



Evaluación de la efectividad de un programa de gestión de casos para pacientes esquizofrénicos en centros de salud mental

Assessment of the effectiveness of a case management programme for schizophrenic patients in mental health centres

Laia Mas-Expósito

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Departamento de Personalidad, Evaluación y Tratamiento Psicológico

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Tesis doctoral

**Evaluación de la efectividad de un programa de gestión de casos
para pacientes esquizofrénicos en centros de salud mental**

*[Assessment of the effectiveness of a case management programme for
schizophrenic patients in mental health centres]*

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RESUMEN

La desinstitucionalización psiquiátrica requirió un incremento de los recursos comunitarios destinados a la población con Trastornos Mentales Severos (TMS). Entre estos recursos destacan los llamados programas de gestión casos cuya función es organizar, coordinar e integrar los recursos disponibles para la atención del paciente, a través de contacto continuo con uno o más profesionales clave. La Estrategia en Salud Mental del Sistema Nacional de Salud Español (2007) recomienda los programas de gestión de casos para la coordinación, el acceso y el uso de los recursos de salud mental. Sin embargo, estos programas no están implementados en todo el territorio y existen diferencias entre Comunidades Autónomas. En Catalunya, estos programas están disponibles en los Centros de Salud Mental de Adultos de la Red de Salud Mental de Utilización Pública del Servicio Catalán de la Salud. En concreto, el Programa de Atención Específica al Trastorno Mental Severo (PAE-TMS) engloba la atención sanitaria de la mayoría de pacientes con TMS por lo que es de especial relevancia que se evalúe su efectividad. Esta tesis trata este tema siendo su objetivo principal evaluar la efectividad del PAE-TMS frente al programa estándar (PE) en personas con esquizofrenia. Este objetivo general se operacionalizó en tres objetivos consecutivos: 1) objetivo preliminar: revisión de la literatura de los programas de gestión de casos; 2) objetivo intermedio: validación de instrumentos de evaluación psicosocial en población con esquizofrenia, y 3) objetivo específico: mejorar el conocimiento de las necesidades de los pacientes con esquizofrenia incluidos en el PAE-TMS y analizar la efectividad del programa. Cada uno de los objetivos se asoció a uno o más estudios.

Del objetivo preliminar surge el Estudio 1 que revisa la literatura en relación a los orígenes, principios, tareas, modelos y efectos de los programas de gestión de casos. Este estudio muestra que la gestión de casos ha experimentado importantes cambios a lo largo del tiempo y que los modelos tradicionales parecen estar en desuso, tal y como se pone de manifiesto en los modelos más recientes. Los resultados de las revisiones metanalíticas sobre la eficacia de los programas de gestión de casos son heterogéneos y, a veces, difícilmente conciliables debido a la heterogeneidad de los estudios en los que se basan. Los estudios más recientes sugieren que algunas variables, tales como las características de los pacientes y la fidelidad al programa, podrían estar asociadas a la efectividad de la gestión de casos. Se sugiere, así, el desarrollo de estrategias de gestión

de casos que podrían ofrecer diferentes grados de intensidad según las necesidades del paciente.

Del objetivo intermedio surgen los estudios 2, 3 y 4. Estos estudios, de tipo psicométrico, se han centrado en la validación, en población con esquizofrenia, de la World Health Organization Quality of Life Brief Version, la Disability Assessment Schedule Short Form y la DUKE-UNC Functional Social Support Questionnaire. Las tres escalas muestran buenas propiedades psicométricas en personas con esquizofrenia. Sus puntuaciones son fiables y válidas y, por tanto, son instrumentos útiles y apropiados para la valoración de la calidad de vida, discapacidad y apoyo social de la población con esquizofrenia.

Del objetivo específico se derivan los estudios 5 y 6. El estudio 5 incide en el conocimiento de las necesidades de los pacientes con esquizofrenia asignados al PAE-TMS o al PE. A partir de los resultados del estudio, se hace una propuesta de criterios y de variables que hay que tener en cuenta cuando se incluya a un paciente en el PAE-TMS. Además, a partir de estas variables, se hace una propuesta de reconfiguración del funcionamiento del programa.

El estudio 6 analiza la efectividad del PAE-TMS frente al PE. El grupo de pacientes del PAE-TMS muestra un perfil caracterizado por peor funcionamiento clínico y psicosocial y mayor uso de servicios que el grupo de pacientes del PE en la evaluación inicial. Al año de seguimiento, ambos grupos mejoran y el grupo en el PAE-TMS alcanza niveles similares a los del grupo en el PE en la mayoría de variables evaluadas.

Los datos de esta tesis profundizan en el conocimiento de dos modalidades de tratamiento comunitario que se dirigen a la mayoría de personas con TMS en el Servicio Catalán de Salud. El PAE-TMS y el PE son efectivos y podrían ofrecerse de forma consecutiva según necesidades del paciente.

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1. INTRODUCTION

This introduction is organized in four subsections. The first of them is an overview of the definition of Severe Mental Illness (SMI) at an international and national level; while the second one focuses on schizophrenia, one of the main diagnostic categories of SMI. The third subsection involve the interventions and therapeutic strategies aimed for persons with schizophrenia and the fourth and last one describes Case Management (CM) as a community based modality of care for this sample population.

1.1. The definition of Severe Mental Illness

According to Schinnar et al¹, the first definitions of SMI were developed in the 70s and were mainly based on the care of institutionalized patients. The deinstitutionalization and the emergence of a new care philosophy based on community resources revealed the need to redefine the term of SMI. At the end of the 70s different definitions of SMI were spread among clinicians, researchers and politicians². It is worth highlighting the definition carried out by Goldman³ where the key criteria of the concept of SMI were already present. Those criteria have been described as a set of three Ds⁴ (i.e. diagnosis, disability and duration) and are the base of the definition carried out by the National Institute of Mental Health or NIMH⁵ of the United States of America which is the one that most helped to spread the concept. The NIMH developed an agreed upon definition in order to find a common language for a tower of Babel that existed among those who talked about SMI. According to the NIMH⁶ the persons with SMI are a group of heterogeneous persons who suffer from severe psychiatric disorders with a changeable degree of disability and social dysfunction, and who need the care from the psychiatric and social healthcare network. Specifically, the NIMH definition classifies persons as suffering from SMI if they meet the following three criteria: 1) diagnosis of non-organic psychosis or personality disorder according to the Diagnostic and Statistical Manual for Mental Disorders Third Edition Revised⁷; 2) long-term illness or long-term treatment operationalized as a two-year or longer history of illness or treatment; and 3) disability operationalized as meeting three out of eight criteria. In Table 1, there is a summary of some of the initial definitions, along with its criteria, of SMI including those by Goldman³ and the NIMH⁵. They both have been considered as the most useful by Thornicroft and Tansella⁸.

