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Acceptability of a digital health intervention to inform women about contraception after pregnancy

Submission date
24/07/2022

Recruitment status
No longer recruiting

Registration date
29/07/2022

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
This research is about evaluating a new way of providing information to pregnant women about contraception after childbirth. Contraception is an important part of pregnancy care as many women experience an unplanned pregnancy in the months after childbirth and a gap of less than a year between pregnancies can is linked to complications for mothers and babies in the next pregnancy. We know that it can be difficult to access consistent and reliable information about their contraceptive options in a convenient way and that making and attending appointments to start contraception can be more difficult when looking after a new baby. We are therefore looking at ways that might make this easier, including the use of technology in addition to current care pathways.

At present, most contraceptive discussions take place with a midwife or doctor during an antenatal clinic visit. In this study, we will evaluate adding a short audio-visual animation and a package of text message alerts/links. Previous research has shown that women like to receive health information this way and it helps them to remember key facts. It can also be easily subtitled and translated into different languages and may be more accessible to patients. By providing clear, consistent and accurate information about fertility and contraception after childbirth, as well as signposting to other reliable sources, we hope to empower and inform women about their choices and simplify the process of starting contraception after having a baby.

This study will evaluate the acceptability of this intervention and its effect on contraceptive decision-making and uptake compared to standard care. We also want to find out more about the views and experiences of pregnant women receiving this new intervention to help us develop this service further in the future as a possible routine part of antenatal care.

Who can participate?
Pregnant volunteers aged 16 years old and over

What does the study involve?
Study participants will be randomised into one of two groups: ‘standard care’ or ‘intervention’. Women in the standard care group will have a routine discussion with their midwife or doctor about contraception. Women in the intervention group will be shown a short video animation about contraception in addition to their routine consultation.

Following their consultation, participants in both groups will complete a survey about their experience. Women in both groups will receive routine care throughout the rest of their pregnancy and labour. Participants in the intervention group will also receive text message alerts at approximately monthly intervals about contraception. These messages would remind them about making a contraceptive plan and provide links to get more information.

Women in both arms of the study will receive a call or text (if preferred) from the research midwife/ nurse at 34-36 weeks pregnant to find out if they have made a contraceptive plan, and if so, which method they intend to use. A further follow-up call or text will be conducted at six weeks postpartum to determine the final method initiation (if any). A small number of participants from the intervention group will also be invited to a follow-up interview with the research team to find out more about their views on the content, frequency and acceptability of the text messages.

What are the possible benefits and risks of participating?
Results from the study may help us to develop services further to best meet the contraceptive needs of women in the future and will be among the first to view this newly-developed video animation before it becomes available to the public. There are no clinical risks from taking part in the study. Participants will contribute some of their personal time to take part and those in the intervention group may find the text messages an inconvenience. This is one of the questions we hope to answer by doing this research and participants can also choose to opt out of receiving these at any time.

Where is the study run from?
Chalmers Sexual Health Centre (United Kingdom)

When is the study starting and how long is it expected to run for?
January 2022 to April 2023

Who is funding the study?
Edinburgh Family Planning Trust (United Kingdom)

Who is the main contact?
Dr Michelle Cooper (Principal Investigator) (United Kingdom)
michelle.cooper@ed.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Michelle Cooper

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
310285

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 310285

Study information

Scientific Title
Acceptability of a digital health intervention to inform women about contraception after pregnancy (DIGICAP): A pilot study

Acronym
DIGICAP

Study objectives
Access to a digital health intervention to provide information about contraception is acceptable to women during pregnancy and can increase the rate of a documented antenatal contraceptive plan and postpartum uptake of methods

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/05/2022, South East Scotland Research Ethics Committee 01 (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 (0)131 536 9000; sandra.wyllie@nhslothian.scot.nhs.uk), ref: 22/SS/0036

Study design
Single-centre pilot randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Contraception

Interventions
Women who consent to participate in the study will be randomised to one of two groups: 'standard care' or 'intervention'. Randomisation will be conducted using a simple list of 50 successive allocations with sealed envelopes, provided by our statistical expert. Envelopes will be stored in a locked cabinet in the research office to which only designated personnel have access. Women in the standard care group will proceed to their antenatal clinic consultation with a midwife or doctor as usual. Women in the intervention group will be shown a video animation about postpartum contraception (duration 5 minutes) on a laptop/tablet device in a private interview room prior to their routine antenatal clinic consultation with a midwife/doctor. The video animation used during the study was developed by Palindromicals Ltd as a co-funded collaboration between NHS Lothian, NHS Greater Glasgow & Clyde and Edinburgh & Lothian Health Foundation Charity.

Following their consultation with the midwife/doctor, participants in both groups will complete a structured survey administered by the research midwife/nurse about their experience. Information will be recorded on a standard proforma. If women prefer, this information could be collected via a survey sent by text/email rather than in person

Women in both groups will receive routine care throughout the rest of their pregnancy and labour. However, participants in the intervention group will also receive text messages at monthly intervals about contraception. These messages are expected to remind women about making a contraceptive plan and where to get more information on contraception. With each text message, women will be asked to rate the acceptability of the text.

Women in both arms of the study will receive a call or text (if preferred) from the research midwife/nurse at 34-36 weeks gestation to determine if they have made a contraceptive plan and if so, which method they intend to use postpartum. A further follow-up call or text will be conducted at six weeks postpartum to determine the final method initiation (if any).

A subset of women in the intervention arm will also be invited to follow-up short structured interviews with the research investigators about the content, frequency and acceptability of the text messages.

Intervention Type
Other

Primary outcome(s)
Trial feasibility: Proportion of screened women who are eligible/consented/randomised measured using protocol adherence and retention of participants at study endpoint

Key secondary outcome(s))
1. Acceptability and satisfaction measured using a participant-rated (Likert scale) at the first visit (antenatal) and second visit (postpartum follow-up)
2. Information recall measured using a participant-rated from pre-defined list at the first visit (antenatal)

3. Contraceptive decision-making and initiation:
3.1. Intended contraceptive method measured via antenatal questionnaire
3.2. Actual contraceptive method measured via questionnaire at 6/52 postpartum
3.3. Timing/site of method initiation measured via questionnaire at 6/62 postpartum
3.4. Proportion of women in each group using a LARC method at 6/52 postpartum

Completion date
14/04/2023

Eligibility

Key inclusion criteria
1. Aged 16 years old and over
2. Fluent in written and spoken English
3. Between 20 and 24 weeks pregnant
4. Capacity to give consent for study participation
5. Willingness to be randomised to receive the intervention
6. Have access to a personal mobile phone able to receive SMS messages

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
52

Key exclusion criteria
1. Unable to consent to participation

Date of first enrolment
01/08/2022

Date of final enrolment
26/01/2023

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Study participating centre
St John's Hospital
Howden West Road
Howden
Livingston
United Kingdom
EH54 6PP

Sponsor information

Organisation
Accord (United Kingdom)

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type
Charity

Funder Name
Edinburgh Family Planning Trust

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Michelle Cooper, michelle.cooper@ed.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/01/2025	28/01/2025	Yes	No
Participant information sheet	version 002	11/05/2022	29/07/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes