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Interventions for improving outcomes for pregnant women who have experienced genital cutting (Review)

Balogun OO, Hirayama F, Wariki WMV, Koyanagi A, Mori R

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TABLE OF CONTENTS

[Intervention Review]

Interventions for improving outcomes for pregnant women who have experienced genital cutting

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ABSTRACT

Background

Female genital cutting (FGC) refers to all procedures that involve the partial or total removal of the external female genitalia, or other injury to the female genital organs for cultural or other non-therapeutic reasons. There are no known medical benefits to FGC, and it can be potentially dangerous for the health and psychological well-being of women and girls who are subjected to the practice resulting in short- and long-term complications. Health problems of significance associated with FGC faced by most women are maternal and neonatal mortality and morbidity, the need for assisted delivery and psychological distress. Under good clinical guidelines for caring for women who have undergone genital cutting, interventions could provide holistic care that is culturally sensitive and non-judgemental to improve outcomes and overall quality of life of women. This review focuses on key interventions carried out to improve outcome and overall quality of life in pregnant women who have undergone FGC.

Objectives

To evaluate the impact of interventions to improve all outcomes in pregnant women or women planning a pregnancy who have undergone genital cutting. The comparison group consisted of those who have undergone FGC but have not received any intervention.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 December 2012) and organisations engaged in projects regarding FGC.

Selection criteria

Randomised controlled trials (RCTs), cluster-randomised trials or quasi-RCTs with reported data comparing intervention outcomes among pregnant women or women planning a pregnancy who have undergone genital cutting compared with those who did not receive any intervention.

Data collection and analysis

We did not identify any RCTs, cluster-randomised trials or quasi-RCTs.

Main results

There are no included studies.

Authors' conclusions

FGC research has focused mainly on observational studies to describe the social and cultural context of the practice, and we found no intervention trials conducted to improve outcomes for pregnant women presenting with complications of FGC. While RCTs will provide the most reliable evidence on the effectiveness of interventions, there remains the issue of what is considered ethically appropriate and the willingness of women to undergo randomisation on an issue that is enmeshed in cultural traditions and beliefs. Consequently, conducting such a study might be difficult.

PLAIN LANGUAGE SUMMARY

Care for pregnant women who have experienced genital cutting

Female genital cutting (FGC) also known as female genital mutilation (FGM) or female circumcision is when some or all of a woman's or girl's external genital organs are cut or damaged for cultural beliefs, or reasons not connected with medical treatments. It is often performed by traditional practitioners such as traditional birth attendants without any form of anaesthesia or analgesia using non-sterile instruments. There are no known medical benefits to FGC, and it can be dangerous for the health and psychological well-being of these women and girls, resulting in both short- and long-term problems. Long-term complications include chronic pelvic infection, formation of cysts, vaginal obstruction and infertility. Some of the greatest health problems associated with FGC and faced by most women arise during pregnancy and when giving birth. In some cases, complications from FGC can result in death.

Care offered to these women may include 1) surgery to widen the vaginal opening (deinfibulation), 2) cutting the perineum during birth to widen the outlet to help the baby to be born (episiotomy), 3) removal of cysts and 4) treatment of infections. Women and their partners may also benefit from counselling to enable them to explore and understand the problems caused by FGC. This may also help them make informed decisions about the care they might receive.

We looked for randomised controlled trials to find out what might work best for women. However, we did not find any studies for inclusion in this review. So, there remains the problem of how best to care for pregnant women and women planning a pregnancy in these circumstances. Trials are urgently needed, although conducting such studies might be difficult. In the meantime, caregivers will do their best to look after these women during pregnancy and childbirth.

BACKGROUND

Worldwide, an estimated 100 to 140 million girls and women have undergone female genital cutting (FGC) and more than three million girls are at risk for FGC each year on the African continent alone (Feldman-Jacobs 2010; WHO 2008). Several other terminologies including female genital mutilation (FGM), female circumcision (FC) (Turner 2007) or female genital surgeries (FGS) have been used to describe this practice (Rahman 2001; WHO 2008), all of which refer to the altering of the external female genitalia (WHO 2008). According to the World Health Organization (WHO) definition, FGC refers to all procedures that involve the partial or total removal of the external female genitalia, or other injury to the female genital organs for cultural or other non-therapeutic reasons (WHO 2008).