After the initiative of the NIMH, there was a proliferation of definitions for SMI linked to the proliferation of community resources for this sample population. For instance, Schinnar et al¹ found 17 definitions of SMI developed during the 80's in the United States; while Slade et al⁴ found little consensus on the definition of SMI between 20 agencies from England. This lack of consensus explains the differences on SMI estimates of prevalence¹ and the need to develop agreed-upon and operationalized definitions^{1,4}, which would help to: 1) study illness costs; 2) prioritize resources; and 3) allocate resources in equity⁹. Parabiaghi et al⁹ and Ruggeri et al¹⁰ tested operational definitions of SMI based on the NIMH⁵, and showed that it could be used for prevalence estimates and that it had high predictive and external validity as well as high sensitivity. Even so, their study considered two European cities (i.e. Verona and London), so there is a need to generalize the validity of their SMI definition in other mental health care contexts.

Although there is lack of consensus on the criteria that the definition of SMI should include, it seems there is an agreement to develop a multidimensional and integrative concept based not only on diagnosis.

In Spain, SMI is defined in all autonomous community care plans and in all national care plans from a holistic approach that places mental illness as the core of a global care process that takes into account its characteristics and needs¹¹.

Table 2 shows the definitions of SMI that have been considered as the most accepted in Spain¹¹ alongside with the most recent concept stated in 2009 in the Clinical Practice Guidelines for Psychosocial Interventions in SMI of the Spanish Ministry of Health and Social Policy⁶. This definition is based on the NIMH⁵ but considers only non-organic psychoses and includes operational criteria for disability in view of the Diagnostic and Statistical Manual of Mental Disorders 4th edition¹² (DSM-IV) and the International Statistical Classification of Diseases and Related Health Problems 10th Revision¹³ (ICD-10).

Table 1. Definitions of Severe Mental Illness

Author	Criteria
Goldman (1981)	<p>Diagnosis DSM-III-R diagnosis criteria of the following disorder:</p> <ul style="list-style-type: none"> - Schizophrenia and schizoaffective - Bipolar and major depression - Delusional (paranoid)
	<p>Duration At least one year from illness beginning</p>
	<p>Disability Enough to lessen severely functioning in at least one of the following areas:</p> <ul style="list-style-type: none"> - Occupation - Family responsibilities - Accommodation
National Institute of Mental Health (1987)	<p>Diagnosis Diagnosis criteria of the following disorders:</p> <ul style="list-style-type: none"> - Non-organic psychosis - Personality disorder
	<p>Duration History of:</p> <ul style="list-style-type: none"> - Two or more years of treatment - Two years of illness duration
	<p>Disability Severe and recurrent disability. At least three of the following criteria:</p> <ul style="list-style-type: none"> - Stress vulnerability - Disability to have an autonomous life - Limited capacity to obtain needed care - Social behaviour requires mental health or justice services - Impairment in daily life activities and basic needs - Impairment of social functioning - Occupational functioning is limited and deteriorated - Non occupational functioning limited and deteriorated
McLean and Liebowitz (1989)	<p>At least one of the following criteria:</p> <ul style="list-style-type: none"> - Two or more years of contact with services - Prescription of depot medication - ICD9 295.x o 297.x - Three or more hospitalizations in the last two years - Three or more times as day patient in the last two years - The highest level of functioning according to DSM-III is C or more during last year
Audit Commission (1994)	<p>A Diagnosis of psychosis, illness or organic disease and history of involuntary admissions OR More than one year of hospital admissions during the last 5 years OR Three or more admissions during the last five years</p>
	<p>B Diagnosis of psychosis, illness or organic disease OR Previous hospitalizations during the last 5 years</p>
	<p>C No hospital admission and no diagnosis of psychosis, illness or organic disease</p>

Overall, the situation in Spain is quite similar to that described in section 1.1. and it is been highlighted the lack of consistent and homogeneous criteria for defining SMI, establishing its prevalence and morbidity, and determining and quantifying resources¹⁴.

Table 2. Definitions of Severe Mental Illness in Spain

Author	Criteria
AEN (2002)	<p>Diagnosis: Priority given to functional psychoses</p> <p>Duration: At least two years in treatment</p> <p>Disability: Self-care, social and occupational autonomy, self-control, interpersonal relationships, leisure and free time, cognitive functioning</p>
IMSERSO (2007)	<p>Diagnosis: Schizophrenia, psychotic disorders, bipolar disorder, major affect disorders</p> <p>Symptoms: Delusions, mood disorders, hallucinations, neurocognitive disorders, behavioural and impulse control problems, negative symptoms</p> <p>Social functioning: Participation restrictions, social relationships, access to community resources, spare time, occupational functioning, active social functioning</p> <p>Duration: Functional and clinical status lasting for at least 6 months</p>
Ministry of Health and Social Affairs (2009)	<p>Diagnosis: Schizophrenic disorders, schizotypal disorders, persistent delusion disorders, induced delusion disorders, schizoaffective disorders, other non-organic psychotic disorders, bipolar disorders, serious depressive episode with psychotic symptoms, recurrent depressive disorders and compulsive obsessive disorder</p> <p>Duration: 2 years or more of evolution of the disorder <i>OR</i> progressive and marked impairment in symptoms over 6 months although symptom remission <i>OR</i> having received more intensive psychiatric treatment than at outpatient level more than once throughout life <i>OR</i> having received continuous residential support other than hospitalization enough time to have interrupted life</p> <p>Disability: Moderate to severe affectation of personal, occupational, social and family functioning, and measured through different scales (GAF < 50 or DAS-s scores > 3 in all items) <i>OR</i> at least 2 of the following criteria: 1) Unemployment, or sheltered or supported employment, limited skills or occupational history; 2) Need for public economic support to stay out of hospital and may require support to get this aid; 3) Difficulties to establish and maintain personal support systems, need for help in daily living skills; and 4) Inappropriate social behaviour that needs Mental Health or Judicial System services <i>OR</i> moderate to severe affection of occupation, social and family functioning as measured by the GAF (cutoff ≤ 70 or ≤ 50)</p>

AEN: Asociación Española de Neuropsiquiatría; IMSERSO: Instituto de Mayores y Servicios Sociales; GAF: Global Assessment of Functioning; DAS-s: Disability Assessment Schedule Short Form

In Catalonia, the first definition of SMI was carried out along with the definition of a community program aimed to this sample population. Specifically, it is the Severe Mental Illness Specific Care Program which was developed by the Catalan Health Service in 1997 in order to improve the care offered to persons with SMI¹⁵. According to that definition, SMI includes a set of nosologic entities of different nature and clinical presentation, that share criteria of severity and time persistence, prone to deterioration and alteration of personal, family and social relationships of the persons who suffer them. Also, it considers that their presentation is continuous or recurrent over two years and that meet specific criteria at a diagnostic, clinical severity and chronicity criteria. Table 3 shows a summary of these criteria.

Table 3. SMI criteria according to the Catalan Health Department

Criteria	Description
Diagnoses	Schizophrenia Recurrent major depression Manic bipolar disorder Depressive bipolar disorder Mixed bipolar disorder Paranoia Agoraphobia with anxiety or panic attacks Obsessive compulsive disorder Borderline personality disorder Schizotypal personality disorder
Clinical severity	Reality distortion or non-adaptative behaviour because of disease or lack of containment
Evolution	Chronic evolution based on clinical prognostic and use of health care resources

The situation in Catalonia is not different to that perceived at an international and national level. There is consensus regarding the main criteria of SMI but there is no consistent definition of them.

1.2. Schizophrenia

As seen in section 1, schizophrenia is one of the diagnostic criteria of SMI. The term schizophrenia is used to describe a severe psychotic mental disorder characterized by the presence of disturbances of perception, thoughts, affect and conduct^{16,17}. Next, there

is a summary of the disorder taking into account its definition over the time, diagnosis, epidemiology, course and prognosis, and causes.

1.2.1. The definition of schizophrenia

There is controversy about the origins of the definition of schizophrenia, whether it has always existed or it is a relatively new one^{18,19}. Even so, there is agreement that the evidence in favour of the existence of a definition for schizophrenia increases at the end of the nineteenth century¹⁶. By that time, psychiatrists from Europe started describing disorders of an unknown aetiology that affected young people and progressed to deterioration. In France those disorders were called *démence précoce* by Morel²⁰; while in Germany, Kahlbaum²¹ called them catatonic syndrome and Hecker²² hebephrenia, and in Scotland, Clouston²³ named them adolescent insanity. Kraepelin²⁴ used the term *dementia praecox* to integrate the above-mentioned disease manifestations into one nosologic entity and to describe a general pattern of course of disease that led progressively to severe cognitive and behavioural decline. At the beginning of the twentieth century, Bleuler²⁵ replaced *dementia praecox* by schizophrenia. Contrasting with Kraepelin²⁴, Bleuler suggested a more optimistic view regarding the disease since he did not consider it lead to progressive deterioration of individual and linked it to dissociation of psychic life. The definition of Bleuler is the foundation of the current criteria diagnosis of schizophrenia.

1.2.2. Clinical characteristics

Table 4 presents the current diagnosis criteria for schizophrenia according to the International Classification of Disease and Mental Disorder 10th version¹³(ICD-10) and the Diagnostic and Statistical Manual of Mental Disorders 4th edition revised¹² (DSM-IV-TR).

None symptom is by itself pathognomic or specific of schizophrenia and symptom manifestation is heterogeneous among individuals and over time within the same individual^{16,26}. The signs and symptoms of schizophrenia may include hallucinations, delusions, loose associations, flatness, inappropriate affect, catatonia, disorganization as well as problems with cognition, motivation and judgment.

Table 4. Diagnostic criteria of schizophrenia

ICD-10	DSM-IV-TR
<p>One very clear symptom from any of the groups 1 to 5 (or two or more if less clear)</p> <p>1. Thought eco, thought insertion or withdrawal, and thought broadcasting</p> <p>2. Delusions of control, influence, or passivity, clearly referred to body or limb movements or specific thoughts, actions, or sensations; delusional perception</p> <p>3. Persistent delusions of other kinds that are culturally inappropriate and completely impossible</p> <p>4. Persistent hallucinations in any modality, when accompanied either by fleeting or half-formed delusions without clear affective content, or by persistent over-valued ideas, or when occurring every days for weeks or months on end.</p> <p>5. Breaks or interpolations in the train of thought, resulting in incoherence or irrelevant speech, or neologisms</p> <p>Presence of symptoms from at least two of the groups</p> <p>6. Catatonic behaviour</p> <p>7. Negative symptoms usually resulting in social withdrawal and lowering of social performance</p> <p>8. Significant and consistent changes in the overall quality of behaviour (e.g. loss of interest, aimlessness, idleness, a self-absorbed attitude and social withdrawal)</p>	<p>A. At least two symptoms present for a significant part of time at least for one month: Delusions, hallucinations, disorganized speech, grossly disorganized or catatonic behaviour, negative symptoms</p> <p>B. Social/Occupational dysfunction</p> <p>C. Duration: Continuous signs for at least 6 months, including at least 1 month of active-phase symptoms and may include periods of prodromal or residual symptoms. During prodromal or residual periods, the signs of the disturbance may be manifested by only negative symptoms or two or more Criterion A symptoms in an attenuated form</p> <p>D. Schizoaffective and mood disorder exclusion</p> <p>E. Substance/general medical condition exclusion</p> <p>F. Relationship to a pervasive developmental disorder: If there is a history of autistic disorder or another pervasive developmental disorder, the additional diagnosis of schizophrenia is made if only prominent delusions or hallucinations are also present for at least one month</p>
<p>Subtypes: Paranoid, hebephrenic, catatonic, undifferentiated, postschizophrenic depression, residual, simple, other and unspecified</p>	<p>Subtypes: Paranoid, disorganized, catatonic, undifferentiated and residual</p>
<p>Course classification: Continuous, Episodic with progressive defect, Episodic with stable deficit, Episodic with complete remissions, Incomplete remission, Other, Course uncertain, Period of observation too short</p>	<p>Longitudinal course: Episodic with interepisode residual symptoms, Episodic with no interepisode residual symptoms, Continuous, Single episode in partial remission, Single episode in full remission, Other of unspecified pattern</p>

ICD-10: International Classification of Disease and Mental Disorder 10th version; DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders 4th Edition Revised

The symptoms of schizophrenia are categorized as follows: 1) positive symptoms including hallucinations and delusions; 2) negative symptoms involving flat affect, alogia, anhedonia and avolition; and 3) disorganized symptoms including disorganized speech and behaviour and decreased attention. As observed in Table 4, subtypes of

schizophrenia are defined according to the principal symptoms present at assessment time.

Persons with schizophrenia may experience as well other mental and general medical comorbid conditions^{16,26}. Symptoms of depression, obsessive and compulsive symptoms, somatic preoccupations, dissociative symptoms and other anxiety and mood symptoms can be comorbid to schizophrenia. Disorders related to use of substance such as alcohol, stimulants, nicotine, cannabis, phencyclidine and LSD are as well frequently associated to schizophrenia. As for general conditions, the most frequent comorbid conditions and risk factors are tuberculosis, hepatitis, cigarette-related problems, obesity, HIV, antipsychotic-induced movement disorder and polydipsia.

Schizophrenia is related to disability on personal, social and occupational functioning, which can be explained by the recurrence of symptoms but also by side effects of treatment, social adversity and isolation, poverty, homelessness, stigma and social exclusion¹⁷.

1.2.3. Epidemiology, course and prognoses

Schizophrenia has been described as the most common form of psychotic disorder¹⁷. Specifically, it seems to affect just under 1% of the population at some point of life²⁷. The World Health Organization²⁸ conducted a study in ten European countries and showed that the mean incidence of schizophrenia ranges from 0.07 to 0.17 per 1000 when limited to core criteria and corrected for age; while it ranges from 0.07 to 0.52 per 1000 when broader criteria are applied. A more recent study²⁹ estimates the life time prevalence of schizophrenia at 0.87%. although it is worth highlighting that there are differences depending on geographical area and migratory status. The incidence of schizophrenia has been considered to be constant geographically and temporally¹³. Even so, there is evidence that does not confirm so. For example, McGrath³⁰ showed a range for schizophrenia incidence from 7.7 to 43.0 per 100.000 inhabitants per year in developed countries and it has been showed that differences in schizophrenia incidence are associated with gender, geographical area, ethnicity, month of birth³¹⁻³³ and age³³. With regard to the onset of disease, it is worth highlighting the Aetiology and Ethnicity of Schizophrenia and Other Psychoses Study³³. It supported that the peak incidence of schizophrenia was earlier in males than in females; that is, between 20 and 24 years in

males; while between 29 and 32 years in females. It has been shown that there are greater differences in schizophrenia incidence between males and females when using restricted diagnostic criteria³⁴ and that schizophrenia tends to be more severe in males than in females^{30,33,35,36}. Lastly, mortality in patients with schizophrenia is higher than in the general population. Specifically, persons with schizophrenia have a two- to threefold increased risk of dying^{37,38}. Suicide and cardiovascular disease are considered key contributors to the death risk associated with schizophrenia and the standardized mortality ratio seems to have raised over time³⁸.

The onset of schizophrenia can be acute or insidious and generally schizophrenia develops in phases that overlap¹⁶. Figure 1 shows the different phases of schizophrenia according to international clinical practice guidelines^{16,26,39}. The first phase in the development of schizophrenia is called premorbid phase. In this phase, the individual's functioning is normative but there might be risk factors that might contribute to the development of schizophrenia such as pregnancy, prenatal and perinatal problems or family stress at youth⁴⁰. The second phase is called prodromal phase and it is characterized by difficulties in functioning and the presence of cognitive problems, social withdrawal, uncommon behaviour, affective problems, problems with communication, peculiar ideas, perceptual experiences, poor self-care, reduced or lack of interest and motivation in daily life activities³⁹. This phase has an average length from 2 to 5 years and it lasts till the presence of the first frank psychotic symptoms²⁶. Then, the so-called acute phase takes place. Characteristic positive symptoms such as hallucinations, delusions and behavioural disturbances are present³⁹ and negative symptoms observed in the prodromal phase usually become more severe^{6,26}. The fourth phase is called the stabilization phase and it lasts from 6 to 18 months after the acute phase. Negative and residual positive symptoms are present but they are less severe and consistent in magnitude²⁶. Finally, there is the stable phase or maintenance phase where symptoms may have disappeared or stabilized and, if recurrent, they are usually less severe than in the acute phase¹⁶.

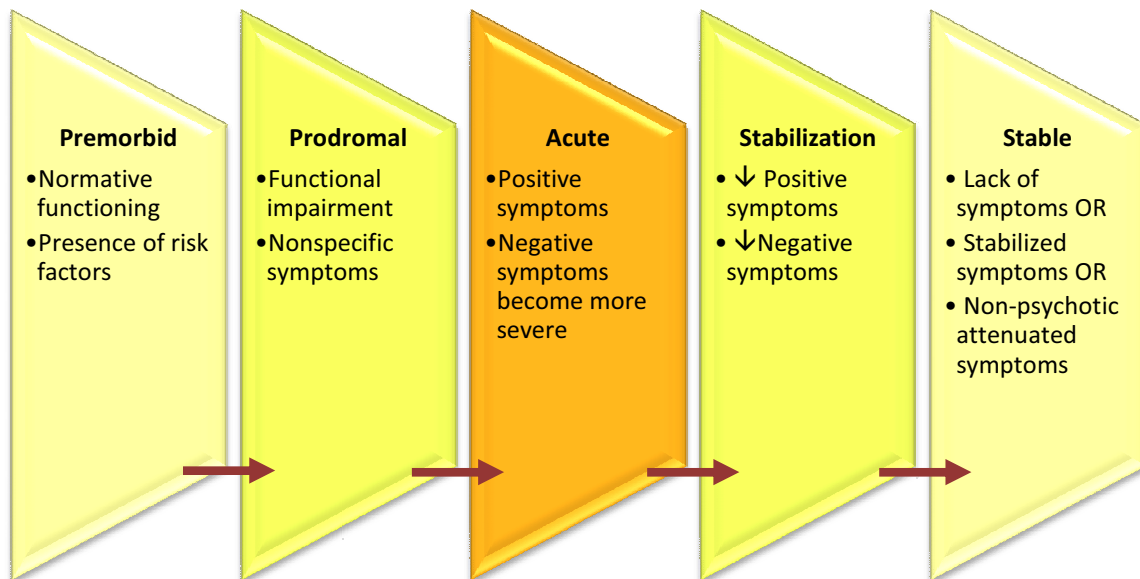


Figure 1. Phases of schizophrenia and its characteristics according to international clinical practice guidelines

It is worth highlighting that the course of schizophrenia is variable¹⁶. Although most patients alternate acute episodes and stable phases of partial or total remission, some of them do not have new episodes while some of them may be at a severe chronic state.

After a first episode of psychosis, between 14 and 20% of persons will recover fully; while others will get better but have relapses, which have been associated with isolation, social difficulties and stress³⁹. Half of the persons diagnosed with schizophrenia will have sporadic problems in the long-term (i.e. till 15 years). Between 20 and 40 years, some studies have shown quite positive outcomes in more than half of persons with schizophrenia diagnosis and in a smaller proportion have shown entire periods of symptom remission without relapses⁴¹⁻⁴³. Although some persons do not experience recovery, they show good functioning if adequate support is provided³⁹. Recovery is associated with the provision of treatment in early stages¹⁶, but also with cultural factors and societal complexity, and other socio-demographic and clinical variables such as age, gender, marital status, comorbidity, intelligence quotient, pattern of episodes and remissions, predominant symptoms, premorbid functioning, previous schizophrenia episodes, psychiatric family history, schizophrenia subtype and type of disease onset³⁹.

1.2.4. Causes

The causes of schizophrenia are still not well understood¹⁷ because rather than a single one they are a complex interaction of biological, psychological and social factors. There have been many attempts to try to explain the causes of schizophrenia. Kraepelin²⁴ under the term of *daementia precox* explained it by means of a neurodegenerative model. More recent approaches are the so-called vulnerability-stress⁴⁴ model, the neurodevelopmental hypothesis⁴⁵ or the dopamine hypothesis^{46,47}. According to the vulnerability-stress model⁴⁴, the development of schizophrenia depends on the presence of biological, psychological and social factors but also on environmental stress. For example, if vulnerability is high, low levels of stress might affect the development of schizophrenia; while high levels of stress might be necessary for the development of schizophrenia when vulnerability is low. Neuchterline and Lawson⁴⁸ suggested a more comprehensive stress-vulnerability model. In this model, information-processing deficits, increased reactivity of the autonomic nervous system and deficits in social competence and coping are considered factors for schizophrenia vulnerability. Life events and social stress interact with vulnerability factors that guide to vicious loops and, in the last term, to schizophrenia development. According to the neurodevelopmental hypothesis⁴⁵, schizophrenia is associated with pathologic process that take place during adolescence before the constitution of adult brain and that are produced by genetic and environment factors. Neurodevelopmental defects in gestation are considered to set up pathologic neural networks that guide to the development of schizophrenia. Finally, the dopamine hypothesis^{46,47} sustains that dopamine and its mechanisms are inner to schizophrenia⁴⁹. This theory shifted from an overall increased transmission at the receptors for dopamine^{46,47} to a more specific theory where schizophrenia is explained by low levels of dopamine at frontal areas while high ones at subcortical areas⁵⁰. Nowadays, the dopamine hypothesis and the neurodevelopmental hypotheses are seen as complementary since there is rising evidence suggesting that developmental risk factors for schizophrenia seem to aid dopamine dysfunction which is considered the last ordinary pathway beneath schizophrenia⁴⁹⁻⁵².

