

SHARECONTRACEPT, a shared decision-making tool for hormonal contraception

Submission date 07/03/2019	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 15/04/2019	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 09/06/2023	Condition category Pregnancy and Childbirth	☐ 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://decisioncompartides.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?

Dr Maria Inmaculada de Molina Fernandez

inmaculada.demolina@urv.cat

Contact information

Type(s)

Principal investigator

Contact name

Dr Maria Inmaculada de Molina-Fernandez

ORCID ID

<https://orcid.org/0000-0002-1429-4455>

Contact details

Avenida Catalunya No. 35

Nursing Department

Tarragona

Spain

43002

+34 (0)625454741

inmaculada.demolina@urv.cat

Type(s)

Scientific

Contact name

Ms Dolores Creus-Pujol

Contact details

Institut Català de la Salut.

Gran Via de les Corts Catalanes, 587, 589

Barcelona

Spain

08004

(+34) 627480724

dcreus.lleida.ics@gencat.cat

Type(s)

Scientific

Contact name

Dr Miriam De la Flor-López

ORCID ID

<https://orcid.org/0000-0002-6232-7266>

Contact details

Hospital Universitari de Tarragona Joan XXIII
Tarragona
Spain
43005
(+34) 977295800
mdelaflor.hj23.ics@gencat.cat

Type(s)

Scientific

Contact name

Dr José Ramón Escuriet-Peiro

ORCID ID

<https://orcid.org/0000-0002-7277-3331>

Contact details

Catalan Health Service
Government of Catalonia
Faculty of Health Sciences Blanquerna-URLL
Barcelona
Spain
-
(+34) 933156966
rescuriet@gencat.cat

Type(s)

Scientific

Contact name

Dr Isabel Font-Jimenez

Contact details

Universitat Rovira i Virgili
Tarragona
Spain
-
(+34) 977299414
isabel.font@urv.cat

Type(s)

Scientific

Contact name

Ms Gemma March-Jardí

Contact details

Institut Català de la Salut.
Gran Via de les Corts Catalanes, 587, 589
Barcelona
Spain
08004
(+34) 977920400
gmarch.tgn.ics@gencat.cat

Type(s)

Scientific

Contact name

Dr Cristina Martinez-Bueno

ORCID ID

<https://orcid.org/0000-0001-5437-812X>

Contact details

Institut Català de la Salut
Barcelona
Spain
-
(+34) 934824391
cmartinezbu@gencat.cat

Type(s)

Scientific

Contact name

Ms Maria Dolores Martinez-Romero

ORCID ID

<https://orcid.org/0000-0003-2797-4166>

Contact details

Dirección general de asistencia sanitaria del SERGAS
Santiago de Compostela
Spain
-
(+34) 881548640
maria.dolores.martinez.romero@sergas.es

Type(s)

Scientific

Contact name

Dr Lucia Martinez-Villarejo

Contact details

Midwifery training unit
Madrid
Spain

-

(+34) 917277470
luciamartinezvillarejo@gmail.com

Type(s)

Scientific

Contact name

Ms Montserrat Moharra-Frances

Contact details

Agència de Qualitat i Avaluació Sanitàries
Generalitat de Catalunya
Barcelona
Spain
08005
(+34) 935513905
mmoharra@gencat.cat

Type(s)

Scientific

Contact name

Prof Jose Cruz Quilez-Conde

Contact details

Hospital Universitario de Basurto
Bilbao
Spain

-

(+34) 944006000
josecruz.quilezconde@osakidetza.eus

Type(s)

Scientific

Contact name

Dr Lourdes Rubio-Rico

Contact details

Universitat Rovira i Virgili
Tarragona
Spain

-

(+34) 977299416
lourdes.rubio@urv.cat

Type(s)

Scientific

Contact name

Ms Demetria Patricio-Peña

Contact details

Institut Català de la Salut

Barcelona

Spain

-

(+34) 675782222

dpatricio.tgn.ics@gencat.cat

Type(s)

Scientific

Contact name

Dr Francesc Valls-Fonayet

Contact details

Universitat Rovira i Virgili

Tarragona

Spain

-

(+34) 977558350

francesc.valls@urv.cat

Type(s)

Scientific

Contact name

Dr Federico Villagrasa-Rocher

Contact details

Centro de Salud Sexual y Reproductiva

Departamento de Alcoi. Conselleria de Sanitat.