Depending on the local customs and circumstances, FGC is usually carried out on girls aged between four and 14 years (UNICEF 2005) but may also be performed on infants, or adult women just prior to marriage, or after the delivery of the first child (Toubia 1994).

It is reported that FGC is primarily practiced in at least 28 countries in Africa (Feldman-Jacobs 2010) and certain countries in Asia (e.g. Indonesia, Malaysia, Pakistan and India) and the Middle East (e.g. Oman, Yemen and the United Arab Emirates) (Elchalal 1997; Feldman-Jacobs 2010). Nevertheless, FGC is increasingly being regarded as a global issue with the influx of refugees and immigrants from practicing communities to Europe (Bosch 2001; Leye 2008), North America (Burstyn 1995), Australia and New Zealand (Utz-Billing 2008). The prevalence of FGC among women of reproductive age can be as high as 88%, as for example in Somalia (Yoder 2008).

The reasons for FGC include a mix of cultural and social factors within practicing families and communities. FGC is often considered a necessary part of raising a girl properly, and a way to prepare her for adulthood and marriage (Althaus 1997; Dirie 1991; Furuta 2008). It is often motivated by beliefs about what is considered proper sexual behaviour, linking the procedure to premarital virginity (Shandall 1967) and marital fidelity (Gruenbaum 2005; Gruenbaum 2006). It is also associated with the cultural ideals of femininity and modesty, and in areas where FGC is a social convention, the pressure to conform to social norm is a strong motivation to perpetuate the practice (Furuta 2008; Gruenbaum 2005). Furthermore, although FGC is not condoned by any major religion, some societies claim that it is a religious requirement (Chalmers 2000; Dirie 1991; Isa 1999), while others believe that genital cutting enhances fertility and child survival (Turner 2007).

FGC is often performed by traditional practitioners such as traditional birth attendants (Al-Hussaini 2003; Asekun-Olarinmoye 2008; Chalmers 2000; Dirie 1991; Morison 2001; Turner 2007), without any form of anaesthesia or analgesia (Al-Hussaini 2003) using non-sterile instruments such as scissors, razor blades or broken glass (Turner 2007). It is always traumatic and is associated with a series of health risks with short- and long-term consequences (Agugua 1982; Banks 2006; Behrendt 2005; Chalmers 2000; Jones 1999; Morison 2001; Toubia 1994) and even death (Morison 2001). There are no medical benefits, and it can be potentially dangerous for the health and psychological well-being of the women and girls who are subjected to the practice (Lax 2000). At the time of cutting, the women usually experience extreme pain, severe bleeding, urinary retention due to difficulty passing urine and infections, mostly due to the use of contaminated instruments (Hakim 2001; Morison 2001). Long-term complications, often associated with the Type III cut (infibulation) include chronic pelvic infection, formation of cysts, vaginal obstruction and infertility (WHO 2001). Major health problems associated with FGC faced by most African women today are maternal and neonatal mortality and morbidity and the need for assisted delivery (Banks 2006). Other consequences include psychological distress (Behrendt 2005; Chibber 2011), domestic violence (Refaat 2001) and although still controversial, the spread of HIV/AIDS due to the frequent use of unclean and non-sterile instruments (Brady 1999; Yount 2007). Recent findings from a large WHO multi-country hospital-based study showed that the deliveries of women who had undergone FGC were significantly more likely to have adverse health outcomes such as necessity for caesarean section, postpartum haemorrhage, extended maternal hospitalisation, infant resuscitation, stillbirth or early neonatal death compared with those without FGC (Banks 2006). The true magnitude of the harmful effects of FGC may have been underestimated in this study as it was a hospital-based study and institutional delivery rate is low in Africa (Banks 2006). Women who deliver at home may be even more vulnerable to serious complications as they are not under the help of experienced doctors and midwives. Additionally, the traumatic experience of FGC, which is usually carried under force, leaves behind a lasting psychological sequel and may adversely affect their mental health (Behrendt 2005; Chibber 2011). Some studies have reported post-traumatic stress disorder, anxiety, depression and memory loss (Behrendt 2005; Elnashar 2007). Furthermore, decreased quality of sexual life due to memories associated with the procedure, damage to the sensitive genital tissues and scar formation have been reported (Behrendt 2005; Elnashar 2007; Thabet 2003).