Taking into account the complexity in the causes of schizophrenia, research has focused on the study of specific biological and social/environmental factors^{27,53} such as genetics, parental age, pre- and perinatal complications, urban residence, migration, childhood adversity and adulthood adversity. Table 5 shows further details about the

aforementioned factors in the development of schizophrenia according to the review conducted by Stilo and Murray²⁷. Moreover, research about psychological factors (i.e. basic cognitive functions and emotion and reasoning processing) show that they may be considered links between biological and social/environment factors¹⁷.

Table 5. Biological and social/environmental risks for schizophrenia

Biological risk factors	
Drug abuse	Stimulants Cannabis
Genetics	Heritability of the disorder is high (range: 66% - 83%) Heritability is not explained by any single gene locus Many genes may contribute to illness No gene is sufficient or necessary for schizophrenia development No single allelic variant can be considered a gene for schizophrenia
Parental age	Increased parental age
Pregnancy and birth events	Obstetric difficulties: complications of pregnancy, abnormal fetal growth and development and complications of delivery Winter-spring birth
Social /environmental risk factors	
Adulthood difficulty	Stressful/disturbing life events
Area of residence	City social isolation and disorganization Deprivation Large urban area Long time of residence in an urban area Poor social cohesion To be born or raised in an urban area
Childhood difficulty	Bullying Child abuse Parental loss Parental separation
Migration	To be migrant To be from an ethnic minority group
Social isolation	Unemployment To live alone Social housing Lack of social support

1.3. Interventions and Management of Schizophrenia

This section reviews interventions and management strategies of schizophrenia. It is based on the Clinical Practice Guideline for Schizophrenia and Incipient Psychosis¹⁶ of the Spanish Ministry of Health and Consumer Affairs. This Clinical Practice Guideline aims to provide recommendations for the management of patients with schizophrenia and incipient psychotic disorder based on the best scientific evidence available.

The treatment and management of schizophrenia is based on: 1) a careful selection of the available interventions; 2) their integration; and 3) the adoption of the most appropriate scope of intervention¹⁶.

1.3.1. Pharmacological and other biological interventions

Among somatic interventions, the pharmacological interventions are considered the key of the treatment of persons with schizophrenia. The main pharmacological interventions for those patients are antipsychotic drugs although they may also benefit from other drugs such as coadjutants.

1.3.1.1. Antipsychotic drugs

Antipsychotic drugs were introduced in clinical practice during the 1950s and they have been classified as follows: first-generation or conventional antipsychotics and second-generation or atypical antipsychotics. This categorization was made taking into account advantages of the later over the former in efficacy, safety and distinctive pharmacokinetics⁵⁴. Atypical antipsychotic were considered better for negative symptoms and to produce less extrapyramidal side-effects. Even so, today the distinction between first-generation or conventional antipsychotics and second-generation or atypical antipsychotics are not so clear. Leucht et al⁵⁵ conducted a meta-analysis of 150 double-blind controlled trial involving 21.533 participants on the efficacy of second-generation versus first-generation antipsychotic drugs for schizophrenia. They showed that second-generation antipsychotic drugs differed in efficacy (i.e. overall efficacy and side effects) when compared to first-generation antipsychotic drugs and were not a homogeneous class. Therefore, the dichotomy first-generation antipsychotics versus second-generation antipsychotics have been questioned.

Antipsychotic drugs are used for acute states, prevent relapses, acute behavioural disturbances, symptom reduction and in the long-term maintenance of patients with schizophrenia. They have an antagonistic effect on D₂ dopamine receptors and, in fact, their potency is linked to their affinity to such receptors. The higher the affinity, the higher the potency and the lower the dose required to administer. They can be administered orally, intramuscularly, intravenously and by medium- or long-acting depot preparations.

The antipsychotic drugs authorized in Spain are the following: amisulpride, aripiprazole, chlorpromazine, clozapine, haloperidol, levomepromazine, olanzapine, paliperidone, perphenazine, periciazine, pimozide, quetiapine, risperidone, sertindole, sulpride, thioproperazine, trifluoperazine ziprasidone, and zuclopenthixol.

According to the clinical practice guidelines about schizophrenia management of the National Institute for Health and Clinical Excellence¹⁷, all antipsychotics have side effects but they depend on type of drug and patient's characteristics. The affinity of antipsychotic to D₂ receptor has been related to extrapyramidal symptoms such as drug-induced parkinsonism, acute dystonia, akathisia, neuroleptic malignant syndrome (i.e. rigidity plus hyperthermia plus autonomic instability plus hypertension plus tachycardia) and tardive dyskinesia as well as to increase of serum prolactin that may cause menstrual alterations, galactorrhea, sexual dysfunction and even decrease of mineral density of bones. The affinity of antipsychotics to other receptors (for example, histaminergic or cholinergic) have been linked to other side effects such as sedation, increase of weight, lipid abnormalities, glucose regulation problems that may lead to metabolic syndrome, and postural hypotension. Taking into account all the above mentioned, clinicians must guarantee continuous monitoring of patients for antipsychotic side effects but also for possible interaction with other drugs that patients may be taking.

1.3.1.2. Coadjuvant medication

Antipsychotic drugs are used in combination of another antipsychotic drugs or other drugs when the response of antipsychotic alone is not enough, for behaviour control, to decrease antipsychotic side effects and for the treatment of comorbid conditions as for example depression or anxiety. The drugs used in combination with antipsychotics are

the following: lithium, benzodiazepines, anticonvulsivants and antidepressants. Table 5 shows a summary of their indications.

Table 5. Summary of indications of coadjutant drugs for patients with schizophrenia

Drug	Indication
Anticonvulsants	To treat patients with convulsive activity or with agitated or violent behaviours
Antidepressants	To treat post-psychotic depression not easy differentiable from negative symptoms caused by conventional or first-generation antipsychotics
Benzodiazepines	To treat psychotic agitation while allowing a reduced dose of antipsychotics when patients are in acute phases
Lithium	To boost antipsychotic treatment when symptoms are resistant. Lithium can increase antipsychotic response and decrease negative and affective symptoms

1.3.1.3. Other biological interventions

Besides antipsychotic and adjuvant drugs, there are other biological interventions such as electroconvulsive therapy (ECT). Its beneficial effects seem to be related to the global seizure and a global activation of central nervous system that it causes¹⁷. It is considered a second choice in the treatment of schizophrenia and it is usually indicated for catatonic schizophrenia, in cases with severe agitation and/or confusion, when antipsychotic are contraindicated and for comorbid depression and resistant schizoaffective disorders¹⁶.

