in-person interviews.

Data collectors contacted midwives over the phone, explaining the study's objectives, participation as a voluntary exercise and their rights to refuse or stop interviews at any point before obtaining verbal consent. Upon obtaining verbal consent, data collectors then interviewed and entered electronic data. The data collection period started on October 2022 and ended in January 2023.

#### Data analysis

The PI (WA) and co-PI (MA) reviewed, cleaned, and coded the autogenerated data set from google survey into Microsoft Excel (2018). The open-ended responses on FGM types and complications were coded according to WHO definitions and categories.(3) The data set was then imported into StataCorp. 2021. Stata: Release 17. The scale of missing data was less than 5% and randomly missing that did not require any imputation. We conducted descriptive analysis of study population and the trainings. Student t and Chi square tests were conducted for continuous and categorical variables respectively.

We conducted univariable and multivariable logistic models to examine the association between ever being trained (independent variable) and outcomes on knowledge, attitude, and practices (dependent variables) as primary analysis. For the multivariable models we controlled for age, a characteristic that was significantly different between the two groups and was also related to training exposure, midwifery expertise and training outcomes. Because we conducted multiple testing we used Holm-Sidak corrections for *P*-values. We conducted exploratory analysis to examine associations between training outcomes and training year as a proxy for training curriculum content, as well as number of trainings received.

We obtained ethical approval from the University of Washington Institutional Review Board (STUDY00012584) and Sudan's FMoH National Health Research Ethics Review Committee (P2-3-21). The study was considered as programmatic research not subject to human research protections; nevertheless, we conducted the research following research ethics guidelines including obtaining verbal consent before data collection.

#### **Public Patient Involvement Statement**

This research did not involve patients in the development of research questions and outcomes. It was not appropriate or possible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research as we did not conduct the study at health facility level to retrieve patient records or have access to them. We note this limitation in method and discussion section and recommend their involvement in future studies.

# **RESULTS**

Among the sample of 246 midwives, we interviewed 182 (74%); 74 (30%) were not traceable because of non-valid phone numbers, 5 (2%) were not eligible because they were not midwives, 2 (1%) were dead and 2 (1%) had left Sudan. All the 182 midwives reached agreed to participate and completed phone interviews lasting 10 – 15 minutes.

Most midwives (70%) reported having received an FGM training by the time of data collection (Table 2). All the midwives interviewed were female, most trained as village midwives (92%) and most worked in health centers (89%) (Table 2). The mean age was 51 years (SD=10), and mean years of midwifery experience was 23 years (SD=12). Both study populations had similar demographic and professional characteristics, but the groups differed in mean age. Midwives who did not receive any FGM training were older (M=56 years, standard deviation (SD) = 11) than

those who were trained (M=49 years, SD = 9) and this difference was statistically significant (P= <.001).

Table 2: Characteristics of midwives who received and did not receive trainings on female genital mutilation in Khartoum State, Sudan.

	Total	Not Trained	Trained
	N=182	N=55	N=127
		M (SD)† or n (%)	§
Age (years)	51.3 (10.3)	55.7 (11)	49.3 (9)
Job Title			
Village midwife	168 (92%)	50 (91%)	104 (92%)
Health visitor	7 (4%)	3 (6%)	4 (4%)
Assistant health visitor	6 (3%)	1 (2%)	5 (4%)
Midwifery work experience (years)	23.1 (12.2)	24.5 (13.2)	22.5 (11.7)
Health facility level			
Hospital	2 (1%)	1(2%)	1 (1%)
Health center	161 (89%)	41 (75%)	120 (95%)
Other	19 (10%)	13 (24%)	6 (5%)

<sup>&</sup>lt;sup>†</sup>Mean (standard deviation) § Number (percentage)

The largest group of trained midwives (46%) reported receiving two trainings (Table 3). There were similar proportions of midwives who received each of the three FGM training curriculum versions i.e., prior to 2016, 2016 – 2018 and after 2018 versions. The mean duration of in-service

training was 3 days (SD=1) during 2016 – 2018, 3 days (SD=1) after 2018 and 2 days (SD=1) for trainings prior to 2016. Most of in-service training was conducted by the Ministry of Health (94%) followed by non-governmental organizations (6%).

Table 3: The reported type, year, and number of trainings with female genital mutilation content received by 127 midwives in Khartoum State, Sudan.