Generalitat Valenciana

Valencia

Spain

-

(+34) 966527766

villagrasa_fed@gva.es

Additional identifiers**Protocol serial number**

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

Primary study design

Interventional

Study design

Longitudinal and prospective community clinical trial

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

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

Study participating centre

Consulta Anticoncepción Hospital Clínico Universitario Area 2 y 3
Zaragoza (Aragón)

Spain
50009

Study participating centre
Consulta Atención Primaria CEM Casetas
Spain
50620

Study participating centre
Zona Salud Fuentes de Ebro, Belchite y Azuara
Zaragoza (Aragón)
Spain
50740

Study participating centre
Centro Salud Picarral
Zaragoza (Aragón)
Spain
50015

Study participating centre
Centro de Salud Torrero-La Paz
Zaragoza (Aragón)
Spain
50007

Study participating centre
Centro de Salud San Pablo
Zaragoza (Aragón)
Spain
50003

Study participating centre
Centro de Salud Luna
Zaragoza (Aragón)
Spain
50610

Study participating centre

Centro de Salud Zuera

Zaragoza (Aragón)

Spain

50800

Study participating centre

ASSIR Esquerra - CAP Manso. Institut Català de la Salut

Barcelona (Catalunya)

Spain

08015

Study participating centre

ASSIR Esquerra - CAP Numància. Institut Català de la Salut

Barcelona

Spain

08015

Study participating centre

ASSIR Dreta - Roger de Flor. Institut Català de la Salut

Barcelona (Catalunya)

Spain

08013

Study participating centre

ASSIR Dreta - Pare Claret. Institut Català de la Salut

Barcelona (Catalunya)

Spain

08037

Study participating centre

ASSIR Dreta - La Sagrera. Institut Català de la Salut

Barcelona (Catalunya)

Spain

08027

Study participating centre

ASSIR Muntanya - Ciutat Meridiana. Institut Català de la Salut
Barcelona (Catalunya)
Spain
08033

Study participating centre
ASSIR Muntanya .Chafarines. Institut Català de la Salut
Barcelona (Catalunya)
Spain
08033

Study participating centre
ASSIR Muntanya - Rio de Janeiro. Institut Català de la Salut
Barcelona (Catalunya)
Spain
08016

Study participating centre
ASSIR Muntanya - Guineueta. Institut Català de la Salut
Barcelona (Catalunya)
Spain
08042

Study participating centre
ASSIR Muntanya - Roquetes. Institut Català de la Salut
Barcelona (Catalunya)
Spain
08042

Study participating centre
ASSIR Muntanya - Horta. Institut Català de la Salut
Barcelona (Catalunya)
Spain
08032

Study participating centre

ASSIR Sabadell - CAP St Fèlix. Institut Català de la Salut
Barcelona Metropolitana Nord (Catalunya)
Spain
08204

Study participating centre

ASSIR Sabadell - CAP Creu Alta. Institut Català de la Salut
Barcelona Metropolitana Nord (Catalunya)
Spain
08280

Study participating centre

ASSIR Sabadell - CAP Centre. Institut Català de la Salut
Barcelona Metropolitana Nord (Catalunya)
Spain
08201

Study participating centre

ASSIR Sabadell - CAP Sant Quirze. Institut Català de la Salut
Barcelona Metropolitana Nord (Catalunya)
Spain
08192

Study participating centre

ASSIR Sabadell - CAP N'Oriac. Institut Català de la Salut
Barcelona Metropolitana Nord (Catalunya)
Spain
08207

Study participating centre

ASSIR Sabadell - CAP Castellar. Institut Català de la Salut
Barcelona Metropolitana Nord (Catalunya)
Spain
08211

Study participating centre

ASSIR Mataró - CAP Ronda Prim. Institut Català de la Salut
Barcelona Metropolitana Nord (Catalunya)
Spain
08302

Study participating centre

ASSIR Cerdanyola-Ripollet - CAP Cerdanyola-Ripollet. Institut Català de la Salut
Barcelona Metropolitana Nord (Catalunya)
Spain
08291

Study participating centre

ASSIR Santa Coloma de Gramanet - CAP Santa Coloma de Gramanet. Institut Català de la Salut
Barcelona Metropolitana Nord (Catalunya)
Spain
08922

