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A website to help choose contraception - a pilot trial

Submission date
03/04/2017

Recruitment status
No longer recruiting

Registration date
06/04/2017

Overall study status
Completed

Last Edited
10/10/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Control of fertility is crucial to the health and wellbeing 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, and England still has the highest rate of teenage pregnancy in Western Europe. A key report on the economics of sexual health concluded that it should be feasible to improve contraception and abortion services in ways that better meet the preferences of service users and that this could lead to a net saving of up to £1 billion over 15 years. In addition to the economic burden of unintended pregnancy and abortion to the NHS, and the emotional burden to individual women, unintended pregnancy plays a prominent role in persistent health inequalities in the UK and globally. Preventing unintended pregnancy involves many steps, including timely education, awareness and socially patterned behaviours that lead women to seek, choose, and use contraception consistently and correctly. Long-acting reversible contraceptive (LARC) methods, including intrauterine devices, depo injection and subdermal implants, offer women the most effective protection against pregnancy. The vast majority of young people have access to digital technology through Internet or mobile phones, which offers huge potential for health promotion. It is known that younger women are likely to turn to digital resources for information on contraception. The aim of this study is to look at the acceptability of a website designed to increase the acceptability, uptake and adherence to long-acting reversible contraceptive (LARC) methods in young women.

Who can participate?
Women aged 15-30 who are in need or current or future contraception.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive access to standard contraceptive care only. Those in the second group are given access to the study website, displayed on a tablet computer. The website includes general information about contraceptives, including side effects and benefits of different types; videos of women and health professionals discussing contraceptive experiences, concerns and misconceptions; an interactive tool that helps women to choose a method of contraceptive for themselves; and a page offering a link to NHS clinics, information websites and support websites. Participants in

both groups are asked to complete questionnaires online after three and six months via an automated email. At the end of the study, the number of those who took part and participant views on the website are collected in order to see if a full scale study would be possible.

What are the possible benefits and risks of participating?
Participants may benefit from increased awareness about the different types of contraception available and what they involve. Contraception may be viewed as a sensitive or embarrassing topic by some people, although the study questions about contraception do not differ from those that are asked in routine contraceptive consultations. If participants express discomfort, anxiety or distress while completing the questionnaire, this will reported by the researcher or clinic / pharmacy staff as an adverse event. All concerns will be discussed with at least one other member of the research team, and consider referral to social services if this is felt to be in the person's best interests (even if this is against their wishes), particularly if they are under the age of 18.

Where is the study run from?
1. Margaret Pyke Centre (UK)
2. British Pregnancy Advisory Service (UK)
3. Green Light Pharmacy (UK)
4. Clerkenwell Medical Practice (UK)

When is the study starting and how long is it expected to run for?
June 2016 to March 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Anasztazia Gubijev
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33563

Study information

Scientific Title
Increasing uptake and adherence to long-acting reversible contraceptive (LARC) methods in young women OR Designing a digital intervention to help when choosing contraception

Study objectives
The aim of the study is to develop and test the feasibility of an online trial of a website to increase the acceptability, uptake and adherence to long-acting reversible contraceptive (LARC) methods in young women. LARC methods include the intrauterine device (IUD), intrauterine system (IUS), subdermal implant (SDI) and depo injection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board: Camden and King's Cross Research Ethics Committee, 15/02/2017, ref: 17/LO/0112

Study design
Randomised; Interventional; Design type: Not Specified, Education or Self-Management, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: Reproductive and Sexual Medicine; UKCRC code/ Disease: Reproductive Health and Childbirth/ Pregnancy with abortive outcome

Interventions
Participants are randomised to one of two groups.

Intervention group: Women are given access to the intervention website, displayed on a 'tablet' computer. This consists of:
1. General information on contraception, including information on each method as well as contraceptive benefits and side-effects and other common concerns
2. Videos of women as well as health professionals discussing contraceptive experiences, concerns and misconceptions
3. An interactive tool to help women choose a method of contraception which provides individually tailored results
4. A page offering a link to NHS clinic finders as well as links to other useful resources, such as further information on sexual health, or websites offering support and advice for sexual abuse for example
Whilst in clinic, users allocated to the intervention group will be asked to work through a tailored package of individualised website content. After leaving clinic, the website will be available for them to re-visit and explore freely, and will be accessible on mobile phones as well as desktop computers. Participants will be taken through a series of questions designed to identify appropriate method(s) that best suits individual preferences e.g. for a non-hormonal method, or one that does not require insertion by a health care professional, or one that is invisible, or one that can be forgotten about once inserted. The website will give information to address women's concerns and barriers to uptake of LARC. A contraceptive choice tool will take account of women's views and preferences on the benefits and side effects of contraception and three suitable contraceptive options will be recommended with brief annotation, that can be emailed, texted to a mobile phone and used in a subsequent consultation and / or taken home.

Control group: Participants will be thanked for their participation and will then access standard contraceptive care only.