FGM training content received	Midwives <i>n</i> (%) §
In-service <2016	72 (48%)
In-service 2016 – 2018*	65 (43%)
Induction 2016 – 2018	27 (21%)
In-service >2018**	79 (53%)
Number of FGM training content received	Midwives n (%) §
One training	46 (25%)
Two trainings	58 (46%)
Three trainings	23 (13%)

<sup>§</sup> Number (percentage)

# FGM training content satisfaction levels (Kirkpatrick Level 1)

<sup>\*</sup>FGM training content version was adapted to World Health Organization's 2016 guidelines on the management of health complications

<sup>\*\*</sup> FGM training content version was adapted to United Nations Population Fund and United Nations Child Fund's manual on social norm change

Generally, the satisfaction levels on the knowledge and skills gained on FGM prevention and care management were high for in-service or midwifery induction trainings. Overall, most of the trained midwives (89 - 100%) reported being either "very satisfied" or "satisfied" on FGM prevention and health complications management knowledge and skills. A higher proportion (12%) of midwives who received midwifery induction trainings (N=26) reported less satisfaction on skills on FGM complications management compared to midwives (5%) who received in-service training (N=64). This finding was affirmed by all midwives (N=24) who received both types of trainings.

# Knowledge of FGM types and health complications (Kirkpatrick Level 2)

Overall, less than a third of all midwives knew four FGM types<sup>1</sup> or four health complications. However, 44% and 80% were able to name more than 2 FGM types and health complications respectively. Of the FGM types named, type 3 and type 1 were the most common. While obstetric and chronic complications were the most reported FGM health complications. FGM related acute, psychological, and sexual complications were the least reported.

The difference in knowledge on FGM types and FGM health complications between midwives who reported receiving FGM training to those who did not, was not statistically significant.

# FGM related attitudes and practices (Kirkpatrick Level 3)

<sup>&</sup>lt;sup>1</sup> WHO definitions for FGM types: Type 1: "Partial or total removal of the clitoral glans and/or prepuce", Type 2: "Partial or total removal of the clitoral glans and the labia minora, with or without excision of the labia majora", Type 3: "Narrowing of the vaginal opening with the creation of a covering seal by cutting and appositioning the labia minora or labia majora with or without excision of the clitoral prepuce and glans (infibulation)", Type 4 "All other harmful procedures for example pricking, piercing, incising, scraping and cauterization"

Most of the midwives who reported ever receiving FGM training (99%) and most of those who did not (96%) were supportive of the abandonment of FGM and its medicalisation. A high proportion of midwives thought that FGM is a harmful practice that needs to stop (99%) and not a religious requirement (95%). They also believed that FGM medicalisation does not make the practice safer (97%) and is a violation of professional code of conduct (71%).

With regards to practice related knowledge, 95% of all midwives reported that they always provided FGM counseling. In contrast, only 11% cited the correct de-infibulation surgical procedure during labor.

We found two statistically significant differences in FGM related attitudes and practice-related knowledge between the two groups. Midwives who received FGM training were more aware that FGM medicalisation violates their professional code of conduct (P = .001) and reported always counseling patients to abandon FGM (P < .001) compared to midwives who did not receive FGM training.

See Table 4 provides detailed findings on training outcomes among midwives who received and did not receive FGM content during induction and in-service trainings in Khartoum State.

Table 4: Training outcomes among midwives who received and did not receive female genital mutilation content during induction and in-service trainings in Khartoum State, Sudan

Kirkpatrick Level	Total	Not Trained	Trained	P value
	N=182	<i>N</i> =55	N=127	
Level 2		n (%)		
Midwives who named:				
4 FGM types	33 (18%)	6 (11%)	27 (21%)	0.11
• >2 FGM types	81 (45%)	20 (37%)	61 (48%)	0.17
4 health complications	50 (27%)	14 (26%)	36 (29%)	0.62
<ul><li>&gt; 2 health complications</li></ul>	144 (80%)	45 (82%)	99 (80%)	0.76
Level 3		901		
Midwives who agreed that:		1	>	
FGM is a harmful practice that should stop	176 (98%)	52 (96%)	124 (99%)	0.17
FGM is a religious requirement	12 (7%)	6 (11%)	6 (5%)	0.11
FGM is a meaningful culture and should continue	8 (4%)	5 (9%)	3 (2%)	0.04

