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[Intervention Protocol]

Male versus female condoms for contraception

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The main objective of this review is to compare the female condom to the male condom as a method of contraception.

BACKGROUND

In response to rapidly growing populations, governments aim to achieve a balance between the number of individuals and available resources. Ensuring access to and adequate use of effective contraceptive methods (Rabe 1999) slows down population growth. Access to safe abortion and delivery is also essential in controlling population growth and improving reproductive health. About 208 million women become pregnant each year worldwide, 123 million(59%) of which are intended pregnancies leading to a live birth, a miscarriage or a stillbirth and 85 million(41%) of which are unintended pregnancies (WHO 2012c). About 41 million of these unintended pregnancies end in induced abortions and almost an equal proportion end in delivery (Ahmed 2012).

India was the first country to establish a national family-planning program in 1952 (Rabe 1999), and several other countries followed this example shortly afterwards. Low educational levels, political, religious and socio-cultural factors limit the spread of contraceptive methods and lead to uncontrolled population growth (Rabe 1999). An example of political measures to control births is China, where the number of children a couple is allowed to have is restricted and India where emphasis is laid on specific family planning methods like sterilisation (Filshie 1991). However, a contraceptive method must be available before any decisions regarding it's use by the public are considered.

With the advent of the Human Immuno-Defficiency Virus (HIV) pandemic, the role of condoms became critical in the control of its spread. It is estimated that there were 3.1 million new HIV infections in 1999 and 2.6 million new HIV infections in 2009 (UNAIDS 2010). A systematic review found that consistent condom use is effective in reducing sexual transmission of HIV (Weller 2012). Only male and female condoms provide dual protection by reducing the risk of HIV transmission and preventing unintended pregnancies (Ahmed 2012). Condoms are therefore essential not only as a contraceptive method, but also as a means of reducing the risk of HIV transmission.

Description of the condition

Each year, about 22 million unsafe abortions take place leading to an estimated 47 000 pregnancy-related deaths and an additional 5 million women who suffer disability as a result of complications due to unsafe abortion (WHO 2012c). Adequate family planning services are necessary in order to reduce the number of unwanted pregnancies and hence, the number of induced abortions. Despite availability of several contraceptive methods, several factors influence the choice of contraceptive use. Recently, the role of emotions in decision making when it comes choice of condom use has been shown to be significant (Gutnik 2006). Religious and/or cultural issues also influence the acceptability of various contraceptive methods depending on their advantages and disadvantages (Rabe 1999).

Several factors influence the success of any program on contraception and the acceptability of each method is a key issue. Some factors that affect acceptability of a contraceptive method include(Deniaud 1997):

-The method; the visual aspect of the device, its tolerance and efficacy,

-The way the method is distributed; cost and accessibility of the method.

-The users; personal motivations, perception of STI risk, previous use of device, religious and moral considerations.

-The users' partner; his/her motivations and co-operation.

-The context; both socio-economic context and type of personal relationship that exists between the partners in the couple.

Description of the intervention

Condoms belong to the group of male and female barrier contraceptives methods (Filshie 1991), and they are the oldest known method among these (Rabe 1999). The earliest publication that describes condoms was in 1564 and they have been used as far back as the Roman times for preventing STIs (Filshie 1991). There are two types; the male and the female condom and both consist of a sheath that is open at one end and closed at the other. The male and female condom have different designs, adapted to the anatomy of the male and female reproductive organs respectively. The FC requires an anchor outside the vagina to prevent invagination, which is usually a ring or frame, and a mechanism for inserting the device and stabilizing it once fitted (Beksinska 2011). Several types of materials can be used for making condoms like natural latex, polyurethenes and synthetic rubbers (WHO 2012b). There are a number of adverse effects associated with condom use like condom-associated erection problems (either during application or during intercourse while using a condom) and problems with the 'fit' or 'feel' of condoms, including problems related to the size and shape of the condom, or discomfort or interference with sensation (Sanders 2012).

How the intervention might work

Condoms serve as a mechanical barrier during sexual intercourse, that prevent semen from getting into the vagina (Filshie 1991). They are worn by the male or female partner, prior to the sexual encounter and must be removed and disposed of correctly in order to carry out their desired function. Assessment of the protective properties of condoms must consider their effectiveness, which is their performance under real conditions, and their efficacy, which is their performance under ideal conditions (Haddad 2012). Condoms can be used along with another contraceptive method. The double Dutch method is when condoms are used together with oral contraceptive pills and in this case, they provide increased protection against unwanted pregnancies (Bromham 1995).

