An interactive website to aid young women's choice of contraception: feasibility and efficacy RCT

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Scientific summary

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Background

Control of fertility is crucial to the health and well-being of women, but unintended pregnancy remains common and costly for both health services and individuals. In the UK, despite a range of freely available effective contraceptive methods, abortion rates have changed little over two decades (at around 190,000 per year for women resident in England and Wales).

Preventing unintended pregnancy involves many processes, including timely education, awareness and socially patterned behaviours, that lead women to seek, choose and use contraception consistently and correctly. Health services have a key role to play by supporting women to choose and use an appropriate method that best meets their needs, but many women are still not aware of the range of methods available to them. The combined oral contraceptive pill and condoms are well known and widely used, but are not the most effective contraceptive methods. Long-acting reversible contraception, that is intrauterine devices, intrauterine systems, implants and injections, is over 20 times more effective than oral contraceptives and condoms, but these methods are less well known to women and may not even be discussed in settings without the capacity to provide them.

Increasingly, women turn to online sources of information on health care. However, online information is of variable quality and misperceptions about contraception are common. This study aimed to develop and test the effectiveness of an interactive website to aid informed choice of contraceptive method.

Phase I objectives

1. To systematically review evidence on individual-level education or decision aid interventions relating to acceptability and uptake of and adherence to contraception (including underpinning theories, and user and provider views).
2. To obtain the views of contraceptive service users and providers in five settings (general practice, sexual and reproductive health services, abortion services, maternity services and community pharmacies), relating to access to and acceptability and uptake of contraception.
3. To apply the information from objectives 1 and 2 to identify the key design issues and content for an interactive digital intervention or website.
4. To co-design the website with young women and health-care professionals.

Phase II objectives

5. To conduct a randomised feasibility trial of the website in five different service settings (general practice, sexual and reproductive health services, abortion services, maternity services and community pharmacies).
6. To assess, through qualitative process evaluation, the acceptability of the trial procedures, women's views of the intervention itself and NHS implementation considerations.
7. To write a protocol for a definitive trial of an interactive digital intervention to aid informed choice of contraception and the acceptability and uptake of and adherence to long-acting reversible contraception methods in young women.

Methods

Overview

In Phase I, we completed three systematic literature reviews, a review of YouTube (YouTube, LLC, San Bruno, CA, USA) videos and discussion threads about contraception, and conducted focus groups and interviews with young women to explore barriers, benefits, concerns, myths and misperceptions relating to contraception. In addition, we sought the views of health professionals and held an expert workshop. From these findings, we developed a logic model to guide design of a new interactive website: Contraception Choices [URL: www.contraceptionchoices.org (accessed January 2020)]. The website was designed through an iterative process of consultation with young women and a commercial software company. In Phase II, we evaluated the effectiveness of the website in an individually randomised trial using qualitative and quantitative methods.

Recruitment and trial methodology

For both phases, women aged 15–30 years were recruited from clinical sites representing the settings in which the great majority of contraceptive consultations occur: a general practice (Clerkenwell, North East London), sexual health services (Brook, Euston and the Margaret Pyke Centre), a maternity service (Ashford and St Peter's Hospitals NHS Foundation Trust), a community pharmacy (Green Light Pharmacy London) and an abortion service (British Pregnancy Advisory Service, East London).

In the feasibility trial, women were recruited in clinic by a researcher using a tablet computer. The trial software was designed to enable participants to go through the steps of screening, consent, automatic randomisation, data collection and website viewing without assistance, although in practice this process was nearly always supported by a researcher. Participants allocated to the intervention condition were immediately directed to the Contraception Choices website. Those allocated to the control condition were invited to view the website at the end of the trial in 6 months' time. All participants were followed up by e-mail, text or mobile phone at 3 and 6 months, and asked to complete an online questionnaire for outcome data. Free-text comments from the questionnaire were used for qualitative analysis.

