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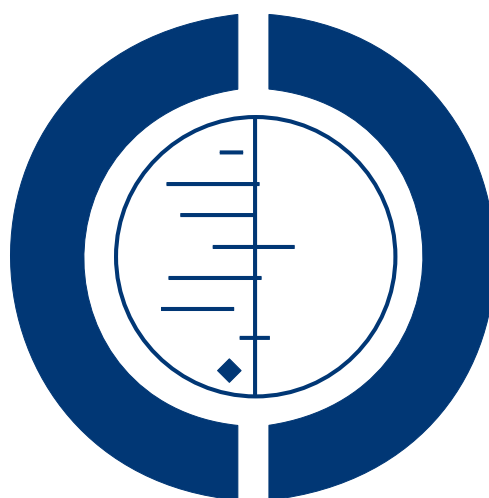
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Mobile phone-based interventions for improving contraception use (Protocol)

Smith C, Gold J, Ngo TD, Sumpter C, Free C



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[Intervention Protocol]

Mobile phone-based interventions for improving contraception use

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ABSTRACT

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

To determine whether interventions delivered by mobile phone can improve contraception use

BACKGROUND

The rapid expansion in use of mobile phones in recent years has had a dramatic impact on interpersonal communication. Within the health domain, phone calls, text messages and smartphone applications offer new means of communication between service providers and clients. This review focuses on interventions delivered by mobile phone to improve contraception use.

Description of the condition

Contraception - methods or devices to prevent pregnancy - has significant benefits for women's and child health. The use of contraception prevents unintended pregnancies, reduces the number of abortions and maternal deaths, and can improve perinatal outcomes and child survival by widening the interval between successive pregnancies (Cleland 2012). There are also substantial social and economic benefits of contraception such as improved educa-

tional and employment opportunities for women leading to increasing family savings and economic growth (Singh 2009).

Despite these benefits, there is significant unmet need for contraception. Unmet need refers to women not using a modern contraceptive method despite not wanting to have a child in the next two years, or have no more children. An estimated 222 million women of childbearing age in 2012 had unmet need for contraception (Singh 2012). Unmet need for contraception can be due to non-uptake or non-adherence to contraception. The most common reasons for non-use are health concerns, including fear and experience of side effects. (Ali 2010; Bradley 2009; Westoff 2012). If unmet need for modern methods of contraception were met amongst women in developing countries, this would prevent an additional 54 million unintended pregnancies, 26 million abortions (of which half would be unsafe), 79,000 maternal deaths and 1.1 million infant deaths (Singh 2012).

Description of the intervention

In the last decade there has been a rapid expansion in the delivery of health care interventions via mobile phone (Mechael 2010). Interventions delivered by mobile phone have been designed to improve health outcomes for individual clients for acute and chronic disease management and for health promotion. These include interventions designed to improve medication adherence, appointment attendance or promote behaviour change (Free 2013a; Free 2013b; Whittaker 2009). Interventions delivered by mobile phone have also provided a novel means for delivering patient tests (Bastawrous 2012).

Interventions can utilise different functions of mobile phones for example, text message, voice message, video and application. They may involve one-direction or two-way (interactive) communication (Free 2010; Kallander 2013). Interventions could employ single functions or combined functions of mobile phones such as interactive text message based support, or voice messaging combined with telephone counselling. Interventions delivered by mobile phone to improve contraception use could be delivered as an adjunct or alternative to face-to-face services. Interventions could aim to increase uptake of contraception amongst non-users. Interventions for existing contraceptive users could aim to increase adherence to contraception, reduce discontinuation of contraceptives and/or encourage swapping contraceptives rather than stopping contraceptives if side effects are experienced.

How the intervention might work

Interventions delivered by mobile phone have potential advantages over face-to-face healthcare delivery as support can be delivered wherever the person is located, and whenever it is needed (Rodgers 2005). Such interventions could be popular with youth populations who are regular mobile phone users (Whittaker 2009). Furthermore, these interventions have the potential to reach rural populations, where geographical distances can restrict access to services (Car 2012).

