Health behaviours, lifestyles, and addictions in a population with affective-emotional problems from primary care

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | | |
|-------------------|---|---|--|--|--|
| 21/03/2022 | | [X] Protocol | | | |
| Registration date | Overall study status Ongoing Condition category | Statistical analysis plan | | | |
| 10/05/2022 | | ☐ Results | | | |
| Last Edited | | Individual participant data | | | |
| 18/07/2023 | Mental and Behavioural Disorders | Record updated in last year | | | |

Plain English summary of protocol

Background and study aims

From the perspective of the health system, studies confirm that 25-35% of patients who consult primary care suffer from a psychiatric disorder and that more than 80% of them are depression and anxiety disorders. It is interesting to propose various approaches to depression from the primary care setting, among which programs that promote health and change lifestyles are implemented. Today and in more and more studies it is being shown that prevention programs reduce depression in any age range. It has also been observed that healthy lifestyle and exercise programs are effective in preventing affective disorders and addictions. The main aim of this study is to analyze the relationships between personal factors on health behaviour and lifestyle habits.

Who can participate?

People from Aragón (Spain) between the ages of 35 and 74 years

What does the study involve?

Participants answer questions about their lifestyle, perceived quality of life, health behaviours, and addictions. A blood sample will be collected and analysed. The researchers will collect from their medical history if they suffer from any other type of chronic illness, and any drug treatments that they are taking. This first evaluation will last 45 minutes. A total of two visits will be required. Participants will have to travel to a care centre that may not be close to their place of residence, for which there will be no financial compensation.

What are the possible benefits and risks of participating?

As this is a research study aimed at generating knowledge, it is unlikely that participants will obtain any personal benefit from participation, although they will contribute to scientific advancement and social benefit. Participants will not receive any financial compensation. Both for the evaluation and for the blood sample that will be done in this study, participants are not at risk and should not have any discomfort. The questionnaires to be used do not involve any

invasive or painful tests and are widely used in research and clinical practice. Both the evaluation and the extraction will be carried out by qualified personnel. The only discomfort participants may have is that of the blood sample, which is a small puncture and slight subsequent bleeding.

Where is the study run from? Arrabal Health Center in Zaragoza (Spain)

When is the study starting and how long is it expected to run for? May 2020 to December 2025

Who is funding the study?

- 1. Instituto de Investigación Sanitaria Aragón (Spain)
- 2. Carlos III Institute (Spain)

Who is the main contact? Dr Rosa Magallón Botaya rosamaga@unizar.es

Contact information

Type(s)

Scientific

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Analysis of health behaviours, lifestyles and addictions in a population with affective-emotional problems from primary care: a cohort study

Study objectives

The presence of depressive symptomatology is associated with a low level of health literacy and self-efficacy when seeking, evaluating, understanding and applying health information about self-care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 24/06/2020, Comité de Ética de la Investigación de la Comunidad Autónoma de Aragón (CEICA, Avda. San Juan Bosco, 13, 50009, Zaragoza, Spain; +34 (0)976 716584, +34 (0)976 715836; ceica@aragon.es), ref: C.P. - C.I. PI20/302

Study design

Prospective randomized cohort study

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Affective-emotional problems

Interventions

From the health center, an information letter will be sent to the participants obtained from said randomization, which includes information on the study procedure and contact details of the research unit so that the participants who are interested in it can contact the equipment for the corresponding initial appointment of the study. The research assistant will call patients who have shown interest in participating in the study and an appointment will be made at their health center. In said appointment, the study will be explained, the inclusion and exclusion criteria will be confirmed, the patient's file will be provided and the informed consent will be signed. If the participants meet the criteria, the research assistant will administer the different questionnaires at the same appointment. At the end of the questionnaire, the researcher prepares a new appointment for blood collection at their assigned health center.

