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Training of primary care practitioners to improve the management of common mental health disorders

Submission date	Recruitment status	[_] Prospectively registered
24/06/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
27/06/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/05/2026	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Mental health disorders are a major cause of disability worldwide, accounting for over 30% of the burden measured in terms of years of healthy life lost. These disorders can greatly worsen people's lives by reducing their overall well-being. The most common and burdensome mental health disorders include depression, anxiety, somatoform disorders, and suicidal behaviors, collectively known as common mental disorders (CMD). CMDs can lead to higher rates of suicide, increased healthcare expenses, and decreased productivity at work. Unfortunately, many family doctors in different countries lack sufficient knowledge to recognize, treat, and manage these issues, resulting in poor mental health literacy. Similarly, the general population also has limited understanding of mental health, making it difficult for those affected by CMDs to seek appropriate help and care. It is crucial to educate these individuals on how to cope with their disorders through psychoeducation. Affordable programs aimed at assisting people with mental health problems can involve training primary care professionals to better handle CMDs and establishing psychoeducational groups for patients attending primary care clinics.

Who can participate?
Adults over 18 years, suffering from common mental health disorders.

What does the study involve?
These are the basic interventions of this study: to train primary care professionals and psychoeducate CMD patients in order to improve the outcomes of these patients measured by depressive, anxiety, somatic symptoms and suicidal behaviours.

What are the possible benefits and risks of participating?
The potential benefit for patients is improving their mental health literacy and potential risks are time spent on the attendance of the courses. If the concepts are misunderstood it can lead to incorrect scientific knowledge.The risks for patients are nil since in control condition treatment as usual will be applied whereas in case condition GPs and other primary care professionals are expected to address CMD patients more adequately.

Where is the study run from?
The study was run in primary care practices in Portugal, Lisbon area, coordinated by NOVA Medical School in Lisbon. The analysis has now been taken over by the Instituto de Saúde Pública da Universidade do Porto (ISPUP).

When is the study starting and how long is it expected to run for?
July 2007 to May 2013

Who is funding the study?
Fundação para a Ciência e Tecnologia (FCT; Foundation for Science and Technology Portugal)

Who is the primary contact?
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Contact information

Type(s)
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Additional identifiers

Protocol serial number
PIC/IC/82737/2007

Study information

Scientific Title
Improving symptoms of patients affected by common mental health disorders in primary care: a cluster randomised control trial of a combined intervention

Acronym
PSITRAIN

Study objectives
Hypothesis 1: A training programme for all health care practitioners in a primary care clinical unit will have a higher effect on the wellbeing and symptoms of patients diagnosed with common

mental disorders than an awareness session.
Hypothesis 2: Patients with common mental disorders attending psychoeducational sessions led by trained primary care practitioners will improve more in wellbeing and symptoms than patients that did not receive it in the intervention group.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/07/2011, Comissão de Ética da Faculdade de Ciências Médicas da Universidade Nova de Lisboa (CEFCM-UNL) -- The Ethical Committee of the NOVA Medical School, NOVA University of Lisbon (Campo dos Mártires da Pátria 130, Lisbon, 1169-056, Portugal; +351 21 8803039; cefcm@fcm.unl.pt), ref: Nil known

Primary study design
Interventional

Study design
Cluster randomized controlled trial

Study type(s)
Diagnostic, Prevention, Quality of life, Screening, Treatment

Health condition(s) or problem(s) studied
Management of common mental disorders in patients attending primary care practices

Interventions
The intervention is a two-level training programme.

(1) Training for professionals: in the case condition arm, we led one programme of 8-hour to family doctors to improve the management of primary care patients affected by CMD involving enhancing recognition, diagnosis, treatment, referral and general management; another 8-hour programme to nurses and clinical psychologists to strengthen and capacitate for psychoeducational sessions. In the condition control arm, all health practitioners were offered a 2-hour awareness session on mental health in primary care and clinical care, as usual (tau), was in place. All primary care practitioners were invited to participate in the training program (case) or awareness session (control). It was a condition to be accepted by enrolled primary care practices in the study to avoid contamination or bias. All GPs were trained in the procedures to select patients (see below).
(2) Psychoeducation for patients: voluntary nurses and clinical psychologists in the case condition arm were supported to create psychoeducational patient groups consisting of six weekly sessions of 75 minutes each. No such intervention was offered on the condition control arm, and clinical care was in place as usual (tau).

Participants in case and control conditions were recruited through the following steps (CONSORT guidelines for cRCT).

(1st step) Selection of clusters: for this study, the Metropolitan Region of Lisbon and the Setúbal Peninsula Region were chosen by convenience, aggregating 16 Groups of Health Centres (GHC; Agrupamentos de Centros de Saúde - ACES), including 90 eligible multi-professional primary care practices of higher-level management and services, called Health Family Units (HFU; Unidades

Funcionais de Saúde - USF). We excluded primarily 27 HFUs because projects of primary care professionals training on mental ill-health were currently or had been implemented in the integrating GHCs, in the last three years (Cascais, Oeiras, Amadora, Almada). Therefore, 12 GHCs and 63 HFUs were still considered eligible, and their coordination was contacted to whom the study was described. The question was raised if they would consider entering the project and replying to fill out a written consent mail. Twenty-two HFUs explicitly sent written non-consent, four failed to respond, and two were excluded because of other reasons (lack of human resources, about to be changed organically); thus, 35 HFUs gave written consent and were eligible to enter the randomisation matrix and procedure.