The two main types of male condom failure are breakage and slippage (Steiner 1994). Female condom failure is defined as a condom for which a non clinical breakage, a clinical breakage or a slippage occurs or is associated with misdirection or invagination or any additional identified failure mode. Nonclinical breakage is defined as breakage noticed before intercourse or occurring after withdrawal of the condom from the vagina. Nonclinical breakage is breakage without potential adverse clinical consequences. Clinical breakage is defined as breakage during intercourse or withdrawal of the FC from the vagina. Clinical breakage is breakage with potential adverse clinical consequences. Clinical breakage includes events in which the outer frame or ring breaks. Total breakage is defined as breakage at any time before, during or after intercourse. It includes clinical breakage and non clinical breakage. Slippage is defined as an FC that slips completely out of the vagina during intercourse. Misdirection is defined as vaginal penetration whereby the penis is inserted between the FC and the vaginal wall. Invagination is defined as part or the entire external component of the FC being pushed into the vagina during intercourse. Total Clinical Failure is defined as the number of FCs that clinically break or slip, or are associated with misdirection or invagination during intercourse or any additional failure mode(s) identified in the risk assessment (Beksinska 2007).Condom failure can be affected by a number of factors including condom age and storage conditions, penis size, condom fit, use of lubricants, user experience with the condom type and intensity of coital activity (Haddad 2012). However, the frequency of occurrence of female condom failures reduces with user experience (Beksinska 2012).

Why it is important to do this review

The World Health Organisation (WHO) defined a medium-term strategic plan from 2008-2013 defining the strategic direction to be taken by member states in order to attain a set of health goals and provide a monitoring and assessment framework to measure progress over time. The WHO's second strategic objective is to combat HIV/AIDS, tuberculosis and malaria (WHO 2012a). The strategic objectives number four and six involve improving re-

productive health and reducing unsafe sex respectively (WHO 2012a). Condoms are key components in improving sexual and reproductive health and they ensure safer sex for their users. Female condoms have been available to the public since the early 1990s (WHO 2012b, Beksinska 2011) and are now widely used as an effective method of contraception. A study carried out among female sex workers found that female condoms gave them more power and also increased their ability to control their sexual and reproductive health (Mathenjwa 2012). It is therefore important to find out if the female condom is comparable to the male condom as a method of contraception.

OBJECTIVES

The main objective of this review is to compare the female condom to the male condom as a method of contraception.

METHODS

Criteria for considering studies for this review

Types of studies

Condoms can be used for various periods of time, implying that users have to be followed up for long periods in order to assess long term effectiveness and side-effects. We intend to include only randomised controlled trials in this review bearing in mind that follow-up time of participants may not allow for evaluation of long term benefits and side-effects.

Types of participants

It is possible for a man or woman to have multiple sexual partners. In this case, condoms can be used for preventing unwanted pregnancies and for preventing STIs. A relationship in which the man or woman has multiple sexual partners introduces several factors that affect assessment of the effectiveness of the condom due to individual variations in anatomy and sexual preferences or practices.
We will focus on data from the female partner and include data on the male partner if adequate information is available. Our participants will be healthy women of reproductive age who engage only in heterosexual vaginal intercourse and who are in a monogamous relationship.

Types of interventions

We will compare use of the female condom to the male condom as a contraceptive method.
Condoms are used by a couple during sexual intercourse. The fact that the man wears the MC and the woman, the FC, represents a difference in the manner in which the two interventions function. Effectiveness of each type of condom is therefore influenced by each individual partner in the couple. However, since both MC and FC carry out their contraceptive function during intercourse by protecting the woman from semen exposure, we can consider them comparable as two interchangeable devices for contraception.

Types of outcome measures

Primary outcomes

The primary outcomes will be:
- Incidence of pregnancy.
- Incidence of condom failure. Participant-reported condom failure can be used in estimating the incidence of condom failure. It is also possible to test the condom for mechanical failure using laboratory tests. Recently, testing for prostate-specific antigen (PSA) which is a bio-marker of semen exposure has been shown to be a more objective measure of condom failure (Mauck 2007). We will therefore include participant-reported and objective measures of assessment of condom failure in this review.