The popularity of the Contraception Choices website among young women and the demand from contraception providers to disseminate the website led to the feasibility trial becoming a Phase III, or efficacy, trial. To achieve this, we increased the recruitment target – from 400 in the feasibility trial to 930 in the efficacy trial – and changed the primary outcome from a feasibility measure (6-month follow-up rate) to clinical outcomes that were originally secondary outcomes in the feasibility trial. This resulted in two primary outcomes for the efficacy trial: use of long-acting reversible contraception at 6 months and satisfaction with contraceptive method at 6 months. A sample size of 930 was estimated to be sufficient to detect (with 82% power) an increase in uptake of long-acting methods from 35% to 47%, assuming a follow-up rate of 70%. We also conducted a budget impact analysis of the website and contraception, reporting the total costs to each payer [NHS (primary care vs. secondary care), local government, private and out of pocket] and the total cost of contraception and pregnancy outcomes for a range of population sizes.

Rapid expansion in recruitment was achieved by recruiting women online (rather than in clinic) from one of the study sites, the Margaret Pyke Centre. When women request an appointment for contraception at this clinic, they are routinely directed to the trust website to book their appointment. Once an appointment is booked, the patient receives a text message confirming the date and time of the clinic appointment. For the trial, we inserted into the routine text an invitation to take part in contraception research by clicking on a hyperlink, which took women to the trial recruitment home page. From this point, the trial procedures were the same as for women recruited in clinic.

In effect, by changing from a feasibility trial to an efficacy trial, we completed the trial referred to in objective 7 (see *Phase II objectives*) rather than writing a protocol for it.

Results from Phase I

Review of published literature

Our meta-synthesis of 18 systematic reviews of factors affecting choice and use of contraception showed that pathways to successful contraception choice and use are complex and strongly shaped by factors that are often outside the control of individual women. Globally, use of contraception is influenced by the perceived likelihood and appeal of pregnancy, relationship status, knowledge, beliefs, and perceptions of side effects and health risks. Male partners have a strong influence on contraception uptake, as do the views and experiences of peers, and family members' expectations. Lack of education and poverty are linked with low contraception use, and social and cultural norms influence expectations of family size and timing. Contraception use also depends on the availability of methods, the accessibility, confidentiality and costs of health services, and attitudes, behaviour and skills of health-care personnel.

Our second systematic review of trials of interactive digital interventions for contraception choice and use found one significantly positive trial and showed that digital interventions for contraception are feasible and promising, and that offering access in clinic waiting rooms is appropriate.

Our third review of 21 systematic reviews of face-to-face interventions for contraception and theories about contraception decision-making included a meta-analysis of eight randomised controlled trials (which found that motivational interviewing significantly increased effective use of contraception) and a synthesis of eight trials of educational interventions (which found educational interventions to be effective for knowledge acquisition, but not for change in attitudes or behaviour). Goal-setting and self-monitoring are important elements of many successful interventions.

Women's views: qualitative fieldwork

Qualitative data, from focus groups, interviews with 74 women and review of 35 YouTube videos and discussion threads, were coded and categorised by theme and subtheme. The key findings can be summarised as follows:

- The most commonly expressed concern about contraception was the 'unnaturalness' of hormones contained in hormonal contraceptive methods.
- Other commonly expressed concerns or anxiety about contraception related to infertility, irregular bleeding, having no periods, risk of cancer and side effects.
- Many women think it is unhealthy to skip periods.
- Many women think their bodies need a break from contraception.
- Women do not have a good understanding of contraceptive side effects.
- There is a strong tendency to underestimate contraceptive benefits and to overestimate contraceptive side effects.
- Partners' views are important to women.
- Women like seeing honest videos of other women talking about their experiences of contraception.
- Women dislike seeing a lot of text on a website and would prefer to have options to view more information if they wish to know more.

Views of health-care providers

The interviews with health-care professionals gave rise to all the same issues raised by women themselves in relation to contraceptive knowledge, concerns and misperceptions. Other issues explored in interviews with health-care professionals were practical ones relating to the feasibility trial design and the practicalities of recruiting in clinics, such as access to Wi-Fi.