Health workers should follow this social norm	19 (11%)	11 (20%)	8 (6%)	0.005
Health workers who conduct FGM make it safer	12 (7%)	7 (13%)	5 (4%)	0.03
Health workers who perform FGM violate professional code of conduct*	134 (74%)	31 (57%)	103 (82%)	0.001*
Health workers do not have any influence to change this practice	63 (35%)	24 (45%)	39 (31%)	0.06
Health workers have no time to provide prevention and care services	29 (16%)	9 (17%)	20 (16%)	0.91
Self-reported to "always" provide counseling against FGM practice*	174 (96%)	47 (86%)	127 (100%)	<0.0001*
Identified the correct de-infibulation <sup>2</sup> surgical procedure during labor	20 (11%)	8 (15%)	12 (10%)	0.29

<sup>\*</sup>P value for Chi square test was statistically significant using Holm-Sidak Correction

<sup>&</sup>lt;sup>2</sup> De-infibulation as defined by WHO refers to the practice of cutting open the sealed vaginal opening of a woman who has been infibulated to allow intercourse or to facilitate childbirth. Infibulation is a type of FGM where vulval folds are opposed leaving a small opening for urine or menstrual flow.

# Univariable, Multivariable and Exploratory Logistic Model Analysis

The univariable logistic model analysis (Table 5) showed that trained midwives were more likely to be aware that FGM medicalisation was a violation of professional code of conduct (OR: 3.3, 95% Cl: 1.6 – 6.7, P=.001) compared to non-trained midwives. However, after adjustment for age, this association was no longer statistically significant.

Exploratory analysis for training outcomes by reported training type (induction, in-service), training year (<2016, 2016 - 2018 and >2018) and training dose (1 - 3 trainings) showed higher odds ratio in overall knowledge, correct attitude and practice among midwives who reported receiving FGM during in-service training before 2016 (Appendix Table 1). In particular, the knowledge on four correct FGM health complications (aOR 5.1, 95% CI: 1.9 - 13.5, P = .001) and awareness that FGM medicalisation as a violation of professional code of conduct (aOR 15.6, 95% CI: 3.7 - 66.1, P < .0001) was significant after adjustment for age. Similarly, midwives who received one training (aOR 27.0, 95% CI: 3.4 - 211.8, P = .002) or two trainings (aOR 6.2, 95% CI: 2.1 - 18.1, P < .0001) were more likely to be aware that FGM medicalisation as a violation of professional code of conduct. Interestingly, midwives who received FGM content during induction training in 2016 - 2018 (aOR 13.8, 95% CI: 2.1 - 88.6, P = .01) and those who reported FGM training before 2016 (aOR 11.9, 95% CI: 2.0 - 70.5), P = .01) had comparable results on knowledge of four FGM types.

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Table 5. Female genital mutilation related knowledge, attitudes, and practices among trained compared to non-trained midwives in Khartoum State, Sudan.

Kirkpatrick's evaluation model Levels		Crude Estimates <sup>+</sup>			Adjusted Estimates‡		
	OR <sup>¶</sup>	95% CI°	P value	aOR <sup>†</sup>	95% CI°	P value	
Learning Outcomes (Kirkpatrick Level 2)							
Knowledge of four health complications	1.2	0.6 – 2.5	0.62	1.0	0.5 – 2.0	0.92	
Knowledge of four FGM types	2.2	0.8 – 5.6	0.11	3.4	1.2 – 9.9	0.02	
Behavior Outcomes (Kirkpatrick Level 3)							
Believe that health workers should follow FGM as social	0.3	0.1 – 0.7	0.01	0.3	0.1 - 0.9	0.03	
norm							
Aware that performing FGM violates professional code	3.3	1.6 – 6.7	0.001*	2.4	1.1 – 5.1	0.03	
of conduct							
Correct de-infibulation <sup>3</sup> surgical procedure	0.6	0.2-1.6	0.30	0.6	0.2 - 1.7	0.34	

<sup>&</sup>lt;sup>3</sup> De-infibulation as defined by WHO refers to the practice of cutting open the sealed vaginal opening of a woman who has been infibulated to allow intercourse or to facilitate childbirth. Infibulation is a type of FGM where vulval folds are opposed leaving a small opening for urine or menstrual flow.

