

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

Submission date 21/03/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/05/2022	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/07/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

GP practice

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

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 measure

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

Secondary outcome measures

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 O₂ %, 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. Resilience 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
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Previous secondary outcome measures:

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 O₂ %, 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
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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

Overall study start date

31/05/2020

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

Participant type(s)

Mixed

Age group

Adult

Sex

Both

Target number of participants

380

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)

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Sponsor information

Organisation

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Sponsor type

Research organisation

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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)

SaludISCI, Instituto de Salud Carlos III, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal and exhibition at international conferences.

Intention to publish date

31/01/2023

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?
Participant information sheet	version 3	26/06/2020	28/03/2022	No	Yes
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