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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

Registration date
10/05/2022

Overall study status
Completed

Last Edited
18/07/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Clinical Trials Information System (CTIS)
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

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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

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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

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
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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