The Contraception Choices website draws on all these findings to provide information that addresses women's concerns about and barriers to uptake of contraception, including, for example, a dynamic infographic to compare the effectiveness of different methods. Young women's perspectives and concerns are integral to the design and content, which acknowledge explicitly the challenges that

women often face, and offer straightforward advice in a way that does not judge women for their choices or situations. A key feature is an interactive decision tool that takes the user through a series of questions designed to identify appropriate method(s) that best suit individual preferences (e.g. for a non-hormonal method, one that does not require insertion by a health-care professional or one that is invisible), and then generates three suitable contraceptive options, with brief annotation. The three options can then be sent by e-mail or text to a mobile for further personal consideration, discussion with friends and family or discussion during a contraceptive consultation (although contraceptive consultations were not assessed in the trial).

Results from Phase II: randomised trial

Quantitative and qualitative findings

The first participant was randomised on 4 July 2017 and the last on 22 December 2017. The first woman was recruited through the online central booking service on 31 October 2017 and the last on 22 December 2017. Recruitment online was much faster than in the clinics. It took approximately 6 months to recruit 400 women from the clinic sites, as originally planned (we recruited 530 women via the online booking system in just over 7 weeks).

Two-thirds of participants were from white ethnic groups, half were educated to degree level and four-fifths reported English as their first language. Ten per cent were pregnant, whereas 90% indicated a current need for contraception to avoid unintended pregnancy. The most common method at baseline was the pill, followed by long-acting reversible contraception methods. Around two-thirds of women were satisfied with their current method at baseline.

In total, 927 women were randomised to the website group ($n = 464$) or to the control group ($n = 463$), of whom 739 (80%) provided follow-up data at 6 months. A total of 786 women (86%) provided data at 3 or 6 months, or at both time points, and were included in the analysis of primary outcomes with imputation. Written feedback about the website was provided by more than four-fifths of trial participants in the intervention group. The main themes were about the website information and content, the design and format, interaction with health professionals, being part of the study and a range of impacts of the website. The last theme included switching to another method, changing behaviour as a result of correcting a misperception about contraception, personal sexual responsibility, discussing the website with others and barriers to accessing contraception. Apart from barriers to access, comments were strikingly positive and appeared to affirm the purpose of the website.

Across both study arms, satisfaction with method of contraception improved from around two-thirds at baseline to four-fifths at follow-up. There was no statistically significant difference between intervention and control groups in the proportion of women using long-acting reversible contraception at 6 months [30.4% intervention vs. 31.0% control, adjusted odds ratio after imputation 0.87 (95% confidence interval 0.60 to 1.27)], nor in level of satisfaction with contraceptive method [proportion being 'satisfied' or 'very satisfied', 82.6% intervention vs. 82.1% control, adjusted ordinal odds ratio 0.93 (95% confidence interval 0.69 to 1.26) based on the five ordered responses]. In the budget impact analysis, there was no statistically significant difference between the two groups in publicly funded contraception costs excluding pregnancy (£3.67, 95% confidence interval −£18.17 to £28.56) or including pregnancy (£73.65, 95% confidence interval −£46.38 to £192.40) or private out-of-pocket costs (£11.19, 95% confidence interval −£2.84 to £26.72).

Conclusions

The Contraception Choices website was popular among young women because of its design, presentation of trustworthy information and guidance in choosing a method tailored to individual

preferences. However, it was not associated with any statistically significant difference in use of long-acting reversible contraception or satisfaction with contraceptive method at 6 months. Our systematic reviews confirmed multiple factors affecting women's choice and use of contraception, which go beyond informed choice. The lack of effect on clinical outcomes in this trial, despite highly positive feedback from participants, highlights a gap between improving delivery of personalised information and impact on contraceptive use. We hypothesise that this gap can be narrowed by shared reference to the website between patients and health-care professionals during contraception consultations. Contraception providers are keen to promote the website. The priority for further research is to determine whether or not use of the website during contraceptive consultations improves the quality of consultation and thereby clinical or service outcomes, ideally over a follow-up period of at least 1 year.

Trial registration

This trial is registered as ISRCTN13247829.

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This report

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