\*Logistic regression model

¶Odds Ratio †Adjusted Odds Ratio

\*P value was statistically significant using Holm-Sidak Correction



#### DISCUSSION

This exposure-based cross-sectional study found there were no significant long-term differences between trained and non-trained midwives with regards to the levels of knowledge, opposition towards FGM practice and its medicalization and clinical practice in FGM prevention and care during labor. We did not find existing literature on long-term effectiveness for small or large scale FGM trainings to make direct comparisons. The closest comparable study we found, assessed effectiveness after four years elapsed post training, showed no differences in domestic violence knowledge levels between trained educators and non-trained educators.(17)

The long-term effectiveness of large-scale trainings could be affected by the training modality used, by the quality and amount of FGM content received, or by training fidelity. Most midwives reported receiving in-service trainings, a method which has been shown in a systematic review to improve health workers practice in low income settings.(18) Our exploratory analysis compared the effectiveness of different curricula versions which had different content emphasis and suggests gaps in content especially after 2016 but the sample size was too small to impact regression model results and would need further investigation. Moreover, the global low knowledge on practical skills for the de-infibulation procedure among all the midwives in the study indicates training gaps in midwifery schools that would need to be investigated further. The low training effectiveness could also be explained by the absence of supportive mentoring and supervision. Studies have shown that monitoring and evaluation (M&E) is an effective strategy in improving health workers' practice in low income settings.(19,20) A study which assessed Sudan's health programmatic interventions found no FGM related data at facility

level,(6) suggesting limited tracking for M&E and low accountability for health workers on the quality of care and FGM medicalisation.

The finding on midwives reporting re-infibulation as a correct step in clinical management is concerning because re-infibulation increases genital tissue scarification in subsequent deliveries, thus increasing the risks to a wide range of gynecological, obstetric and neonatal health complications. Furthermore, the reported preference for re-infibulation is incongruent with midwives' high knowledge of FGM health complications, with their awareness that FGM medicalisation as a violation of professional code of conduct, and with their reported high frequency of counseling on FGM abandonment. This inconsistency in findings could be explained not only in training gaps but possibly due to deeply ingrained values (21) that are harder to change. The anticipated findings of a current randomized cluster trial testing the effectiveness of a training targeting midwives in FGM prevalent settings using value clarification exercises (22) may shed light on effective training content that changes midwives' value systems and clinical practices.(8) Midwives in our study also reported having low influence in changing FGM practice, a finding similar to a study among trained Somali midwives who were not able to provide interventions because they were apprehensive in going against prevailing culture and religion.(23) Finally, the financial incentive to perform re-infibulation may have outweighed individuals moral compass and professional code of conduct, in the prevailing context of high unemployment rates and low pay if employed. (6,24) Financial incentives have been repeatedly found to be a driver for health workers in performing re-infibulation or involvement in FGM in general.(25-27)

Our study brings in new evidence on the long-term FGM training outcomes among health workers involved in the practice or working in a high FGM prevalent setting. Though our study design was cross-sectional, the use of comparative arms and multivariable analyses strengthened rigor which was noted to be absent from previous pre-post study designs.(7) The retrospective, exposure-based study design was a practical approach to inform policy makers and program managers who require timely data for decision making but may not have the financial budgets to conduct prospective studies.(28) Finally, we used objective questions to assess actual knowledge instead of midwives' perceptions as was done previously (9) to generate non-biased data for decision makers involved in training programs and quality of care.

One of our study limitations was the absence of qualitative data to complement our survey data as well data from midwives' clients to determine the impact of midwives' knowledge, attitudes, and practices on the quality of care received by their clients or their quality of life (Kirkpatrick Level 4). Additional qualitative data from midwives could have strengthened data triangulation and provided contextual depth and additional understanding of the factors affecting the training outcomes, such as translating their opposition towards FGM medicalisation and their current reinfibulation i.e., FGM medicalisation practice. Future evaluations may need to complement Kirkpatrick evaluation model with an ecological framework which recognizes the complex interplay between individual, family, community and societal (29) and the health system factors on midwives' knowledge, attitudes and practices on FGM. Finally, some of the study questions would need further improvements, testing and validation to build on the existent gap on validated comprehensive knowledge, attitude and practice assessment tools for health workers.(30) For instance, midwives' high response rate in providing FGM abandonment

counseling did not align with their belief that health workers have no time to provide FGM prevention services or influence to change FGM practice. Their high response may have been due to social desirability bias to meet the Ministry of Health expectation.

