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# Effectiveness of brief psychotherapy in the treatment of common mental disorders in public mental health centers

**Submission date**
07/10/2020

**Recruitment status**
No longer recruiting

**Registration date**
03/11/2020

**Overall study status**
Completed

**Last Edited**
29/10/2020

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims
Common mental disorders (CMD), which fundamentally comprise depression, anxiety disorders and adaptive disorders, have a vital prevalence rate close to 20% with the very high cost that this implies at an emotional, social and economic level.
The attention that is being given to CMD, both from Primary Care and from Mental Health, is being almost exclusively psychopharmacological. This is reflected in the fact that almost 17% of the population in Asturias (Spain) is using psychotropic drugs and those benzodiazepines and antidepressants are the most prescribed drugs in the region. This treatment strategy would not be questionable as long as it were proving effective, but reality shows that these treatments tend to become chronic and relapses are very frequent. This means that the level of resolution of the prescribed treatments is very low.
On the other hand, there are numerous studies and meta-analysis that have shown high efficacy of psychological treatments for CMD and the main Clinical Guidelines recommend their application as the first-choice treatment. Nevertheless, the problem is that these studies are carried out in contexts and conditions that are difficult to extrapolate to Public Mental Health Services: very selective samples (up to 70% of cases are excluded), highly protocoled treatments, professionals related to the model and highly trained in the same, greater availability of time, etc.
The first aim of this study is to analyze whether a short psychological treatment program for CMD would be feasible and effective, but adapted and implemented in the real context of Public Services, which implies heterogeneity of disorders and therapists, and high assistance pressure.
The second aim is to analyze whether psychological treatment is more effective and efficient than usual treatment, which is fundamentally psychopharmacological.

Who can participate?
Adult patients (18 and over) with common mental disorders, referred to mental health services by their GP

What does the study involve?
Patients in both groups receive the assigned treatment. In the control group the usual

treatment given in the Mental Health Center, and in the experimental group the Brief Psychotherapy Treatment. Patients including in phase 1 in both groups, must carry out a telephone evaluation interview and complete 3 questionnaires (GSI, SCL-90R and SDI) at 6, 12 and 24 months after the start of treatment. They will also respond to a satisfaction questionnaire at the end of the treatment or 6 months after it started. Patients including in phase 2, in addition to carrying out the same questionnaires as those in phase 1, also answer it before starting treatment.

What are the possible benefits and risks of participating?
Control group patients receive the same treatment as if they had not participated in the research. The risks and benefits are the same as those of the rest of the patients treated in the Mental Health Centers with the usual treatments, mainly psychopharmacological treatments with benzodiazepines and antidepressants. The patients of the experimental group, given that they receive fundamentally psychological treatment, avoid risks associated with an increase in the consumption of psychotropic drugs.

Where is the study run from?
Mental Health Services of the Health Services of the Principality of Asturias (Spain)

When the study starting and how long is it expected to run for?
March 2004 to February 2015

Who is funding the study?
Coordination Unit of Mental Health Services of the Principality of Asturias (Spain)

Who is the main contact?
Dr Javier Fernández Méndez
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# Contact information

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Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
33-2004-2015

# Study information

### Scientific Title
Effectiveness of brief psychotherapy in the treatment of common mental disorders in public mental health centers in comparison with habitual treatment: a clinical randomized trial

### Acronym
EBPCMD

### Study objectives
The main objective of this research is to evaluate the feasibility and efficacy of a brief psychotherapy program in a public context of high care pressure, compared with the usual treatments (psychotropic drugs) used to treat common mental disorders in public Mental Health Centers.

The hypotheses to be verified are that brief psychotherapy is viable in public services, that it is at least as effective as the usual treatment with psychoactive drugs and that it is more efficient.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 30/09/2004, the Comite Ético de Investigación Clínica de Asturias (Asturias Clinical Research Ethics Committee, Hospital Universitario Central de Asturias, Avenida Roma, Oviedo, 33011, Spain; +34 985107927; ceim.asturias@asturias.org)

### Study design

Multicenter interventional randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use contect details to request a participant information sheet

## Health condition(s) or problem(s) studied
Psychological and psychopharmacologic interventions in adult patients with common mental disorders (mainly depressive and anxiety disorders)

## Interventions
285 patients attending six Mental Health Centers for the first time are randomly assigned to two treatment groups, 148 to the experimental group and 137 to the control group.

A brief psychotherapy is applied to the experimental group and can be complemented with psychopharmacological treatment. It is a general and flexible guide with a contextual approach and the common principles of Psychotherapy. It involves the use of techniques from different theoretical models according to the preference of the therapist. It does not have a predetermined number of sessions.

The control group receives the usual treatment, which is fundamentally psychopharmacological and which in some cases is complemented with therapeutic advice and/or psychological treatment.

In a first phase, 76 subjects from the TPB and 67 from the LT are compared, with evaluation at 6, 12, 24 and 36 months after the start of treatment and with double-blind for the control group. In a second phase, 72 subjects from the TPB and 72 from the LT are compared, however, a pre-treatment evaluation is added. Both groups are compared in variables of clinical status, psychosocial functioning and health indicators of treatment and use of services.

