

# A program to promote positive mental health through the web and an app

<b>Submission date</b> 23/04/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/05/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/01/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The care of chronic and/or dependent patients falls mainly on non-professional caregivers and constitutes an intensive and extensive task over the years, compromising the health of the caregiver. Caring for the caregiver is an essential element in ensuring the care of patients and the maintenance of their quality of life, as well as significantly reducing the costs of care and the use of health services. The aim of this study is to evaluate the effectiveness of the "CuidadorasCronicos" website ([www.cuidadorasronicos.com](http://www.cuidadorasronicos.com)) and mobile phone application to promote the positive mental health of non-professional caregivers of people with chronic problems.

### Who can participate?

Non-professional caregivers of chronically ill patients, aged over 18, selected from those attending the primary care team and/or users of family associations in the cities of Tarragona, Reus, Tortosa, Barcelona and Alicante (Spain)

### What does the study involve?

Caregivers are randomly allocated to one of two groups. The caregivers in the intervention group can access the mobile phone application. This mobile phone application has been designed as an intervention program that lasts at least a month. During a month, the caregiver performs activities related to promoting positive mental health. The mobile phone application includes gamification, motivational phrases and questions to evaluate their emotions over 28 days (4 weeks). The program includes references to the website "CuidadorasCronicos" where the caregiver can continue using this tool after the study. The caregivers in the control group have regular attention from the primary care team. After the study, the app is offered to this group. Measurements are taken in both groups at the beginning of the study, after the first month and then at the third and sixth month. Positive mental health scores are compared between the two groups.

### What are the possible benefits and risks of participating?

The results obtained from this study may show the utility of an interventional program to promote positive mental health in caregivers and prevent care burden. 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?

1. CAP Sant Boi
2. CAP Riu Nord
3. CAP Riu Sud
4. CAP Llevant
5. CAP Jaume I
6. CAP Tarraco
7. CAP Alt Penedés
8. CAP Maria Fortuny
9. CAP Dr. Gimbernat
10. CAP Temple
11. CAP Baix Ebre
12. CAP Roquetes
13. CAP Amposta I

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

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?

1. Dr Carme Ferré-Grau  
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2. Dr Nuria Albacar-Rioboó  
nuria.albacar@urv.cat
3. Dr Laia Raigal-Aran  
laia.raigal@urv.cat

### **Study website**

<http://www.cuidadorascronicos.com/web/infoApp.php>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

PI16/01576

## Study information

**Scientific Title**

Effectiveness of a program to promote positive mental health through the web and an app  
"Cuidadoras crónicas": a randomized clinical trial

**Acronym**

Cuidadoras crónicas

## **Study objectives**

Non-professional caregivers who use the web and the App "CuidadorasCronicos", as a complement to face-to-face care, will have better positive mental health than the nonprofessional caregiver control group that uses only the professional's usual care.

The study primary outcome is:

1. To assess the effectiveness of the web and App "CuidadorasCronicos" in promoting positive mental health for non-professional caregivers of people with chronic health problems.

The study secondary outcomes are:

1. Design an mHealth tool to promote the positive mental health of non-professional caregivers.
2. Design and implement an intervention program to improve overall positive mental health and each of the six factors (personal satisfaction, prosocial attitude, self-control, autonomy, problem-solving, interpersonal relationship skills).
3. Evaluate the total positive mental health and by factors of the pre and post intervention caregivers.
4. To compare the differences in the evolution of the overall positive mental health and by factors between the caregivers of the intervention group with respect to the control group.
5. To identify the degree of adherence to the intervention and satisfaction in the use of the website and the App "CuidadorasCronicos" for caregivers.
6. To measure the degree of use of the web and the App by the caregivers.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 08/03/2019, 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, ref: P18/207

## **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)**

Quality of life

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

## **Health condition(s) or problem(s) studied**

Mental health of caregivers

## **Interventions**

The study involves a control group and an experimental group of non-professional caregivers of chronically ill patients. These will be included in the study from the primary care centres participating in the study. These will be randomly assigned to the control group or intervention. The assignment to the control group and experimental group will be made using the non-commercial Epidat 3.0 software.

In the control group, they will receive regular care from the health professionals in the centre.

In the intervention group, in addition to regular care by the health professional, they will participate in a 1-month program to promote positive mental health through a mobile application (App). For 1 month, they will receive daily activities based on the positive mental health decalogue (Lluch, 2011) and related to the tasks of caring for the family member. The App includes daily motivational phrases, a greeting to evaluate the daily emotional state and basic gamification by the activities performed by the user. The App is related to the website [www.cuidadoraschronicos.com](http://www.cuidadoraschronicos.com), which is presented during the month of intervention to be a tool to use after the App program.

## **Intervention Type**

Device

## **Phase**

Not Applicable

## **Primary outcome measure**

The effectiveness of the website and App "CuidadorasCronicos" in promoting positive mental health for non-professional caregivers of people with chronic health problems, measured using the scale of Positive Mental Health (Lluch, 2008) at the start of the study and at 1, 3, and 6 months

## **Secondary outcome measures**

1. Sociodemographic characteristics of the caregiver measured using an ad hoc questionnaire at the start of the study
2. Caregiving burden measured using Zarit Burden Inventory at the start of the study and at 1, 3, and 6 months
3. Satisfaction with the App measured using questionnaire (intervention group only) at the end of the App intervention

## **Overall study start date**

01/01/2019

## **Completion date**

31/12/2019

## **Eligibility**

### **Key inclusion criteria**

1. Primary, secondary and formal non-professional family caregivers of people with chronic health problems with a minimum of 4 months of experience
2. Caregivers over 18 years of age
3. Caregivers using a mobile device and WhatsApp
4. Access to a mobile device with Android operating system
5. Consent to participate
6. Comprehension and reading of Spanish language

**Participant type(s)**

Carer

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

54 in each group (control and experimental)

**Total final enrolment**

113

**Key exclusion criteria**

1. Caregivers with cognitive impairment
2. Caregivers who do not understand Spanish or do not have access to the Internet

**Date of first enrolment**

01/03/2019

**Date of final enrolment**

01/10/2019

**Locations****Countries of recruitment**

Spain

**Study participating centre**

CAP Sant Boi

Sant Boi (Barcelona)

Spain

08830

**Study participating centre**

**CAP Riu Nord**

Santa Coloma de Gramenet (Barcelona)

Spain

08921

**Study participating centre**

**CAP Riu Sud**

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**Study participating centre**

**CAP Llevant**

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43007

**Study participating centre**

**CAP Jaume I**

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08720

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**Study participating centre**

**CAP Baix Ebre**  
Tortosa (Tarragona)  
Spain  
43500

**Study participating centre**

**CAP Roquetes**  
Roquetes (Tarragona)  
Spain  
43520

**Study participating centre**

**CAP Amposta I**  
Amposta (Tarragona)  
Spain  
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## **Sponsor information**

**Organisation**

Universitat Rovira i Vigili



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**Sponsor type**

University/education

**Website**

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**ROR**

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

**Funder(s)****Funder type**

Government

**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)

**Results and Publications****Publication and dissemination plan**

Planned three publications in a high-impact peer-reviewed journal:

1. The design of the project (June 2019)
2. An App revision over caregivers (May 2019)
3. Results of the study (end of 2019)

**Intention to publish date**

31/12/2019

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Carme Ferré Grau ([carme.ferre@urv.cat](mailto:carme.ferre@urv.cat)). Data will be available at the end of the study (around 2020).

**IPD sharing plan summary**

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	05/07/2019	09/12/2020	Yes	No
<a href="#">Results article</a>	results	22/01/2021	25/01/2021	Yes	No