In conclusion, our study findings highlight the need to review all existing FGM training curricula content to assess adequacy in addressing midwives' value systems on FGM and re-infibulation, self-efficacy in changing their clients' stance on re-infibulation, and practical skills in performing de-infibulation and managing FGM health complications. Appropriate evaluation tools will need to be developed and used pre- and post-trainings and during supportive M&E. Finally, the influence of health system and societal factors on midwives' practices should not be ignored in future evaluations to identify modifiable intervention areas that will enable midwives to translate their newly acquired knowledge and skills into practice.

#### **DECLARATIONS**

# **Ethics approval**

The study was approved by the University of Washington Institutional Review Board (STUDY00012584) and Sudan's FMoH National Health Research Ethics Review Committee (P2-3-21). The study was considered as programmatic research not subject to human research protections, nevertheless, we conducted the research following research ethics guidelines. Verbal consent was obtained from all study participants.

# **Competing Interests**

The authors have no conflict of interest.

# **Consent for publication**

Not applicable

# Availability of data and materials

The datasets generated and/or analyzed are available from the corresponding author on reasonable request.

# **Competing interests**

The authors declare no competing interests.

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#### **Authors' contributions**

WA conceptualized the study design, conducted analysis and interpretation and manuscript write up. MA translated study tool into Arabic, designed its electronic format, coordinated, and supervised data collection, cleaned and coded data set as well as reviewed manuscript. CF, SG and NP supervised WA and provided guidance in the whole process from conceptualization to substantive input in manuscript write up. All authors read and approved the final manuscript.

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Appendix Table 1: Exploratory analysis between training outcomes and female genital mutilation training curriculum type and number of trainings received among midwives in Khartoum, Sudan

	4 FGM types	4 correct FGM health	FGM violates health	Correct de-
		complications	professionals code of	infibulation <sup>1</sup> steps in
Training			conduct	labor management
Profile				-
		OR" (95%	CI°) P value	
	Or	aOR <sup>‡†</sup> (95%	CI°) P value	
2016 – 2018 induction	13.8 (2.1 – 88.6) P=0.01	4.0 (0.8 – 19.3) P=0.08	0.2 (0.02 – 2.9) P=0.27	0.7 (0.1 – 7.0) P=0.7
	13.8 (2.1 – 88.6) P=0.01	3.7 (0.8 – 17.7) P=0.10	0.3 (0.03 – 3.0) P=0.32	0.7 (0.1 – 6.9) P=0.7
<2016 in-service	11.9 (2.0 – 70.5) P=0.01	5.0 (1.9 – 13.1)P=0.001*	19.4 (4.7 – 80.6) P<0.0001*	1.7 (0.5 – 5.5) P=0.34
	11.9 (2.0 – 70.5) P=0.01	5.1 (1.9 – 13.5) P=0.001*	15.6 (3.7 – 66.1) P<0.0001*	1.8 (0.6 – 6.0) P=0.31
2016 – 2018 in-service	1.0 (0.2 – 4.0) P=0.97	0.9 (0.3 – 2.2) P=0.76	5.7 (1.1 – 28.6) P=0.04	1.0 (0.3 – 3.3)P=0.94
	1.0 (0.2 – 4.0) P=0.97	0.9 (0.3 – 2.3) P=0.79	4.0 (0.8 – 19.8) P=0.09	1.0 (0.3 – 3.5) P=0.97
>2018 in-service	0.3 (0.1 – 1.2) P=0.09	1.1 (0.5 – 2.6) P=0.75	13.2 (3.8 – 46.6) P<0.0001*	0.2 (0.1 – 0.8) P=0.02
	0.3 (0.1 – 1.2) P=0.09	1.0 (0.4 – 2.4) P=0.95	6.2 (1.6 – 24.2) P=0.01	0.3 (0.1 – 0.9) P=0.04
One training received	0.3 (0.1 – 1.0) P=0.04	0.6 (0.2 – 1.5) P=0.27	37.7 (4.9 – 290.2) P<0.0001*	0.5(0.1 – 2.0) P=0.35
	0.4 (0.1 – 1.4) P=0.13	0.5 (0.2 – 1.3) P=0.15	27.0 (3.4 – 211.8) P=0.002	0.5 (0.1 – 2.1) P=0.37
Two trainings received	0.7 (0.3 – 1.8) P=0.48	1.0 (0.5 – 2.3) P=0.92	7.7 (2.7 – 21.9) P<0.0001*	1.2 (0.4 – 3.5) P=0.72