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measures as of 30/08/2022:

- 1. Severity of depression measured using the Beck Depression Inventory-II (BDI-II) at baseline and 5 years
- 2. Severity of depression measured using the PHQ-9 at baseline and 5 years
- 3. Anxiety level measured using the Generalized Anxiety Disorder-7 (GAD-7) at baseline and 5 years

Previous primary outcome measure:

Severity of depression measured using the Beck Depression Inventory-II (BDI-II) at baseline and 5 years

Key secondary outcome(s))

Current primary outcome measures as of 30/08/2022:

- 1. Sense of coherence measured using the Sense of Coherence Questionnaire (SOC-13) at baseline and 5 years
- 2. Self-esteem measured using the Rosenberg Questionnaire at baseline and 5 years
- 3. Comorbidity with chronic diseases determined according to the International Classification of Diseases, Tenth Revision (ICD-10) at baseline and 5 years
- 4. Clinic variables (TA, Sat O_2 %, BMI, temperature) measured on exploration at baseline and 5 years
- 5. Analytics (basic biochemistry, hemogram, and coagulation) measured using a complete blood count at baseline and 5 years.
- 6. Work-family interaction measured using the Work-Family Interaction Questionnaire (SWING) at baseline and 5 years
- 7. Quality of life in menopausal women measured using the Cervantes Scale at baseline and 5 years
- 8. The frequency of consumption of substances such as tobacco, alcohol, and narcotic substances measured using an ad hoc questionnaire prepared by the research team at baseline and 5 years
- 9. Alcohol use disorder measured with the Alcohol Use Disorders Identification Test (AUDIT) questionnaire at baseline and 5 years
- 10. Pathological gambling measured with the Brief Pathological Gambling Questionnaire (CBJP) at baseline and 5 years
- 11. Addiction to the use of information and communication technologies measured using the MULTICAGE-TIC Questionnaire at baseline and 5 years

- 12. Self-efficacy measured with General Self Efficacy Scale-12 (GSES-12) at baseline and 5 years
- 13. Resilence is measured with Connor–Davidson Resilience Scale (CD-Risc-10) at baseline and 5 years
- 14. Patient activation measured with Patient Activation Questionnaire (PAM-13) at baseline and 5 years
- 15. Health literacy measured with Health Literacy Survey European Questionnaire (HLS-EU-Q16) at baseline and 5 years
- 16. Personality measured with Big Five Inventory-10 (BFI-10) at baseline and 5 years
- 17. Quality of life measured with European Quality of Life-5 Dimensions Questionnaire (EQ-5D + VAS) at baseline and 5 years
- 18. Diet measured with Mediterranean Diet Adherence Screener (MEDAS-17) at baseline and 5 years
- 19. Sleep quality measured with Pittsburgh Sleep Quality Index (PSQI) at baseline and 5 years
- 20. Physical activity measured with International Physical Activity Questionnaire-Short Form (IPAQ-SF) at baseline and 5 years

Previous secondary outcome measures:

- 1. Sense of coherence measured using the Sense of Coherence Questionnaire (SOC-13) at baseline and 5 years
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- 11. Addiction to the use of information and communication technologies measured using the MULTICAGE-TIC Questionnaire at baseline and 5 years

Completion date

01/12/2025

Eligibility

Key inclusion criteria

- 1. People aged 35 to 74 years from Aragón (Spain)
- 2. Understand spoken and written Spanish
- 3. Informed consent in writing

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

400

Key exclusion criteria

- 1. Suffering from a terminal illness
- 2. Being institutionalized at the time of the appointment
- 3. Suffering from an intellectual disability, dementia, or any serious pathology that may seriously interfere with the patient's participation in the study

Date of first enrolment

30/03/2022

Date of final enrolment

30/06/2022

Locations

Countries of recruitment

Spain

Study participating centre

Servicio Aragonés de Salud -Unidad de Investigación Atención Primaria

Aragonese Research Group in Primary Care (GAIAP) Institute of Health Research Avenue San Juan Bosco, 13 Zaragoza Spain 50015

Sponsor information

Organisation

Instituto de Investigación Sanitaria Aragón

ROR

https://ror.org/03njn4610

Funder(s)

Funder type

Research organisation

Funder Name

Instituto de Investigación Sanitaria Aragón

Funder Name

Instituto de Salud Carlos III

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, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient- facing? |
|----------------------------------|--|-----------------|----------------|-------------------|---------------------|
| Protocol article | | 09/06 /2023 | 27/06 /2023 | Yes | No |
| Interim results article | Secondary analysis of baseline data from observational study | 04/07 /2023 | 18/07 /2023 | Yes | No |
| Participant information sheet | version 3 | 26/06 /2020 | 28/03 /2022 | No | Yes |

Participant information sheet

Participant information sheet

11/11 /2025 11/11 /2025

No

Yes