

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

Submission date 23/04/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/05/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/01/2021	Condition category 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) 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
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3. Dr Laia Raigal-Aran
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Study website

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

Contact information

Type(s)

Public

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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, 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

Santa Coloma de Gramenet (Barcelona)

Spain

08921

Study participating centre

CAP Llevant

Tarragona (Tarragona)

Spain

43007

Study participating centre

CAP Jaume I

Tarragona (Tarragona)

Spain

43007

Study participating centre

CAP Tarraco

Tarragona (Tarragona)

Spain

43007

Study participating centre

CAP Alt Penedés

Vilfranca del Penedès (Barcelona)

Spain

08720

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43520

Study participating centre

CAP Amposta I
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Sponsor information

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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). 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?
Protocol article	protocol	05/07/2019	09/12/2020	Yes	No
Results article	results	22/01/2021	25/01/2021	Yes	No