<sup>&</sup>lt;sup>1</sup> De-infibulation as defined by WHO refers to the practice of cutting open the sealed vaginal opening of a woman who has been infibulated to allow intercourse or to facilitate childbirth. Infibulation is a type of FGM where vulval folds are opposed leaving a small opening for urine or menstrual flow.

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	4 FGM types	4 correct FGM health	FGM violates health	Correct de-			
		complications	professionals code of	infibulation <sup>1</sup> steps in			
Training Profile			conduct	labor management			
	OR <sup>¶</sup> (95% CI°) P value						
	aOR <sup>‡†</sup> (95% CI°) P value						
	0.9 (0.3 – 2.5) P=0.89	1.0 (0.4 – 2.2) P=0.96	6.2 (2.1 – 18.1) P<0.0001*	1.2 (0.4 – 3.7) P=0.69			
hree trainings received	1.2 (0.4 – 3.5) P=0.75	1.1 (0.4 – 3.1) P=0.84	2.7 (0.9 – 7.6) P=0.06	0.3 (0.04 – 2.6) P=0.28			
	1.5 (0.5 – 4.5) P=0.51	1.0 (0.4 – 3.0) P=0.96	2.4 (0.8 – 7.3) P=0.12	0.3 (0.04 – 2.6) P=0.28			

<sup>¶</sup> Odds Ratio

<sup>‡</sup> Logistic regression model adjusted for age

<sup>&</sup>lt;sup>†</sup> Adjusted Odds Ratio

<sup>° 95%</sup> Confidence Interval

<sup>\*</sup> P value is statistically significant using Holm-Sidak Correction

STROBE Statement—Checklist of items that should be included in reports of cross-sectional studies

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or	2
		the abstract	2.4
		(b) Provide in the abstract an informative and balanced summary of what	3-4
		was done and what was found	
Introduction			1
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			•
Study design	4	Present key elements of study design early in the paper	
Setting Setting	5	Describe the setting, locations, and relevant dates, including periods of	8
Setting		recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection	8-9
	O	of participants	0-7
Variables	7	Clearly define all outcomes, exposures, predictors, potential	10-12
variables	,	confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-12
Data gayraag/	8*		11-12
Data sources/	8"	For each variable of interest, give sources of data and details of methods	11-12
measurement		of assessment (measurement). Describe comparability of assessment	
D.		methods if there is more than one group	12
Bias	9	Describe any efforts to address potential sources of bias	13
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If	12-13
		applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	13
		(b) Describe any methods used to examine subgroups and interactions	13
		(c) Explain how missing data were addressed	13
		(d) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(e) Describe any sensitivity analyses	13
D. L		(E) Describe any sensitivity analyses	13
Results	12*	(a) Donard months on a Citation of the standard of the standar	1.4
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers	14
		potentially eligible, examined for eligibility, confirmed eligible, included	
		in the study, completing follow-up, and analysed	1.4
		(b) Give reasons for non-participation at each stage	14
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical,	14-16
		social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of	
		interest	
Outcome data	15*	Report numbers of outcome events or summary measures	16-20
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted	21 –
		estimates and their precision (eg, 95% confidence interval). Make clear	23, 3
		which confounders were adjusted for and why they were included	

		(b) Report category boundaries when continuous variables were	35
		categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute	n/a
		risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions,	21, 35
		and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	24
Limitations	19	Discuss limitations of the study, taking into account sources of potential	26
		bias or imprecision. Discuss both direction and magnitude of any	
		potential bias	
26Interpretation	20	Give a cautious overall interpretation of results considering objectives,	24-27
		limitations, multiplicity of analyses, results from similar studies, and	
		other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	26
Other information			
Funding	22	Give the source of funding and the role of the funders for the present	32-33
		study and, if applicable, for the original study on which the present	
		article is based	

<sup>\*</sup>Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.