Secondary outcomes

We will report the following outcomes in both the male and female partners:
- adverse events related to condom use. This includes allergic reactions to the lubricant gel found in condoms or to the material used to manufacture the condoms.
- measures of acceptability, for example, condom-associated erection problems and problems with fit and feel of the condom.
- incidence of STIs and HIV infection. This refers to any sexually transmitted infection and HIV transmission reported by the authors.

Search methods for identification of studies

Electronic searches

We will contact the trial search coordinator for the Fertility Regulation Group in order to elaborate a comprehensive search strategy. We will search the following databases: MEDLINE, EMBASE, POPLINE, LILACS and CENTRAL (the Cochrane central register of controlled trials).

Searching other resources

We will perform a search of the Family Health International Library (FHI 360) for all relevant trials, books and review articles. FHI 360 is a nonprofit human development organization that participates in research concerning various health issues including contraception.

We will review the reference lists and contact authors of all identified studies for trials that could potentially be included in the review. We will contact pharmaceutical companies that manufacture condoms and request for trials carried out on male and female condoms. We will contact experts in the field in order to find out about possible unpublished trials. We will search conference proceedings of major conferences on gynaecology and reproductive health.

We will not apply any language restriction and the search will be carried out in order to identify published and unpublished studies.

Data collection and analysis

Selection of studies

Two review authors (NVM and CO) will independently assess identified studies for inclusion. We will resolve any disagreement through discussion and if required, we will consult the third author for a final decision.

Data extraction and management

We will design and test a data extraction form. For each included study, the first two authors will extract the data independently using the agreed form. We will then compare our forms and if we do not agree on any aspect, we will discuss it and consult the third author in order to find a consensus. We will enter data into Revman 5.1.2 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 and by consulting the third author.

(1) Random 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); or
- unclear risk of bias.

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

We will describe for each included study the method used to conceal allocation to interventions prior to assignment and will assess 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. This is particularly relevant in this review because, due to differences in presentation and use of the MCC and the FC, it is not possible to blind the participants with respect to the interventions. The lack of blinding may influence participant reported outcomes but is not likely to affect objective outcomes like pregnancy or biomarker testing for semen exposure.

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 due to the amount, nature and handling of incomplete outcome data)

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 and 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. no 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. We will consider studies with more that 20% missing data as high risk of bias);
- unclear risk of bias.

(5) Selective reporting (checking for 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 bias (checking for bias due to problems not covered by (1) to (5) above)

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:

- 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* (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 by undertaking sensitivity analyses - *see* Sensitivity analysis.

Assessment of Quality of Evidence Across Studies

We will assess the quality of evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Guyatt 2008). We will dene the quality of evidence for each outcome as the extent to which one can be condent that an estimate of effect or association is close to the quantity of specic interest (Higgins 2011). The quality rating across studies has four levels: high, moderate, low or very low. Randomised controlled trials are categorised as high quality but can be downgraded; similarly, other types of controlled trials and observational studies are categorised as low quality but can be upgraded. Factors that decrease the quality of evidence include limitations in design, indirectness of evidence, unexplained heterogeneity or inconsistency of results, imprecision of results, or high probability of publication bias. Factors that can increase the quality level of a body of evidence include having a large magnitude of effect, whether plausible confounding would reduce a demonstrated effect, and if there is a dose-response gradient.

Measures of treatment effect

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

For continuous outcomes, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference when combining trials that measure the same outcome using different methods.

Unit of analysis issues

Culster-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 *Handbook* using an estimate of the intra cluster 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 I^2 is greater than 30% and either 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 (Egger 1997), and for dichotomous outcomes we will use the test proposed by Harbord (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 Revman 5.1.2 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 95% confidence intervals, and the estimates of T^2 and I^2.

Subgroup analysis and investigation of heterogeneity

We intend to carry out the following subgroup analysis.

1) Exclusive male or female condom use versus male or female condom use in association with another contraceptive method.

2) Male condom only or female condom only versus male and female condom used concomitantly.

3) Various types of female condoms.

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 use random-effects analysis to produce it.

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.

Sensitivity analysis

Sensitivity analysis will be carried out to explore the effect of trial quality, including studies assessed as having adequate controls in place for the prevention of potential bias.

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* *Indicates the major publication for the study*

CONTRIBUTIONS OF AUTHORS

Nkengafac Motaze developed the topic and wrote the initial protocol. Charles Okwundu andTemfack Elvis read through the drafts, Mboudou Emile provided input as the content expert and all authors approved the final copy which was submitted to the review group.

DECLARATIONS OF INTEREST

None known