Repetitive transcranial magnetic stimulation is seen as another of the biological interventions for schizophrenia²⁶. It is a non-invasive technique that changes local cortical neuronal activity by means of electric currents produced by magnetic fields⁵⁶. In comparison with ECT, it can be used without anaesthesia and causes fewer side-effects²⁶. Although some studies have shown beneficial effects⁵⁶⁻⁶⁰, the evidence, available now is not enough for its recommendation in the management of schizophrenia.

1.3.2. Psychosocial Interventions

Psychosocial interventions are an array of actions that aim to decrease vulnerability, stress, improve global functioning and increase social support. The election of one or another depends on patients' needs as well as on resource availability and they require professionals with specific training, experience and qualifications. They can be

classified in the following three groups: 1) psychotherapeutic interventions; 2) specific psychotherapeutic interventions that can be offered within the frame of other interventions; and 3) rehabilitation interventions and support resources.

1.3.2.1. Psychotherapeutic interventions

They come from various psychological techniques and that differ on the clinician in charge, his/her relationship with patients, his/her active role, his/her flexible attitude, his/her capacity to create a proper framework (i.e. empathetic and kind) and to control own feelings. Psychotherapeutic interventions also consider the establishment of limits to keep away from treatment discontinuation and impulse control lack. They are usually carried out alongside with other psychosocial or pharmacological interventions. As well as rehabilitation interventions, they can be offered to patients individually or by group-based sessions taking into account patients' needs, preferences and resource availability. Group-based sessions are an opportunity to understand own suffering but also suffering from others in a similar situation. Specifically, they offer a setting which is realistic, promote therapeutic alliance and provide better knowledge of one-self and others, which improve social relationships and the ability to handle symptoms.

Cognitive Behavioural Therapy

Cognitive Behavioural Therapy (CBT) is a psychological intervention based on the three following propositions: 1) the influence of cognition on feelings and behaviour; 2) the monitoring, assessment and measurement of cognition; and 3) the change on behaviour is mediated by cognition⁶¹.

There are different approaches to CBT the following are recognized as the three fundamental types⁶²:

- *Coping skills training*: It highlights the importance of a development of skills to cope with in adverse situations.
- *Problem-solving therapies*: It stresses the importance of global strategies to cope with in a wide repertory of personal difficulties
- *Restructuring therapies*: It aims to amend non-adaptative thoughts to support adaptative ones.

CBT is recommended for the treatment of persistent psychotic symptoms, positive symptoms, insight, anxiety, depression, stress and treatment adherence. In early stages of the disease it is recommended to avoid medications and decrease symptoms. In acute phases, it is recommended alongside standard care to boost recovery and discharge from hospital¹⁶.

Supportive psychotherapy

Although there is no clear definition about supportive psychotherapy, it is a term frequently used to describe a type of intervention that combines psychodynamic, cognitive-behavioural, and interpersonal strategies⁶³. It aims to decrease internal divergences that lead to mental health problems by promoting adaptive models of thoughts and behaviours throughout the therapist-patient relationship. The clinician engages actively in this relationship where shows emotional support attitudes.

It is recommended to develop a therapeutic alliance by the provision of emotional support and collaboration but it is not recommended as a specific intervention when other resources are available¹⁶.

Psychodynamic psychotherapy

Psychodynamic psychotherapy it has been considered as one of the “talking therapies”⁶⁴. Sessions are based on a psychodynamic or psychoanalytic model and aim to develop a therapeutic alliance⁶⁵ and to handle with defence mechanisms and internal conflicts. In this way, conscious and unconscious factors that affect symptoms and behaviours are shown. The techniques used are not as strict as in psychoanalysis and include working with transference as well as strategies that are explorative, insight-based, supportive or directive⁶⁴.

It is considered to be useful to facilitate clinicians know about patients’ experiences and social relationships¹⁶.

1.3.2.2. Psychotherapeutic interventions that can be applied within the frame of other interventions

As already stated, there are other psychotherapeutic interventions that can be part of other psychosocial interventions. Those are psychoeducation and family intervention.

Psychoeducation

Psychoeducation is a therapeutic approach rather than a theory model¹⁶ that involves interaction between clinicians and patients. This interaction aims to provide patient with specific information in order to boost comprehension and awareness of illness and training in strategies to deal with daily-life problems that stem from illness^{16,66}. It is a gradual process¹⁷ that may involve as well affect, cognition and psychomotor processes⁶⁷.

It is recommended as a component of treatment plans either for patients or families. The provision of psychoeducation is recommended gradually according to patients' and relatives' needs and illness phase¹⁶.

Family intervention

Schizophrenia influences not only on patients functioning but also on their family functioning. Families also have to deal with the consequences of a disease that may be long-term. Therefore, interventions should take into account family, their needs and their role in patients' management¹⁶.

The first approaches to family intervention were based on systemic theories but they placed too much illness responsibility on families. The family-based theories were developed as an alternative and are based on the relevance of life events and expressed emotions on illness development and progress.

Usually family interventions require more than five sessions and involve various objectives⁶⁶ that are summarized in Figure 2. They work by decreasing expressed emotion, stress, family burden and strengthening family capacity to cope with daily life problems while keeping up medication compliance.

Family intervention is recommended as follows¹⁶:

- By means of groups composed by family members of patients with similar characteristics considering expressed emotion and patient participation, and integrated in standard treatments lasting at least 6 months
- For families in contact with patients who have relapsed or are at-risk of relapse, or with ongoing symptoms

- For moderately or severely ill patients, or patients with long-term disorder
- To decrease family burden
- To improve prognosis
- To improve social functioning
- To reduce costs
- To reduce relapses

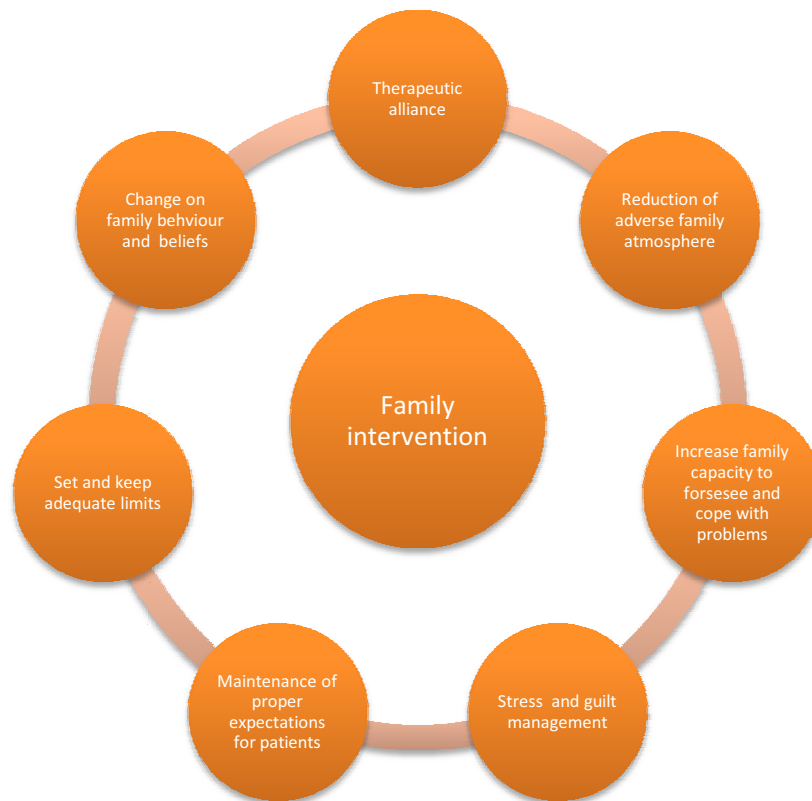


Figure 2. Objectives of family intervention

1.3.2.3. Rehabilitation interventions and support resources

Rehabilitation interventions and support resources aim to facilitate recovery, and support functioning and prevent patient deteriorating at social, educational, family and occupational levels²⁶.