All women in both intervention and control groups will be asked by automated email to complete the same outcome questionnaires online at 3 and 6 months (or 2 months post-partum). The control group will be offered access to the intervention website at the end of the study (after completion of 6 month follow-up).

Intervention Type
Device

Primary outcome measure
Current primary outcome measures as of 28/09/2018:
1. LARC method in use at 6 months, measured by response to study outcome questionnaire
2. Satisfaction with any chosen method of contraception at 6 months, measured by response to study outcome questionnaire using a Likert scale 1-5. How satisfied are you with the contraception you are using currently?

Previous primary outcome measures:
Follow up rate is measured by completing (in full or in part) the study outcome questionnaire via an online link sent by email 6 months after randomisation, for participants recruited from the general practice, sexual & reproductive health service, abortion services, and community pharmacy), and 2 months post-partum for women recruited from the maternity service.

Secondary outcome measures

Current secondary outcome measures as of 28/09/2018:
Quantitative:
1. Follow-up rate at 6 months after randomisation
2. Recruitment rate, measured via the trial website as the time taken to recruit (up to 80) women in each site. Recruitment is assessed by completing (in full or in part) the baseline questionnaire.
3. Effectiveness of contraceptive method in use at 6 months, measured by response to study outcome questionnaire and grouped as follows from least to most effective: no method; withdrawal or natural method; condoms or diaphragm; pill, patch or ring; LARC or sterilisation
4. Change in method between baseline and 6 months, indicating whether any change is to a method of greater, lesser or similar effectiveness (based on grouping above)
5. Pregnancy by 6 months, measured by response to study outcome questionnaire at 3 months and at 6 months
6. Sexually transmitted infection diagnosis by 6 months, measured by response to study outcome questionnaire at 3 months and 6 months
7. Health service and out-of-pocket costs for contraception and other sexual health services, measured by response to study outcome questionnaire at 3 months and at 6 months

Qualitative
1. Patient views and experience of the intervention and trial procedures, assessed through qualitative interviews at 2 weeks after randomisation with five women at each study site (total 25 interviews) (See Topic Guide). Questions to be explored include:
1.1. Are the online trial procedures acceptable to participants? E.g. the process of online registration and consent, the receipt of incentives, completing online questionnaires, contact and follow up by email and text
1.2. What are women's views of the intervention?
1.3. How might trial procedures be improved, to optimise retention in a full-scale trial?
2. Provider views about impacts on the service and trial procedures, assessed through qualitative interviews with 15 key staff in total (3 per site), sampling those who have roles in facilitating the study in each setting (e.g. receptionists, practice managers, nurses, midwives, doctors and pharmacists) (see Topic Guide). Questions to be explored include:
2.1. Are recruitment procedures acceptable to staff?
2.2. How might recruitment procedures be improved, to optimise recruitment to a full-scale trial?
2.3. What are staff views on the feasibility and usefulness of a contraception decision website in each clinic setting?

Previous secondary outcome measures:
1. Recruitment rate is measured via the trial website as the time taken to recruit (up to 80) women in each site at 6 months
2. Satisfaction with chosen method of contraception is measured using a Likert scale at 3 and 6 months
3. Data completeness and descriptive statistics for questions related to service use and out-of-pocket costs for contraception and other sexual health services is assessed by survey at 3 and 6 months
4. Patient views and experience of the intervention and trial procedures, assessed through qualitative interviews 2 weeks after randomisation with five women at each study site
5. Provider views about impacts on the service and trial procedures, assessed through qualitative interviews with 15 key staff in total (3 per site), sampling those who have roles in facilitating the study in each setting (e.g. receptionists, practice managers, nurses, midwives, doctors and pharmacists) at 6 months

Overall study start date

01/06/2016

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. Women
2. Aged 15 to 30 years
3. In need of current or future contraception
4. Attending one of the study sites
5. Able to read English
6. An active email account and access to the internet

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 400; UK Sample Size: 400

Total final enrolment
927

Key exclusion criteria
1. Women unable to provide informed consent (e.g. severe learning difficulties)
2. Women needing a language advocate to understand English since the intervention content is intended to be accessed in private

Date of first enrolment
23/03/2017

Date of final enrolment
23/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Margaret Pyke Centre
Mortimer Market Centre
Bloomsbury
London
United Kingdom
WC1E 6JB

Study participating centre
British Pregnancy Advisory Service
36 Romford Road
London
United Kingdom
E15 4BZ

Study participating centre
Green Light Pharmacy
228-230 Uxbridge Road
London
United Kingdom
W12 7DJ

Study participating centre
Clerkenwell Medical Practice
Finsbury Health Centre
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Sponsor information

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Sponsor type
University/education

Website
www.ucl.ac.uk/jro

ROR
https://ror.org/00wrevg56

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/03/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the confidential nature of the data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	26/01/2021	Yes	No
Protocol file	version 3	23/07/2018	10/10/2022	No	No
HRA research summary			28/06/2023	No	No