Intervention content could include information, pill or appointment reminders and/or content designed to increase or maintain motivation to use contraception. Behaviour change techniques used in face-to-face interventions can be modified for delivery by mobile phone (Free 2013a). Interventions could utilise a range of behaviour change techniques, such as encouraging women to make a clear plan about when, where and how they will use contraception (goal setting) (Abraham 2008). Multi-faceted interventions that address a wide range of barriers to contraception use could be more effective than those targeting single barriers to use. Existing adherence research suggests that multifaceted interventions can be effective but uni-faceted interventions have at best modest benefits (Haynes 2008). Similarly, there is no evidence that medication reminders delivered by mobile phone have benefits (pooled risk ratio 1.00, 95% confidence interval 0.77-1.30)

(Free 2013a), whilst trials of more complex interventions to increase adherence to antiretroviral medication report benefits (Free 2013a; Lester 2010).

There are several potential risks of using mobile phones to improve contraception use. Road traffic accidents are the only adverse health effect of cell phone use for which there is evidence (Rothman 2000). However, in the often sensitive context of contraception, there is potential for physical or psychological adverse effects that could arise as a result of other people accessing intervention content when mobile phones are shared. A further risk relates to the opportunity cost of investing substantial resources in developing a technologically focused intervention with most likely a moderate impact instead of investing in alternative approaches. Additional challenges relating to the implementation of interventions delivered by mobile phone include reduced literacy of target populations, incomplete network coverage, phone number switching, and the risk of incomplete data input and this inaccurate data being acted upon (Bullen 2013; Upadhyay 2009).

Why it is important to do this review

Interventions delivered by mobile phone have been demonstrated to be effective in other areas such as smoking cessation (Free 2011; Horvath 2012; Whittaker 2009). Where interventions delivered by mobile phone have been shown to be effective they have also been shown to be highly cost effective (Guerrero 2013). However, there is more limited evidence related to interventions delivered by mobile phone for contraception.

In recent years there has been growing interest in interventions delivered by mobile phone, reflected in a number of mobile phone-based contraception initiatives that have been launched, and in some cases scaled up, for example, Mobile Technology for Improved Family Planning (MOTIF), mAssist, Mobile for Reproductive Health (m4RH), CycleTel, Mobile Alliance for Maternal Action (MAMA); each with different approaches to the intervention and evaluation (Constant 2010; CycleTel 2011; L'engle 2013; MAMA 2013; Smith 2013). Although these initiatives look promising, to date, the effect of interventions delivered by mobile phone on contraception have not been reliably established. Therefore a review of interventions delivered by mobile phone for contraception is timely.

OBJECTIVES

To determine whether interventions delivered by mobile phone can improve contraception use

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs).

Types of participants

Eligible participants will be men or women of reproductive age who are users or potential users of contraceptive methods. We will include studies in all settings, i.e. primary care settings, outpatient settings, community settings and hospital settings. We will not exclude studies according to the type of healthcare provider (e.g. doctor, nurse, allied staff).

Types of interventions

We will include studies which examine any type of client-provider intervention delivered by mobile phone designed to improve use of contraception compared to standard delivery of care or another intervention. We will include interventions directed at both users and non-users of contraception. We will include interventions designed to:

- Improve uptake of contraception (including post-abortion and post-partum contraception)
- Promote specific methods of contraception
- Improve adherence to contraception e.g. interventions to support clients' experiencing side-effects, reduce discontinuation, safe method switching, pill or appointment reminders

We will include any intervention aimed at mobile phone users delivered by mobile phone, for example, text message, voice message and applications. We will exclude trials where mobile phones were used for two-way voice communication (as a phone) alone. Web-based interventions can be accessed on mobile phones as well as other platforms, but in practice can be difficult to access via mobile phone unless they are adapted for mobile phone use. We will exclude web-based interventions unless the paper states they have been intended for or adapted for mobile phone users. We will exclude trials that only focus on preventing sexually transmitted diseases rather than contraception.