(2nd step) Randomisation procedure: Knowing that each HFU typically integrates between 5 to 10 GPs, we randomised HFUs until each arm reached a minimum of 14 GPs. Five HFUs were randomised, two for the control arm and three for the case arm. The case arm had 24 GPs (the two first to be randomised counted 14 GPs, but to be on the safe side, we randomised a third one which comprised 10 GPs), and the control arm had 14 GPs (one HFU with nine GPs and another with five GPs).

(3rd step) Power calculation and participants: the international literature (no available information in Portugal) pointed to a minimum sample size of 142 patients per group (80% power with a two-sided significance of 5%). Cautiously, the study aimed to enrol 160 patients per arm (or 320 patients) recruited by GPs.

(4th step) General practitioners to enrol participants: according to the number of patients needed for both arms, 320 included and accepting patients, and previous research in Portugal (Gusmão, 2005) where for 100 consecutive patients, 39 presented a WHO-5 screening score less or equal to 7, we needed at least 820 patients screened by GPs, 410 per arm to select 160 patients per arm. We required the minimum number of 14 GPs per arm because we expected each would contribute with around 30 patients recruited, ending with about 12 selected and enrolled participants.

(5th step) Participants (patients) enrolment: firstly, consecutive patients were recruited by all primary care practitioners that worked in the selected primary care practices, HFUs, in successive consultations. The practitioners applied the screening instruments during the scheduled consultation and also the informed consent form: they looked for an International Classification for Primary Care, second version (ICPC-2) clinical diagnosis; they measured the Clinical Global Improvement Severity scale (CGI-S), and patients were asked to complete the Five Wellbeing Index scale (WHO-5).
A total of 827 patients were approached (case=409, control 418); 812 were screened (case=406, control 406); 427 were positive either by presenting a WHO-5 <=7 or a mental health condition with a CGI-S >=4 or a GP particular indication complying with a known ICPC2 diagnosis (case=216, control=211); 392 were included because older than 18, with at least 4-year literacy, no follow-up in psychiatric care and no admission in psychiatric inpatient unit (case=195, control=197); 348 gave consent (case=171, control=177) which was the final number of patients included in the study.

Intervention Type
Behavioural

Primary outcome(s)
Total score of the Beck Depression Inventory, the second version (BDI-II; Beck & Steer, 1993), applied by self-evaluation after enrolment and 12 months after the first evaluation.

Key secondary outcome(s)
1. Five Wellbeing Index (WHO-5; WHO, 1995)
2. Clinical Global Impressions scale for diagnostic Severity (CGI-S; Busner and Targum, 2007)
3. International Classification of Primary Care, 2nd edition (ICPC-2; WONCA, 2003)
4. Beck Anxiety Inventory (BAI; Beck & Steer, 1993)
5. Somatic Patient Health Questionnaire (PHQ-15; Kroenke et al., 2010)
6. Beck Scale for Suicide Ideation (BSI; Beck, Kovacs, & Weissman, 1979)
7. Sociodemographic questionnaire

The hetero-evaluation (CGI-S and ICPC-2) and self-evaluation questionnaires (WHO-5, BAI, PHQ-15, BSI) were applied at baseline (t0), intervention and control patients were reassessed on all the variables and measures by their PCPs and the research assistant on follow-up, 12 months later (t1).

Completion date
31/05/2013

Eligibility

Key inclusion criteria
1. Patients scoring seven or less on the WHO-5 scale, or
2. CGI-S scoring four or higher, or
3. Common mental disorder diagnosis according to ICPC-2

Participant type(s)
Health professional, Patient, Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
348

Key exclusion criteria
1. Patients with chronic alcohol abuse (P15), acute alcohol abuse (P16), drug abuse (P19), dementia (P70), organic psychosis (P71), schizophrenia (P72), affective psychosis (P73), mental retardation (P85), anorexia nervosa/bulimia (P86), serious suicidal risk or history of mania
2. Patients with only four years of studies or less who could not read Portuguese

3. 17 years old or younger
4. Patients who had a psychiatric consultation or admission to the hospital due to a psychiatric cause in the previous three months

Date of first enrolment
01/08/2011

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
Portugal

Study participating centre
Centro de Estudos de Doenças Crónicas, NOVA Medical School, NOVA Lisbon University (CEDOC-NOVA)
Campo dos Mártires da Pátria 130
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Sponsor information

Organisation
Instituto de Saúde Publica da Universidade do Porto (ISPUP)

Funder(s)

Funder type
Government

Funder Name
Fundação para a Ciência e a Tecnologia

Alternative Name(s)
Portuguese Science and Technology Foundation, Foundation for Science and Technology, Fundacao para a Ciencia e a Tecnologia, The Foundation for Science and Technology (FCT), FCT

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Portugal

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version 3	03/04/2026	18/05/2026	No	No