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SHARECONTRACEPT, a shared decision-making tool for hormonal contraception

Submission date
07/03/2019

Recruitment status
No longer recruiting

Registration date
15/04/2019

Overall study status
Completed

Last Edited
09/06/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Decision-making tools represent a paradigm shift in the relationship between the clinician and the user/patient. They offer the advantage of compromising the patient, especially in those decisions that are sensitive to their preferences and values when there is more than one reasonable health option, they reduce the stressful burden that uncertainty can cause due to lack of information, and increase the proportion of people active in the management and management of their health. Allowing the user to freely access them from any digital device, not necessarily located in a clinic, at any time, facilitates personal reflection in making the decision that best suits their preferences, needs and state of health. However, there is a lack of research studies that demonstrate that online digital decision making tools in contraception provide advantages in relation to pre-technological care/attention. The aim of this study is to assess the effectiveness of a decision-making tool in contraception (SHARECONTRACEPT: http://decisionscompartides.gencat.cat/ca/decidir-sobre/anticoncepcio_hormonal/).

Who can participate?
Women aged 16 (updated 06/06/2019, previously: 18) to 49 who attend consultations at the clinical contraceptive counseling units participating in the study

What does the study involve?
The health professionals participating in each unit are randomly allocated to one of two groups. Clinicians allocated to the experimental group perform contraceptive counseling assisted by SHARECONTRACEPT, and those of the control group follow the usual procedure of their clinical unit. The selected users are followed up for one year. Data is collected through questionnaires, a logbook of incidents and validated instruments for measuring decisional conflict and adherence to treatment.

What are the possible benefits and risks of participating?
The results obtained from this study will help us to establish a Decision Support Tool in hormonal contraception, if it is shown that it has clear benefits, in giving better care to women who come for contraception counseling. Participation in this study does not pose any risk, but there may not be any health benefits from participating in this study.

Where is the study run from?
Clinical contraceptive counseling units of six autonomous regions in Spain

When is the study starting and how long is it expected to run for?
January 2019 to June 2023

Who is funding the study?
Instituto de Salud Carlos III (Ministry of Science, Innovation and Universities co-funded by the European Fund for International Development of the European Union)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PI18/00915

Study information

Scientific Title
SHARECONTRACEPT, a digital decision-making-tool. Does it improve adherence to the chosen contraceptive method?

Acronym
SHARECONTRACEPT

Study objectives
This study will find out the effectiveness of a shared decision-making tool in contraception in health settings in Spain.

The study aims are to evaluate the effectiveness of shared decision-making tool on hormonal contraception (SHARECONTRACEPT) measured by:
1. The improvement of counseling on hormonal contraception at the clinic consultation
2. The increase of clinical healthcare professionals knowledge on contraception
3. The improvement of adherence to contraception treatment selected
4. The decreasing unwanted pregnancies and voluntary interruption of pregnancy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committees of Clinical Research:
1. Comité Ético de investigación del Instituto Pere Virgili, Institut d'Investigació Danitària Pere Virgili (IISPV), Centre d'R+D+I en Nutrició i Salut, Avda. de la Universitat, 1 - 2a planta, 43204 Reus (Tarragona), Spain, Tel: +34 (0)977 75 93 94, ref: 186/2018
2. Comité Ético Investigación Clínica del IDIAP Jordi Gol, Fundació Institut Universitari per a la recerca d'Atenció Primària de Salut Jordi Gol i Guirina (IDAPJGol), Gran Via Corts Catalanes, 587, 08007 (Barcelona), Spain, Tel: +34 (0)93 482 41 24, Email: idap@idiapjgol.org, 28/11/2018, ref: PI18/208

Study design
Longitudinal and prospective community clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Community

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
Contraception

Interventions
This study will include an intervention group and a control group and data will be collected during a year in 6 autonomous regions in Spain. The health professionals participating in each unit will be randomly assigned by simple randomization to one of two groups. Clinicians assigned to the experimental group will perform contraceptive counseling assisted by SHARECONTRACEPT, and those of the control group will follow the usual protocol of their clinical unit.

It is planned to study 1,708 health users, recruited from women who attend the consultations of the units participating in the study. The selected users will be followed for one year. The data will be collected through ad-hoc questionnaires and validated instruments for measuring decisional conflict and adherence to treatment. A set of bivariate and multivariable descriptive analyses, besides a regression study analysis, will be carried out.

Intervention Type
Other

Primary outcome measure
Adherence to treatment: compliance with dosage and method of administration and persistence in the duration of prescribed treatment, evaluated through a structured interview ad-hoc including questions about a) the compliance with the contraceptive method chosen in the clinical consultation, b) information about the usage of this method and c) unwanted pregnancy incidences. Assessed by a phone call at 1 month, 6 months and 1 year.

Secondary outcome measures
1. Sociodemographic characteristics of the patient: age, educational level, occupation, marital status/couple, assessed at a structured interview ad-hoc at the first contact in the clinical consultation
2. Medical history: smoking habits, HBP, uterine malformations, diabetes, assessed at a structured interview ad-hoc at the first contact in the clinical consultation
3. Obstetric and gynecological antecedents: menstrual formula, menarche, term or premature pregnancies, ectopic pregnancies, spontaneous abortions, IVE, gynecological reviews according to the guidelines of each community, active sexually transmitted diseases, living children, desire to have children, assessed at a structured interview ad-hoc at the first contact in the clinical consultation
4. Contraceptive method: contraceptive method contemplated by the patient before counseling, prejudices against other contraceptives, experiences with other methods, possible beneficial non-contraceptive effects, importance of the cost in her choice, women's behavior with respect to compliance (Morisky-Green's adherence to treatment), finally chosen contraceptive, incidents

with the chosen method, management of the incidences, decisional conflict of the woman before the choice of the contraceptive method (O'Connor Scale), assessed at a structured interview ad-hoc at the first contact in the clinical consultation
5. Professional: satisfaction of the advisor or clinician with the use of the Digital HATD (Likert scale), acquired knowledge (ad-hoc knowledge test) assessed after the first year recruiting women for the study

Overall study start date
01/01/2019

Completion date
30/06/2023

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 28/05/2019:
1. Women aged 16 or older
2. Women aged 49 years or younger
3. Have primary studies and are proficient in Spanish and/or Catalan
4. Have access to the internet
5. Agree to voluntarily participate in the study

Previous participant inclusion criteria:
1. Women aged 18 or older
2. Women aged 49 years or younger
3. Have primary studies and are proficient in Spanish and/or Catalan
4. Have access to the internet
5. Agree to voluntarily participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
1708

Total final enrolment
895

Key exclusion criteria

1. Women aged 17 years or younger
2. Women aged 50 or older
3. Women who wish to have children before one year from the date of the consultation
4. Don't have access to internet
5. Don't understand Catalan and/or Spanish

Date of first enrolment
01/07/2019

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
Spain

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Consulta Anticoncepción Hospital Clínico Universitario Area 2 y 3
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Consulta Atención Primaria CEM Casetas
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Research organisation

Funder Name
Instituto de Salud Carlos III (Ministry of Science, Innovation and Universities co-funded by the European Fund for International Development of the European Union)

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
1. A general report of all results will be made (end of 2021)
2. Congress contributions (poster and communications)
3. At least one or two paper will be submitted to an international journal during 2021 (preferably Q1 Journal)

Intention to publish date
30/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Maria Inmaculada de Molina (inmaculada.demolina@urv.cat). Data will be available at the end of the study.

IPD sharing plan summary
Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		27/11/2021	11/01/2022	Yes	No
Protocol article		04/09/2019	11/01/2022	Yes	No