Types of outcome measures

Contraceptive methods can be classified in different ways. Contraception can be classed as either modern (e.g. condom, oral contraceptive pills, injectables, intra-uterine device, implant, emergency contraception) or traditional (e.g. rhythm/periodic abstinence or withdrawal) (Westoff 2012; WHO 2013). Furthermore, distinctions can be made between hormonal or non-hormonal methods, and short and long-acting or permanent methods. The World Health Organization classifies methods according to effectiveness,

according to estimated rates of unintended pregnancies per 100 women per year (WHO 2011). For this review we define effective modern methods as those associated with <10% 12-month pregnancy rates, as commonly used: oral contraceptive, injectable, implant, intra-uterine device, or permanent methods.

We will include studies which include any form of contraceptive use. We will include studies assessing a range of outcome measures related to contraceptive use including uptake of contraception, selection of a specific method, measures of adherence (including discontinuation and safe-switching), pregnancy or abortion.

Both sustained and point prevalence measures will be considered. Both subjective (self-reported) and objective (e.g. biochemically verified, use of electronic medication monitors, clinical examination) assessment of contraception use will be considered.

Primary outcomes

- Uptake of contraception (including post-abortion and post-partum contraception)
- Uptake of a specific method of contraception (e.g. a long-acting method)
- Adherence to contraceptive method (e.g. number of missed pills, attendance for repeat injection)
- Safe-method switching (e.g. from one effective method to another with no gap)
- Discontinuation of contraception
- Pregnancy or abortion (objectively measured or self-reported)

Secondary outcomes

- Road traffic accidents - the only adverse health effect of cell phone use for which there is evidence (Rothman 2000).
- Any physical or psychological effect reported

Search methods for identification of studies

Electronic searches

We will search the following electronic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL)
- MEDLINE using OVID
- EMBASE using OVID
- Global Health using OVID
- Psyc INFO using OVID

- POPLINE
- Africa-Wide Information
- LILACS

We will include Africa-Wide Information and LILACS given the proliferation of mobile phone-based initiatives in low- and middle-income regions. We will search for recent clinical trials separately via the following databases: clinical trials registry at the WHO International Clinical Trials Registry Platform (www.who.int/trialsearch), “ClinicalTrials.gov”, the search portal of the International Clinical Trials Registry Platform (ICTRP), and Current Controlled Trials (www.controlled-trials.com).

We will search for studies published in all languages since January 1993 until present as the first text message was sent in December 1992 (Kellon 2012). The strategy for MEDLINE (Ovid) is presented in Appendix 1 and will be adapted to the above databases. If additional key words of relevance are identified during any of the searches, electronic search strategies will be modified to incorporate these terms in agreement with the Cochrane review coordinating editor.

Searching other resources

We will write to the contact investigators of identified and included studies to request additional information about the study where appropriate, as well as information about trials not discovered in our search. We will review abstracts of key conferences (mHealth summit, Women Deliver, International Conference on Family Planning) and also review of online repositories of mHealth interventions (Health unbound, Royal Tropical Institute: mHealthinfo, K4Health: mHealth evidence)

Data collection and analysis

Selection of studies

Search results will be exported into a bibliographic citation management software programme and duplicate references excluded. Titles and abstracts of studies retrieved using the search strategy will be screened independently by two review authors. Full articles will be retrieved for further assessment if the information given suggests that the study (1) includes participants who are users or potential users of contraception (2) compares the use of an intervention delivered by mobile phone with routine standard of care or another intervention, (3) assesses one or more relevant outcome measure.

If there is any doubt regarding these criteria from the information in the title and abstract, the full article will be retrieved for clarification. The full text of potentially eligible studies will be retrieved and independently assessed for eligibility by two review authors,

with any disagreement resolved through discussion with a third author.

Data extraction and management

Two authors will independently extract the following data from the included studies using a standardised data extraction form:

- (1) General information: title, authors, complete citation, publication status, date published, language, review author information, date reviewed, sponsoring, setting
- (2) Study characteristics: study design, aim of study, duration, participant recruitment, sampling, inclusion/exclusion criteria including numbers screened and eligible, randomisation, allocation concealment, method of allocation concealment, blinding, informed consent, was a power analysis performed?
- (3) Risk of bias: additional data will be collected depending on the study design (see ‘Assessment of risk of bias in included studies’)

(4) Participants: description, geographic location, setting, number, age, ethnicity, socioeconomic status distribution

(5) Providers: description, geographic location, setting

(6) Intervention: description, aim of intervention, any behaviour change intervention (according to the study authors description and our assessment according to an established typology of behaviour change techniques (Abraham 2008)), duration, frequency

/ dose, control/placebo intervention, technical specifications including device and mobile phone functions used (e.g. text message, voice message), message content, co-interventions

(7) Outcomes: outcomes as specified above, other outcomes assessed, length of follow-up, methods of assessing outcomes, completeness of outcome data, follow up for non-respondents, adverse events

(8) Results: for outcomes and times of assessment, intention to treat analysis (where all randomised participants are included irrespective of what happened subsequently (Newell 1992)).

Any disagreements will be discussed by the authors with any disagreement resolved through discussion with a third author as necessary.

Assessment of risk of bias in included studies

Studies will be assessed for risk of bias in accordance with the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011) across the following domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other potential biases. Two review authors will independently assess the risk of bias with any disagreement discussed by the authors and resolved through discussion with a third author as necessary. We will use a standardised form to guide the assessment of risk of bias, and will judge each domain

as 'high', 'low' or 'unclear'. All included studies will be presented by study type and risk of bias level. As required, we will contact study authors for additional information. The results of the risk of bias assessment will be presented in tables, and as a systematic narrative description.

Measures of treatment effect

We will use risk ratios (RR) as measure of treatment effect for dichotomous outcomes and mean differences (MD) for continuous outcomes. We will report confidence intervals with all measures of effect.

Unit of analysis issues

We will take into account unit of analysis issues resulting from cluster RCTs, repeated measurements, and studies with more than one treatment group. If appropriate, data will be analysed in accordance with the Cochrane handbook (Higgins 2011).

Dealing with missing data

Missing data on individuals will be assessed as guided by the Cochrane handbook. We will ignore the missing data if it is assumed to be missing at random. If feasible, we will contact study authors for missing data where it is assumed to be not missing at random, for example if some randomised participants were excluded from analyses. If feasible, we will use statistical techniques, as appropriate to each study, to impute the missing data in order to enable an available case or intention-to-treat analysis. (Higgins 2011) For missing summary data, if feasible, we will approximate the correct analyses to impute missing summary statistics, e.g. standard deviations, in accordance with the Cochrane handbook (Higgins 2011).

Assessment of heterogeneity

We anticipate that there will be limited scope for meta-analysis due to differences in interventions and outcome measures. However, if sufficient studies are identified, we will examine heterogeneity between the trials using the I^2 statistic, with an I^2 estimate greater than 50% indicating a substantial level of heterogeneity (Higgins 2011).

In the result of substantial clinical, methodological or statistic heterogeneity, study results will not be combined in a meta-analysis and we will attempt to determine reasons for this by examining individual study characteristics.

Assessment of reporting biases

If we identify studies with similar interventions and outcome measures, we will assess reporting biases statistically and using funnel

plots in RevMan 5. We will minimise the potential for reporting bias by using comprehensive search strategies.

Data synthesis

We will conduct statistical analysis according to the guidelines in the Cochrane handbook (Higgins 2011). We will present a narrative overview of the findings together with tabular summaries of extracted data. If study populations, interventions, comparators and outcomes are sufficiently similar, we will pool the data across studies and estimate summary effect sizes. We will use the Mantel-Haenszel risk ratio fixed effects method for dichotomous data and the MD for continuous data. Where meta-analysis is not possible, we will present summary and descriptive statistics. We will summarise the quality of evidence provided by the studies using the GRADE approach (Higgins 2011).