Cognitive rehabilitation

Patients with schizophrenia may show impairments in attention, processing speed, working memory, verbal/visual learning and memory, reasoning and problem solving, and social cognition⁶⁸⁻⁷¹. All those deficits have been seen as expression of essential mechanisms of schizophrenia^{72,73}, predictors of psychosocial functioning and treatment response⁷⁴⁻⁷⁷ and vulnerability indicators of the development of the disease⁷⁸⁻⁸¹. Taking

into account the importance of cognitive deficits in patients with schizophrenia, the development of cognitive interventions that aim to deal with such deficits has raised. There are many ways to categorize such interventions⁸²⁻⁸⁵ and one of the possible categorizations is that conducted by the Canadian Psychiatric Association⁸⁶. According to the Canadian Psychiatric Association⁸⁶, the interventions for the rehabilitation of cognition in patients with schizophrenia can be applied individually or in group format and include at least one of the following strategies:

- Restorative: strategies that aim to reduce beneath cognitive impairment.
- Compensatory: strategies that aim to counterbalance cognitive impairment.
- Environmental: strategies that are based on external clues that aim to alert or remind patients of certain activities and thus reduce the impact of cognitive impairment.

Cognitive rehabilitation is recommended for the improvement of cognition in patients with schizophrenia and in a broad variety of clinical states as well as in daily-life setting of patients¹⁶.

Social skills training

Patients with schizophrenia show a poor level of functioning in a wide range of social daily-life situations such as having conversations, making friends and coping with everyday problems⁸⁷. Social functioning has been closely associated to relapses, hospitalizations and prognosis⁸⁸, which justifies the development of social skills training. According to Kopelowitz et al⁸⁹, social skills training are behaviour-therapy-based strategies to teach persons how to communicate and, then, accomplish objectives and fulfil needs for affiliative relationships and tasks required to live independently. Its main strategies are 1) problem identification, 2) goal setting, 3) role playing and behavioural rehearsal, 4) positive and corrective feedback, 5) social modelling, 6) behavioural practice, 7) positive social reinforcement, 8) homework assignments, and 9) positive reinforcement and problem solving. There are three different models of social skills interventions⁹⁰:

- Motor skills: behaviours are divided into steps that are taught through role playing
- Social problem solving: areas that should change are handled in a module in order to amend abilities at a receptive, processing and expressive level.

- Cognitive resolution: problems are addressed from basic cognitive impairments

The social problem solving model is recommended for patients who are moderately or severely ill and, in general terms, social skills training are recommended for patients with problems associated with social interaction¹⁶.

Training in daily life activities

A great number of patients with schizophrenia show poor levels of functionality and have problems when displaying activities of daily living^{77,91}. In order to cope with these problems and enhance individuals' independence and functioning, strategies regarding training in activities of daily living have been developed. There are two main types of strategies according to the activities they are aimed to:

- Activities of daily living⁹². Activities of daily living are those skills required for daily self-care (e.g.. hygiene, dressing, feeding one-self, etc.)
- Instrumental activities of daily living⁹². Activities that go beyond basic self care and require the interaction with the environment (e.g. taking care of others, financial managing, preparing meals, etc.).

Training in daily life activities is recommended for patients having problems to cope with daily-life tasks¹⁶.

Art therapies

Art therapies started proliferating in hospitals at the end of the 19th century as a promising tool for recovery. Art therapies include art, dance, drama and music and, although they use different strategies and methods, they all focus on a therapeutic relationship in which strong emotions can be articulated and treated²⁶.

According to the British Association of Art Therapies⁹³, art therapy is the use of art materials for the expression of self in the presence of a trained therapist. Previous experience or skill in art is a requirement and the therapist is not mostly concerned with an aesthetic or diagnostic assessment of patients' images. The main aim is to facilitate a patient to effect change and growth at a personal level through the use of art in a safe and facilitating setting.

Although an evidence base for the effectiveness of art therapies in the treatment of patients with schizophrenia is beginning to emerge⁹⁴, further research is required to draw firm conclusions^{16,26}.

Vocational rehabilitation

Persons with SMI have to deal with low rates of employment and in persons with schizophrenia the employment rates range between 10% and 20% partly due to stigma, discrimination, fear of loss of benefits and lack of professional help⁹⁵. In order to maintain patients as functional and as independent as possible in the community, vocational rehabilitation strategies have been developed. There are two main types of vocational rehabilitation strategies⁹⁶:

- Pre-vocational training is a strategy for vocational rehabilitation in which patients have a period of instruction before starting looking for a competitive job position. The period of instruction might involve either a sheltered-environment or pre-employment training or transitional employment. There are two forms of pre-vocational training which are sheltered workshops⁹⁷ and the Clubhouse model⁹⁸.
- Supported employment is a strategy for vocational rehabilitation in which patients are placed immediately in a competitive job position. The Individual Placement and Support model is a specific variation of supported employment⁹⁹.

Vocational rehabilitation is recommended to encourage persons with schizophrenia to find employment, especially supported employment programs and for patients moderately or mildly ill patients or in the stable or maintenance phase¹⁶.

Accommodation resources

Community-based care has progressively leaded persons with SMI to live in the community instead of in psychiatric hospitals and it has implications for housing¹⁰⁰. Nowadays, persons with SMI have other housing alternatives besides living with family or in a residential facility such as group homes, hostels or therapeutic communities. There are two major approaches regarding housing for persons with severe mental illness²⁶:

- Transitional housing: persons live in housing closely connected to psychiatric treatment. Patients move through different housing facilities taking into account the level of support required.
- Supported housing: persons live in a housing not connected directly to psychiatric treatment. Psychiatric treatment is provided according to patients' needs in order to retain their housing.

Housing resources vary considerably since they depend on their local accessibility¹⁰¹. Table 6 shows the housing resources available in Spain¹⁰² according to patient autonomy.

Supported housing resources based on patient-environment interaction and taking into account patient preferences are recommended to achieve patient maximum level of autonomy¹⁶.