Description of the condition

FGC refers to all procedures that involve the partial or total removal of the external female genitalia, or other injury to the female genital organs for cultural or other non-therapeutic reasons (WHO 2008). FGC varies from simple removal of the clitoris and prepuce to more complicated procedures such as infibulations that involve the narrowing of the vaginal orifice with the creation of a covering seal by cutting and appositioning of the labia minora or the labia majora, or both (WHO 2008).

Based on the recent WHO classification (WHO 2008), there are four different forms of FGC depending on the type and degree of cutting.

- Type I: clitoridectomy which involves the partial or total removal of the clitoris and/or the surrounding tissues.
- Type II: excision which is the partial or total removal of the clitoris and the labia minora, with or without excision of the labia majora.
- Type III: infibulation involving the narrowing of the vaginal opening with the creation of a covering seal by cutting and appositioning the labia minora and/or the labia majora, with or without excision of the clitoris.
- Type IV: describes all other harmful procedures to the female genitalia for non-medical purposes, e.g. pricking, piercing, incising, scraping and cauterisation.

Recent estimates based on current prevalence data indicate that 91.5 million women and girls above 10 years old in Africa are currently living with the consequences of FGC (Yoder 2008).

Description of the intervention

Interventions to improve outcome in circumcised pregnant women include deinfibulation (McCafrey 1995; Nour 2006; Penna 2002; Rouzi 2001; WHO 2001) or episiotomy (Widmark 2010), surgical removal of cysts (Penna 2002; Thabet 2003; WHO 2001), and treatment of infections (WHO 2001) as well as counselling by trained healthcare providers or psychologists for women and their partners during antenatal care on the need for deinfibulation and to dissuade them from undergoing reinfibulation after childbirth (Knight 1999; McCafrey 1995; Rouzi 2001; Rushwan 2000; WHO 2001).

How the intervention might work

Under good clinical guidelines for caring for pregnant women who have undergone genital cutting, interventions would provide holistic care that is culturally sensitive and non-judgemental to improve pregnancy outcomes and the overall quality of life of women. Interventions may help by decreasing the risk of perineal laceration (Nour 2006), reducing the risk of maternal and neonatal mortality and morbidity, improving satisfaction with appearance and sexual function (Nour 2006; Thabet 2003) and treatment of post-traumatic stress disorders.

Why it is important to do this review

Although some reviews have examined the impact of various interventions designed to reduce the prevalence of FGC (Denison 2009; Muteshi 2005), none has been carried out to assess the effectiveness of interventions to improve the outcome in women who have undergone FGC. In this review, we planned to summarise data relating to the key interventions carried out to improve outcome and overall quality of life in pregnant women who have undergone FGC.

OBJECTIVES

To critically assess the impact of interventions to improve all outcomes in pregnant women or women planning a pregnancy who have undergone genital cutting. The comparison group consisted of those who have undergone female genital cutting but who have not received any intervention.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCT), cluster-randomised trials or quasi-RCTs.

Types of participants

All pregnant women or women planning pregnancy who experienced genital cutting and who have been identified or examined by a healthcare professional.

Types of interventions

We considered for inclusion studies with all intervention types including, but not limited to:

- deinfibulation;
- management of obstetric and gynaecological complications;
- treatment of infections;
- psychological or counselling and health education.

Types of outcome measures

Primary outcomes

Mother

- Incidence of psychological disorders and/or mental health status measured by validated scales
- Incidences of urinary/faecal problems

Baby

- Perinatal/neonatal mortality

Secondary outcomes

- Mode of birth (caesarean section, operative vaginal birth, normal vaginal birth)
- Incidence of episiotomy
- Incidence of any surgical perineal procedures
- Incidence of third and fourth degree perineal lacerations at birth
- Incidence of postpartum haemorrhage
- Incidence of urinary tract infections
- Incidence of perineal infections
- Incidence of reproductive tract or sexually transmitted infections
- Lesions, scars, cysts and other anatomical damage
- Genital pain
- Infertility
- Women's quality of life measured by validated scales
- Need for neonatal resuscitation (infants)
- Apgar score at five minutes (infants)
- Need for admission to neonatal unit (infants)

Search methods for identification of studies

Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (31 December 2012).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. handsearches of 30 journals and the proceedings of major conferences;

5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

We did not apply any language restrictions.

