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Applicability of the ICF in measuring functioning and disability in unipolar depression in Primary Care settings

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Introduction. We use the biopsychosocial model of the International Classification of Functioning, Disability, and Health (ICF): *a)* to analyze functioning and disability patterns in unipolar depression cases attended in primary care settings; *b)* to study predictive and mediator variables related to disability in depression, and *c)* to determine the impact of traditional interventions in depression cases using functional remission as outcome measure.

Design. Naturalistic, prospective, longitudinal.

Setting. Multicenter study in primary care. Health Area 2. Region of Madrid.

Participants. Adult patients with a diagnosis of unipolar depression who initiate psychopharmacological treatment with selective serotonin reuptake inhibitor (SSRI) in primary care sites. Patients with history of bipolar disorders, psychotic disorders, dementias, and dependence of toxic substances will be excluded.

Main measurements. Level of functioning and disability in different domains of well-being assessed through ICF related instruments. Stressful life events, social support and cognitive schemes will be analyzed as mediator variables. Socio-demographic and clinical characteristics, psychopharmacological treatment and treatment compliance are considered independent factors.

Discussion and practical use. Selection bias may affect the generalization of the results. The biopsychosocial model underlying the ICF and its methodology are applied to the study of depression in primary care settings for the first time in Spain. Improving our understanding of disability related factors in depressive patients is expected. This study is one of the main research priorities of the EU (MHADIE project).

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Depression. Functioning. Disability. ICF. Primary care.

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Aplicación de la CIF para el estudio y evaluación del funcionamiento y la discapacidad en depresión unipolar en el ámbito de atención primaria

Introducción. Se emplea el modelo biopsicosocial de la Clasificación Internacional del Funcionamiento, la Discapacidad y la Salud (CIF) para: *a)* estudiar el perfil de funcionamiento en depresión unipolar tratada en atención primaria; *b)* determinar variables predictoras y mediadoras de discapacidad en depresión, y *c)* analizar la eficacia del tratamiento psicofarmacológico habitual en la remisión funcional de pacientes con depresión.

Diseño. Naturalístico, longitudinal, prospectivo.

Emplazamiento. Estudio multicéntrico en atención primaria. Centros del Área 2 de la Comunidad de Madrid.

Participantes. Pacientes adultos con diagnóstico de depresión unipolar que inician tratamiento con inhibidores selectivos de la recaptación de serotonina en centros de atención primaria. Se excluirán los pacientes con historia de trastorno bipolar, trastornos psicóticos, demencias y con historia de dependencia de sustancias adictivas.

Medidas principales. Nivel de discapacidad en distintas áreas de funcionamiento evaluado con instrumentos desarrollados a partir de la CIF. Sucesos vitales estresantes, apoyo social y esquemas cognitivos serán explorados como variables mediadoras del funcionamiento. Características sociodemográficas y clínicas y el tratamiento psicofarmacológico son tratados como factores independientes.

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Discusión y aplicabilidad clínica. Sesgo en la representatividad y selección de la muestra podrían afectar a la generalización de resultados. Se aplica por primera vez en España el modelo biopsicosocial de la CIF y la metodología desarrollada en el estudio de la depresión en atención primaria. Se espera una mejor comprensión de factores ligados a discapacidad funcional en pacientes con depresión. El proyecto se suma a una de las líneas prioritarias de investigación en la UE (proyecto MHADIE).

Palabras clave:
Depresión. Funcionamiento. Discapacidad. CIF. Atención primaria.

INTRODUCTION

Depression is probably the most frequent mental disorder in the general population[1]. It is estimated that 121 million persons in the world suffer a depressive disorder[2], that 2% to 15% will have it over their lifetime[2,3] and that there will be a relapse in 75% of the cases of depressions[4]. If we add the fact that depression occupies the fourth place in the ranking of diseases with greater global load worldwide (it is responsible for 4.46% of the total of disability adjusted life years and 12.1% of disability life years) and that the future prospect of the WHO for the year 2020 estimates that it will be the second cause of incapacity in the world, only behind ischemic heart disease[5,6] to these values, its study and clinical approach place it as one of the priorities in the research agenda and in health policies[7].