Study participating centre

ASSIR Sabadell - CAP Can Rull. Institut Català de la Salut
Barcelona Metropolitana Nord (Catalunya)
Spain
08206

Study participating centre

ASSIR Lleida - CAP Pla d'Urgell. Institut Català de la Salut
Lleida (Catalunya)
Spain
25230

Study participating centre

ASSIR Lleida - CAP Almacelles. Institut Català de la Salut
Lleida (Catalunya)
Spain
25100

Study participating centre

ASSIR Lleida - CAP Almenar. Institut Català de la Salut
Lleida (Catalunya)
Spain
25126

Study participating centre
ASSIR Lleida - CAP La Bordeta. Institut Català de la Salut
Lleida (Catalunya)
Spain
25001

Study participating centre
ASSIR Lleida - CAP Tàrraga. Institut Català de la Salut
Lleida (Catalunya)
Spain
25300

Study participating centre
ASSIR Lleida - CAP Alcarràs. Institut Català de la Salut
Lleida (Catalunya)
Spain
25180

Study participating centre
ASSIR Lleida - CAP Capponet. Institut Català de la Salut
Lleida (Catalunya)
Spain
25001

Study participating centre
ASSIR Lleida - CAP Eixample . Institut Català de la Salut
Lleida (Catalunya)
Spain
25006

Study participating centre

ASSIR Lleida - CAP Onze de Setembre . Institut Català de la Salut
Lleida (Catalunya)
Spain
25005

Study participating centre
ASSIR Lleida - CAP Agramunt . Institut Català de la Salut
Lleida (Catalunya)
Spain
25310

Study participating centre
ASSIR Lleida - CAP Artesa . Institut Català de la Salut
Lleida (Catalunya)
Spain
25730

Study participating centre
ASSIR Lleida - CAP Ponts . Institut Català de la Salut
Lleida (Catalunya)
Spain
25740

Study participating centre
ASSIR Lleida - CAP Apicat . Institut Català de la Salut
Lleida (Catalunya)
Spain
25110

Study participating centre
ASSIR Lleida - CAP Torrefarrera . Institut Català de la Salut
Lleida (Catalunya)
Spain
25123

Study participating centre

ASSIR Lleida - CAP Primer de Maig . Institut Català de la Salut
Lleida (Catalunya)
Spain
25003

Study participating centre
ASSIR Lleida - CAP Cervera . Institut Català de la Salut
Lleida (Catalunya)
Spain
25200

Study participating centre
ASSIR Lleida - CAP Balafia . Institut Català de la Salut
Lleida (Catalunya)
Spain
25005

Study participating centre
ASSIR Lleida - CAP Les Borges Blanques . Institut Català de la Salut
Lleida (Catalunya)
Spain
25400

Study participating centre
ASSIR Lleida - CAP 11 de setembre . Institut Català de la Salut
Lleida (Catalunya)
Spain
25005

Study participating centre
ASSIR Tarragona-Valls - CAP Jaume I . Institut Català de la Salut
Tarragona (Catalunya)
Spain
43005

Study participating centre

ASSIR Tarragona-Valls - CAP Sant Pere i Sant Pau . Institut Català de la Salut
Tarragona (Catalunya)
Spain
43007

Study participating centre

ASSIR Tarragona-Valls - CAP Torreforta . Institut Català de la Salut
Tarragona (Catalunya)
Spain
43006

Study participating centre

ASSIR Tarragona-Valls - CAP Bonavista . Institut Català de la Salut
Tarragona (Catalunya)
Spain
43100

Study participating centre

ASSIR Tarragona-Valls - CAP Salou . Institut Català de la Salut
Tarragona (Catalunya)
Spain
43840

Study participating centre

ASSIR Reus-Altebrat - CAP Sant Pere . Institut Català de la Salut
Tarragona (Catalunya)
Spain
43202

Study participating centre

Hospital Joan XXIII . Institut Català de la Salut
Tarragona (Catalunya)
Spain
43005

Study participating centre

ASSIR Tarragona-Valls - CAP Valls . Institut Català de la Salut
Tarragona (Catalunya)
Spain
43800

Study participating centre
Centre de Salut Sexual y Reproductiva de Alcoi
Alcoi-Alicant (Comunitat de València)
Spain
203801