Searching other resources

Reports produced by all levels of government, non-governmental organisations and academics, demographic and health surveys, databases of international organisations engaged in projects regarding FGC such as World Health Organisation (WHO), The United Nations Children's Fund (UNICEF), Population Reference Bureau (PRB), Center for Development and Population Activities (CEDPA).

Data collection and analysis

There are no included studies in this review. Data collection and analysis methods to be used in future updates of this review are provided in Appendix 1.

RESULTS

Description of studies

There were no randomised controlled trials (RCTs), cluster-randomised trials or quasi-RCTs identified from the search strategy.

Results of the search

The search retrieved no trial reports.

Risk of bias in included studies

Not applicable.

Effects of interventions

Not applicable.

DISCUSSION

There were no randomised controlled trials (RCTs), cluster-randomised trials or quasi-RCTs identified that compared intervention outcomes for pregnant women or women planning a pregnancy who have experienced genital cutting with those who have not received any intervention. Most female genital cutting (FGC) research to date has looked at issues regarding prevalence, context in which the practice is carried out and the short- and long-term medical consequences in women and their infants. The majority of this research is usually through questionnaire surveys, qualitative research, and anthropological studies (Population Council 2002). In the case of intervention research to improve outcomes for women with genital cutting, medical case histories and case studies have been the norm. We identified one study in which participants were randomly assigned to FGC intervention (Thabet 2003), however, this study did not meet the eligibility criteria for this review. To evaluate the effectiveness of interventions requires a study design that follows the principle of experimentation. However, an important aspect of FGC intervention research that should be given proper consideration are the ethical principles underlying the way the study is designed and the data collected. In this review, this requirement precluded the inclusion of any trial from the onset.

AUTHORS' CONCLUSIONS

Implications for practice

Although female genital cutting (FGC) research has focused mainly on observational studies to describe the social and cultural context of the practice, a few well-designed studies have described the gynaecological and obstetric sequelae of genital cutting including chronic pelvic infection, formation of cysts, virginal obstruction and infertility, maternal and neonatal mortality and morbidity during pregnancy and the need for assisted delivery. Interventions for improving pregnancy outcomes for women presenting with complications of FGC such as deinfibulation, treatment of infections and the management of obstetric and gynaecological consequences are usually delivered as cases. Therefore, most interventions are case-specific and results and conclusions drawn from those cases must be interpreted within the context and limitation of each case.

Implications for research

The unavailability of randomised controlled trials (RCTs), cluster-randomised trials or quasi-RCTs on interventions to improve outcomes from genital cutting among pregnant women or women planning a pregnancy raises the question of the appropriateness of conducting research within this context. Randomised controlled trials provide the most reliable evidence on the effectiveness of interventions, and it may be possible to conduct an RCT, depending on the topic and research question addressed. However, clinicians and researchers may consider the possibility of valid difficulties in conducting RCTs for some forms of complications resulting from FGC. Furthermore, the willingness of women to undergo randomisation on an issue that is enmeshed in cultural traditions and beliefs, which could also be potentially life-threatening when first encountered by medical practitioners, calls to question the acceptability of this research method, depending on the severity of the case. Alternatively, a cluster-RCT of a policy on clinical management of women with genital cutting might provide information on the success of clinical care for women who have experienced this practice.

ACKNOWLEDGEMENTS

As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referees who are external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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APPENDICES

Appendix 1. Methods of Data collection and analysis to be used in future updates of this review

Data collection and analysis

Selection of studies

At least two review authors will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion. If agreement cannot be reached, we would consult a third party.

Data extraction and management

We will design a form to extract data. For eligible studies, at least two review authors will extract the data using the agreed form. We will resolve discrepancies through discussion. We will enter data into Review Manager software (RevMan 2011) and check for accuracy. When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions (* Higgins 2011 *).* We will resolve any disagreement by discussion or by involving a third assessor.

(1) Sequence generation (checking for possible selection bias)

We will describe for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. We will assess the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator),
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number),
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We will describe for each included study the method used to conceal the allocation sequence and determine whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We will assess the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We will describe for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We will consider that studies are at low risk of bias if they were blinded, or if we judge that the lack of blinding would be unlikely to affect results. We will assess blinding separately for different outcomes or classes of outcomes.

We will assess the methods as:

- low, high or unclear risk of bias for participants;

- low, high or unclear risk of bias for personnel;

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We will describe for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We will assess blinding separately for different outcomes or classes of outcomes.

We will assess methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

We will describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We will state whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or can be supplied by the trial authors, we will re-include missing data in the analyses which we undertake. We will assess methods as:

- low risk of bias (e.g. less than 20% missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias

(5) Selective reporting bias

We will describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We will assess the methods as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other sources of bias

We will describe for each included study any important concerns we have about other possible sources of bias. We will assess whether each study was free of other problems that could put it at risk of bias by stating:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We will make explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). With reference to (1) to (6) above, we will assess the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We will explore the impact of the level of bias through undertaking sensitivity analyses.

Measures of treatment effect

Dichotomous data

For dichotomous data, we will present results as summary risk ratio with 95% confidence intervals.

Continuous data

For continuous data, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Unit of analysis will be individual women. We will consider cluster-randomised trials if they are identified.

Cluster-randomised trials

We will include cluster-randomised trials in the analyses along with individually-randomised trials. We will adjust their sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions Section 16.3.4* (Higgins 2011) using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Dealing with missing data

For included studies, we will note levels of attrition. We will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we will carry out analyses, as far as possible, on an intention-to-treat basis, i.e. we will attempt to include all participants randomised to each group in the analyses, and all participants will be analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We will assess statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics. We will regard heterogeneity as substantial if the I^2 is greater than 30% and either the T^2 is greater than zero, or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

If there are 10 or more studies in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually, and use formal tests for funnel plot asymmetry. For continuous outcomes, we will use the test proposed by Egger 1997, and for dichotomous outcomes, we will use the test proposed by Harbord 2006. If asymmetry is detected in any of these tests or is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We will carry out statistical analysis using the Review Manager software (RevMan 2011). We will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect: i.e. where trials are examining the same intervention, and the trials' populations and methods are judged sufficiently similar. If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials is considered clinically meaningful. The random-effects summary will be treated as the average range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials.

If we use random-effects analyses, the results will be presented as the average treatment effect with its 95% confidence interval, and the estimates of T^2 and I^2.

Subgroup analysis and investigation of heterogeneity

If we identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.

We plan to carry out the following subgroup analyses.

- Type I and type II genital cutting.
- Type II and type III genital cutting.
- Type I and type III genital cutting.

The following outcomes will be used in subgroup analysis.

- The need for perineal surgery at birth.
- Incidence of perineal lacerations at birth.
- Psychological disorders.

For fixed-effect inverse variance meta-analyses, we will assess differences between subgroups by interaction tests. For random-effects and fixed-effect meta-analyses using methods other than inverse variance, we will assess differences between subgroups by inspection of

the subgroups' confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

CONTRIBUTIONS OF AUTHORS

Olukunmi Balogun with contribution from Ai Koyanagi wrote the first draft of the protocol. Fumi Hirayama, Ai Koyanag, Windy MV Wariki and Rintaro Mori commented on the draft. Windy MV Wariki and Rintaro Mori provided editorial assistance.

Fumi Hirayama worked with Olukunmi Balogun to produce the second draft of the protocol.

All review authors were involved in subsequent modifications and writing of the full review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- The University of Tokyo, Japan.

External sources

- Ministry of Health, Labour and Welfare, Japan.

INDEX TERMS

Medical Subject Headings (MeSH)

*Pregnancy Outcome; Circumcision, Female [adverse effects] [*rehabilitation]

MeSH check words

Female; Humans; Pregnancy