Subgroup analysis and investigation of heterogeneity

Although we predict number of studies to be low as in previous reviews of mobile phone-based interventions (Horvath 2012; Whittaker 2009), if one of the primary outcome parameters demonstrates statistically significant differences (at $p < 0.01$) between treatment groups we will perform subgroup and sensitivity analyses. These would include meta-analyses on studies amongst specific populations, specifically; younger vs. older women; high income vs low income settings; post-delivery vs post abortion vs general clinic attendees.

It is not anticipated that many studies will be identified that promote traditional contraceptive methods, as family planning programmes and trials are more likely to promote modern, more effective methods. However, if such studies are identified, we will consider undertaking a sub-group analysis only including modern methods or those considered effective or very effective by the WHO (WHO 2011).

Sensitivity analysis

It is not anticipated that we will identify a large number of studies. However, if appropriate, we will perform sensitivity analysis in order to explore the influence of the following factors on effect size:

- repeating the analysis excluding unpublished studies
- repeating the analysis taking account of risk of bias of included studies, as specified above

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* Indicates the major publication for the study

APPENDICES**Appendix I. MEDLINE (Ovid) search strategy**

Intervention delivered by mobile phone

((phone adj3 call*) OR ((cell* or mobile or smart or google or nexus or iphone) adj3 (phone* or telephone*)) OR (smartphone*) OR (smart-phone*) OR (blackberr* NOT extract) OR (black-berr* NOT extract) OR ((mobile adj3 (health NOT (van* or unit*))) OR (mhealth) OR (m-health) OR (e-health*) OR (ehealth*) OR (electronic adj health) OR (mobile adj3 technol*)) OR ((mobile or smartphone or smart-phone or phone or software) adj3 (app*)) OR ((MMS) OR (multimedia messaging service) OR (SMS) OR (short messag* service) OR (text* adj messag*) OR (text-messa*) OR (voice messag*) OR (interactive voice response) OR (IVR)) OR MeSH 'Telemedicine' (not exp.) OR MeSH 'Cellular phone' (exp to include text messaging)

AND

contraception

((contracept*) OR (family adj planning) OR (Birth adj control)) OR (condom) OR ((OC adj pill)) OR ((depot medroxyprogest*) OR (NET-EN) OR (NET EN) OR (Mesigyna) OR (Cyclofem)) OR ((NORPLANT) OR (implanon) OR (Femplant)) OR ((intrauterine

system) OR (intra-uterine system) OR (IUS) OR (intrauterine device) OR (intra-uterine device) OR (IUD)) OR ((vasectomy) OR (sterilisation) OR (sterilization) OR (tubal adj ligation)) OR ((vaginal adj ring) OR (cycletel) OR (cycle-tel) or (abstain) OR (abstinen*) OR (lactational amenorr*)) OR ((pregnan*) OR (abortion)) OR MeSH: Contraception (exp.) OR MeSH: contraceptive devices (includes condom) OR MeSH exp Pregnancy, Unplanned/ OR MeSH exp Pregnancy, Unwanted/ OR MeSH exp Abortion, Induced/ Limits Activated: After 1993, Clinical Trial

CONTRIBUTIONS OF AUTHORS

Chris Smith and Caroline Free conceived the review. Chris Smith will oversee the search and selection process, including the construction and implementation of search and quality appraisal strategies. He will contact authors of papers for additional information, and analyse data from selected papers. Colin Sumpter and Mousumi Rahmen will undertake additional screening and data extraction.

Chris Smith, Caroline Free, Judy Gold, Thoai Ngo, and Colin Sumpter all contributed towards the development of the protocol.

DECLARATIONS OF INTEREST

None known

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