Study participating centre
Instituto Gallego de Ginecología. HM La Rosaleda (Santiago de Compostela)
Santiago de Compostela (Galicia)
Spain
15701

Study participating centre
Centro de Salud Porto do Son y Lousame (EOXI Santiago)
Acoruña (Galicia)
Spain
15970

Study participating centre
Centro de Salud O Pino y Touro (EOXI Santiago)
Acoruña (Galicia)
Spain
15821

Study participating centre
Centro de Salud Ordes (EOXI Santiago)
Acoruña (Galicia)
Spain
15680

Study participating centre

Centro de Salud Melide (EOXI Santiago)

Acoruña (Galicia)

Spain

15800

Study participating centre

Centro de Salud Portazgo Culleredo (EOXI A CORUÑA)

Acoruña (Galicia)

Spain

15174

Study participating centre

Centro de Salud Narón (EOXI Ferrol)

Acoruña (Galicia)

Spain

15570

Study participating centre

Centro de Salud Neda (EOXI Ferrol)

Acoruña (Galicia)

Spain

15510

Study participating centre

Centro de Salud San Roque (EOXI Lugo, Cervo e Monforte de Lemos)

Lugo (Galicia)

Spain

27002

Study participating centre

CS Ribadavia (EOXI Ourense, Verín e O Barco de Valdeorras)

Ourense (Galicia)

Spain

32400

Study participating centre

COF Novoa Santos (EOXI Ourense, Verín e O Barco de Valdeorras)
Ourense (Galicia)
Spain
32003

Study participating centre
Centro de Salud Monteporreiro (EOXI Pontevedra e O Salnés)
Pontevedra (Galicia)
Spain
36162

Study participating centre
Centro de Salud Ponteareas (EOXI Vigo)
Pontevedra (Galicia)
Spain
36860

Study participating centre
Centro de Salud Legazpi (DA Norte)
Madrid (Madrid)
Spain
28045

Study participating centre
Centro de Salud Los Cármenes (DA Centro)
Madrid (Madrid)
Spain
28047

Study participating centre
CS General Fanjul (DA Centro)
Madrid (Madrid)
Spain
28044

Study participating centre

CS Embajadores (DA Norte)

Madrid (Madrid)

Spain

28012

Study participating centre

Centro de Salud Juan de la Cierva (DA Sur)

Madrid (Madrid)

Spain

28901

Study participating centre

Consulta planificación, CARPA, Logroño, La Rioja

La Rioja-Logroño (Pais Vasco)

Spain

26004

Study participating centre

Hospital Donostia (San Sebastián – Gipuzkoa)

San Sebastián-Gipuzkoa (Pais Vasco)

Spain

20014

Study participating centre

Hospital Alto Deba (Arrasate-Mondragón).- Gipuzcoa

Arrasate-Gipuzkoa (Pais Vasco)

Spain

20500

Study participating centre

Hospital de Mendaro, (Mendaro) (Gipuzkoa)

Mendaro-Gipuzkoa (Pais Vasco)

Spain

20850

Study participating centre

Clínica Euskalduna (Bilbao - Bizkaia)

Bilbao - Bizkaia (Pais Vasco)

Spain

48008

Study participating centre

Clínica Ginecológica Bilbao (Bilbao – Bizkaia)

Bilbao (Pais Vasco)

Spain

48006

Study participating centre

Hospital Universitario de Basurto (Bilbao - Bizkaia)

Bilbao (Pais Vasco)

Spain

48013

Study participating centre

Centro de Salud Olárizu. Vitoria (Araba)

Vitoria (Pais Vasco)

Spain

01006

Study participating centre

Centro de Salud Lutxana OSI BDO-Sestao Bizkaia

Bizkaia (Pais Vasco)

Spain

48903

Study participating centre

Centro de Salud La Paz ,Cruces (Barakaldo – Bizkaia)

Bizkaia (Pais Vasco)

Spain

48903

Study participating centre

Centro de Salud Markonzaga, Sestao (Bizkaia)
Bizkaia (Pais Vasco)
Spain
48903

Sponsor information

Organisation

Universitat Rovira i Vigili

ROR

<https://ror.org/00g5sqv46>

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)

SaludISCI, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCI), ISCI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

Results and Publications

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?
Protocol article		04/09/2019	11/01/2022	Yes	No
Other publications		27/11/2021	11/01/2022	Yes	No