## Intervention Type
Mixed

## Primary outcome measure
The result or dependent variables (more than 20) are recorded at each timepoint of follow-up. They analyze the clinical-administrative result, the clinical and disability status, treatment in Primary Care, work situation, consumption of psychotropic drugs, satisfaction, etc. The fundamentals and the measurement instruments used are described below:
1. Clinical-administrative results: describes the status of the patient regarding treatment at the

Mental Health center and consists of the following categories: Continues treatment, Discharge (the patient has been discharged by his/her reference therapist), Abandonment (the patient interrupts treatment against the opinion of the therapist or without having consulted him), Return and Others. Measured at 6, 12, 24 and 36 months after the start of treatment.
2. Clinical status according to the patient evaluated using three scales at 6, 12 and 24 months after the start of treatment. In the second phase it is measured also before the start of treatment:
2.1. Severity scale of the Clinical Global Impression of Severity (CGI-G)
2.2. Scale of change or improvement of the Clinical Global Impression of Change (CGI-C)
2.3. Symptom Check List-90 (SCL-90-R). Three global indices are obtained: Global Severity Index (GSI), Total Positive Symptoms (PST) and Positive Distress Index (PSDI).
3. Degree of disability according to the patient assessed using the Sheehan Disability Inventory at 6, 12 and 24 months after the start of treatment. In the second phase it is also measured before the start of treatment
4. Consumption of psychotropic drugs: only antidepressant drugs and benzodiazepines are analyzed because the consumption of other psychotropic drugs is minimal. The amounts have been standardized according to the equivalence of each medication with the reference drug in each group (equivalence in milligrams of imipramine in the case of antidepressants and in milligrams of lorazepam in the case of benzodiazepines), measured at 6, 12, 24 and 36 months after the start of treatment
5. Recovery Index: this variable has been constructed from a combination of data obtained from the Clinical History of Mental Health and Primary Care, giving priority to those that would be objective indicators of the use of services and treatments. Thus, the researchers have considered recovered cases those who do not follow treatment at the CSM or take psychotropic drugs, have not had more than one consultation in PC in the last 6-12 months for mental health reasons and have not had any days off due to mental health problems in the last 6 - 12 months. Evaluated at 12, 24 and 36 months after the start of treatment.

### Secondary outcome measures
Patient satisfaction with the treatment evaluated using the Satisfaction Questionnaire by Moré and Muñoz (2000) at the end of the treatment

### Overall study start date
01/03/2004

### Completion date
20/02/2015

## Eligibility

### Key inclusion criteria
The sample is randomly selected from among the people referred from primary care to six mental health centers of the public health services of the Principality of Asturias:
1. Over 18 years old
2. Go to that CSM for the first time
3. Diagnosed according to ICD-10 of depressive or anxiety disorders
4. Attend at least at one consultation with the therapist
5. Agree to participate in the research

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
200

### Key exclusion criteria
1. Diagnosed according to ICD-10 criteria of organic mental disorder, psychosis, addictions, eating disorder, mental retardation, psychological development disorder or serious personality disorder (Paranoid, Schizoid, Disocial and Emotional Instability)
2. Have made a serious suicide attempt in the previous 6 months
3. No required specialized care (those cases that do not require treatment are excluded)

### Date of first enrolment
11/02/2005

### Date of final enrolment
13/11/2006

## Locations

### Countries of recruitment
Spain

### Study participating centre
**La Calzada Mental Health Center II**
Simón Bolívar Street
Gijón
Spain
33213

### Study participating centre
**Pumarín Mental Health Center IV**
Orán Street
Gijón
Spain
33211

### Study participating centre
**Luarca Mental Health Center**
El Villar, s/n
Luarca
Spain
33700

### Study participating centre
**La Eria Mental Health Center I**
Alejandro Casona Street
Oviedo
Spain
33013

### Study participating centre
**Teatinos Mental Health Center II**
Puerto del Ponton Street
Oviedo
Spain
33011

### Study participating centre
**Otero Mental Health Center III**
11, Otero Street
Oviedo
Spain
33008

## Sponsor information

### Organisation
Unidad de Coordinación de salud mental del Principado de Asturias (Mental Health Coordination Unit of the Healthcare Services of the Principality of Asturias)

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### Sponsor type
Hospital/treatment centre

### Website
https://www.astursalud.es

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Servicio de Salud del Principado de Asturias, SESPA (Healthcare Services of the Principality of Asturias)

## Results and Publications

### Publication and dissemination plan
1. Planned publication of the results of Phase I in a Spanish national journal.
2. Planned publication of the results of Phase II in a high-impact peer-reviewed journal.

### Intention to publish date
01/10/2010

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | phase one results | 01/10/2010 | 29/10/2020 | Yes | No |
| Thesis results | phase two results | 20/02/2015 | 29/10/2020 | No | No |