In primary care, depression is also a very common disorder[8]. Prevalence of depressive disorders is at about 20%, although this value is surely higher, since a high percentage of depressions are not diagnosed[9,10]. Patients with depression seen in primary care report high functional incapacity[11], that is especially manifested in personal well-being, in social relationships and in work performance[12,13]. In fact, depression is one the main causes of work leave and work days lost[14].

In terms of direct costs, prescription of antidepressants in the Spanish National Health System has increased considerably since selective serotonin reuptake inhibitors (SSRI) have appeared. In 2001, consumption of SSRI reached 80% of all the antidepressants, it being estimated that its prescription by primary care physicians is six time greater than prescription of antidepressants by psychiatrists[15]. However, and even though there are psychodrug interventions that are effective in reducing depressive symptoms, the effect of these interventions in functional improvement has not been studied adequately. Most of the studies have conceptual limitations: *a)* they use a reductionist biological disease model[16], and *b)* they use remission criteria almost exclusively linked to the reduction of severity and number of symptoms[17]. Methodologically, the studies use measurement instruments of heterogeneous functioning that hinder the comparison of the data[18], which have also been mostly used in countries whose health systems have little to do with ours.

In this sense, the International Classification of Functioning, Disability and Health (ICF)[19] provides an adequate, useful and applicable framework in the clinical practice[20] to describe and assess the patient's functioning and incapacity profile. The biopsychosocial model on which it is based makes it possible to analyze interaction between the health condition of one person or population and their environmental and personal characteristics, offering an internationally common and agreed on language for the description and study of functioning and incapacity profiles in different domains of well-beings, both individual and social (fig. 1). Based on the biopsychosocial model, the conceptual model and methodology of NIH is used in this project in a new way in Spain in the study of depression in the primary care setting.

OBJECTIVES

Primary

- To evaluate the functioning and incapacity profile in patients with unipolar depression treated in primary care according to the biopsychosocial model of NIH.
- To analyze the impact and effectiveness of the routine treatment for depression in primary care in different spheres of functioning using the NIH model.

Secondary

- To study what clinical and psychosocial endpoints are linked to the functioning of patients with unipolar depression and analyze what is the nature of the relationship between these endpoints and incapacity grade.
- To determine the relationship and synchrony between the clinical measurements of traditionally used results (e.g., clinical severity and presence of residual symptoms) with the functioning and incapacity measurements of patients with unipolar depression.

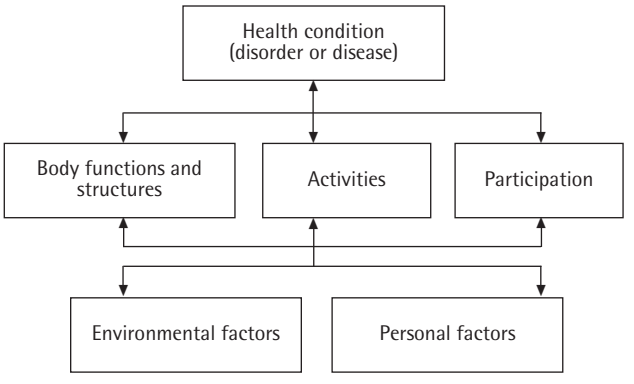

Figure 1 *Interaction between ICF components.*

METHOD

Design

Naturalistic, longitudinal, perspective study with baseline evaluation measurements at 6 weeks, 3 months and 1 year in a cohort of patients with unipolar depression.

Site

Multicenter study in which four primary care Area 2 Health sites of the Regional Community of Madrid and multidisciplinary research team (primary care physicians, psychiatrists and psychologists) participate. The study will take place between 2005 and 2008.

Inclusion and exclusion criteria

They are listed in table 1.

Calculation of sample size

Estimated a priori sample size (n=114) was calculated according to a more conservative bilateral hypothesis that decreased the risk of committing type I error, assuming an 0.05 alpha level, establishing the statistical power of the analyses at 75% (beta: 0.25) and a middle effect size (Cohen index: 0.50) for the magnitude of the difference between the «high incapacity/low incapacity» groups. This sample size was adjusted according to the one-year values of retention in the follow-up (20% losses) obtained in previous studies of depression in primary care conducted in the framework of the collaborative network RIRAG of the FIS. The final sample size was 142 participants.

Table 1 Sample inclusion and exclusion criteria

Inclusion criteria
Adults (≥ 18 years)
Major depressive episode diagnosis (ICD-10 criteria)
Be seen in primary care sites
Initiate treatment with selective serotonin reuptake inhibitors
Exclusion criteria
History of toxic substance and/or alcohol dependence
Background of bipolar disorder, psychotic disorders or organic mental disorders
Illiteracy
Presence of signs or symptoms due to neuropsychological disorders (i.e., dementias)

Participant flow

The patient cohort with depression that initiates treatment with SSRI is initially identified by the primary care physician. After authorization from the patient, the potential participants are given an appointment and then evaluated by one of the project investigators (e.g., psychologist or psychiatrist). All the participants are informed of the study objectives, and sign an informed consent on their voluntary and anonymous participation in it.

Definitions and measurement methods of the primary endpoints

- *Primary dependent endpoints. Incapacity and functioning.* They will be evaluated by instruments developed by the WHO based on the ICF: *a)* the ICF Checklist; *b)* World Health Organization Disability Assessment Schedule II (WHODAS-II), and *c)* Core Set of the ICF for depression. The Health Survey SF-36 will also be used.

- *Secondary dependent endpoints.* Use of health care services, evaluated by Client Service Receipt Inventory (CSRI).

- *Independent endpoints.* Sociodemographic and clinical endpoints: age, gender, work situation, education level, economic level, diagnosis, diagnostic comorbidity, clinical severity, personal and family backgrounds of mental health problems, duration and age of onset of depressive episode, number of relapses and previous episodes, history and number of suicide attempts and treatment received and adherence to it.

- *Mediator endpoints. a)* Stressful life events, evaluated with the List of Threatening Experiences (LTE) questionnaire; *b)* cognitive dysfunctional schema, evaluated with the Dysfunctional Attitudes Scale (DAS), and *c)* social support perceived by the patient, studied through the Multidimensional Scale of Perceived Social Support.

Analysis strategy

The statistical program SPSS v. 12.1 will be used. Two groups of patients will be formed according to the incapacity level (i.e., high incapacity/low incapacity). Descriptive statistics and parametric tests (*t* or χ^2 tests) and non-parametric tests (if appropriate) will be used to analyze the relationship between the endpoints studied and functioning level. The significant endpoints will be analyzed according to the Multivariate analysis and hierarchical or linear regression models to study intergroup differences and determine predictive functioning endpoints. Effect size will be calculated in all the analyses.

DISCUSSION

Study limitations

Basically, they are linked to the possible existence of participant screening bias, because there may be a high percentage of unidentified depressed patients, and to the sample representativeness. The project does not plan an epidemiological study of the depression profile seen in primary care. Thus, the confounding factors, such as idiosyncratic characteristics, limited to the health area and participating sites of the Madrid community would limit the generalization of the results.

Practical applications

The methodology of one of the European project studies Measuring Health and Disability in Europe (MHADIE) (www.mhadie.org) is presented. this is a multidisciplinary initiative in the study of profiles and prevalence of incapacities in different contexts (educational, population and clinical) in the European Union from the ICF framework. The work described represents one of the first applications of the ICF in primary care and in the study of mental health problems. The objectives established help to improve the evaluation and understanding of the types of prevalence and incapacity of the depression cases treated in primary care (regardless of their symptomatic status) and to analyze the efficacy of the usual treatments in such an important parameter as that of functional remission. Identification of endpoints linked to functioning and the extensive description of different incapacity levels or areas is extremely useful in the clinical management of our patients, since they make it possible to clearly identify clinical needs, facilitating the design of more effective interventions that would improve their quality of life and functioning.

The application of the biopsychosocial model of the ICF and of a systematized and standardized classification methodology makes it possible to adopt an internationally agreed on scientific language for the comparison of national and international data. Finally, it should be stressed that as this work is carried out within the MHADIE project, it is expected that its results will help to design social policies and compensation systems that reduce the impact of not only the health condition but also the social and environmental barriers on the functioning and quality of life of persons with depression associated incapacity.

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