1.3.3. Community-based modalities of care

The origins of community-based modalities of care are related to the deinstitutionalization movement that supported the care of patients with SMI in the community instead of in psychiatric hospitals. Therefore, patients with SMI started receiving outpatient care from community mental health centres or day hospitals in the community and the interventions provided there increased in order to fulfil patients' needs. Even so, a considerable number of these patients experienced problems in accessing the services required because those services were multiple, complex¹⁰³ and fragmented¹⁰⁴. These facts led to an increase in hospital admissions¹⁰⁵, loss of patient contact with community services and, subsequently, the failure of community services to fulfil patients' needs^{106,107}. CM emerged as a new service function to deal with the above-mentioned problems.

Table 6. Housing resources in Spain

Type	Description	Degree of autonomy
<i>Autonomous housing</i>	Persons live in complete autonomy in the community and receive individual support from external resources	+++
<i>Home-based care</i>	Persons live in the community alone or with family and receive support from a professional team	++
<i>Supervised housing</i>	Persons live in the community and share a housing facilities with 4 or 6 other persons and with staff support and supervision	++
<i>Residence</i>	Persons live in a facility that can hold from 15 to 40 other residents. Support is provided from a 24-hour multidisciplinary team	+

+++; high levels of patient autonomy; ++; medium levels of patient autonomy; +: low levels of patient autonomy

Community mental health teams

Community mental health teams are considered the foundation of community-based mental health systems¹⁰⁸⁻¹¹². Community mental health teams are multidisciplinary teams composed generally of 10-12 mental health professionals including nurses, occupational therapists, psychiatrists, psychologists and social workers that provide care less focused on institutional settings¹¹³. Next, there is a definition regarding community mental health teams that is widely accepted, easily recognisable and facilitates the differentiation between community mental health teams and other forms of community-based specialized teams¹¹⁴:

“A multidisciplinary team of mental health staff which has a lead responsibility for the provision of specialist assessment, treatment and care to a defined population, often defined by geographical catchment area or primary care registration. Such a team will usually provide the full range of functions necessary at the specialist care level, including initial assessment of general adult patients referred from other agencies and teams, consultation to primary care staff on the management of patients, the initial provision of treatment during the onset of a disorder or the early stages of a relapse, and the continuing care of patients with longer term disabilities. Generic teams may be supplemented by particular specialist teams, for example for early intervention, for home treatment in crisis, or for the assertive community treatment, but the main

provision of care for the majority of patients seen by specialist mental health services”
(quoted in Malone et al¹¹⁴, 2007, p. 2-3)

Community mental health teams are recommended for the care of patients with SMI to decrease suicides and drop-outs, while increasing service satisfaction¹⁶.

Case management

CM is widely considered to be a major component of the services provided to patients with SMI¹¹⁵. Namely, CM has been defined as a community-based package of care which is a way of coordinating, integrating and allocating individualized care within limited resources by means of continuous contact with one or more key professionals¹¹⁶.

CM is recommended for community-based management of patients with SMI. CM is recommended for patients who have a history of rehospitalizations, problems keeping contact with services and those who are frequent users of services or homeless. The more intensive forms of CM are recommended for patients between 18 and 65 years old who need frequently inpatient care or are at high risk of rehospitalizations¹⁶. In section 1.4., CM is explained in further detail considering its importance on the present PhD thesis.

1.4. Case Management as a community-based modality of care

The different practices of CM share a set of principles that derive mainly from social work¹¹⁶ and support a type of intervention aimed at enhancing patient adaptation in the community and at lessening their functional disability. The principles most commonly reported as the basis of CM were described by Thornicroft (1991) and include: 1) Continuity, 2) Accessibility, 3) Staff-patient relationship, 4) Tailoring support to need, 4) Facilitating independence, 5) Patient advocacy and 6) Advocacy for services.

The above principles are put into practice by way of services that CM may involve and that have been described by many authors to a greater or lesser extent¹¹⁶⁻¹²⁵. Table 7 shows an overview of tasks that have mainly been linked to CM over time.

Table 7. Summary of Case Management Tasks

Case management tasks
Detection of patients
Establishment and maintenance of a therapeutic alliance
Advocacy
Needs assessment
Design of an individualized care plan
Continuous monitoring of the care plan
Monitoring of client's mental functioning
Compliance with medication and side effects
Supportive counselling
Coordination of service delivery: referral and linking to services
Monitoring and evaluating the effectiveness of service provision
Modifying provision of services

This summary is based on the works of Chamberlain and Rapp¹¹⁷; Charnley and Davies¹¹⁸; Dincin¹¹⁹; Draine¹²⁰; Drake et al¹²¹; Modrcin et al¹²², Renshaw¹²³; Rothman¹²⁴; and Stein and Diamond¹²⁵.

CM has had to adapt over time evolving into new forms. In this way, the more traditional categorizations and models have been progressively replaced by new ones^{103,116,126-131}. The efficacy of CM has primarily been understood through two Cochrane reviews^{129,130} however, in actual fact, eight meta-analytic reviews have been conducted on the topic. Next, we look at CM categorizations and models and discuss the reviews of CM effects in order to understand its role as a principal component of mental health services.

1.4.1. Case Management categorizations and models

Although the principles and tasks mentioned prevail as the foundation of CM, the scope of activities of case managers has widened over time, including, for example, other populations besides SMI^{132,133}. The increase in the case managers' scope of activities is revealed through various ways of categorizing CM. A conventional way of categorizing CM involves differentiating between direct care and service broker according to the frequency of patient contact and intervention intensity¹²⁶⁻¹²⁸. Over time the definition of CM models has become more complex and comprehensive. For instance, Thornicroft¹¹⁶ categorizes CM into 12 axes and CM programs are classified according to their position in each of these axes. It may be one of the most useful categorizations of CM since it may reflect its complexity in practice. Another way of categorizing CM is in terms of

discrete models^{103,116}. According to Solomon¹³¹, there are four types of CM: 1) Assertive Community Treatment (ACT), 2) Strength CM, 3) Rehabilitation and 4) Generalist. Meanwhile, Mueser et al¹⁰³ describe the following six models: 1) Broker CM, 2) Clinical Case Management (CCM), 3) Strength CM, 4) Rehabilitation, 5) ACT and 6) Intensive Case Management (ICM). Table 8 provides a description of the main characteristics of the CM categorizations carried out by Thornicroft¹¹⁶, Solomon¹³¹ and Mueser et al¹⁰³. Regarding discrete models, there has also traditionally been a broader categorization that differentiates between ACT and any other form of CM^{129,130}. In this categorization, ACT has distinguished elements when compared to any other form of CM. Specifically, it includes lower caseloads, a team approach rather than an individual approach, assertive outreach and direct provision of care.

New categorizations or models have been developed due to the evolution of CM over time. With regard to new categorizations, Burns et al¹³⁴ differentiates between ICM and non ICM. The term ICM is applied to different conceptual models^{104,135-138}, which shows a convergence of ACT with any other form of CM. ICM is an intervention pertaining to the local service organization and it is considered to be a way of organizing teams¹³⁹. ICM addresses the social and health needs of people with SMI at high risk of rehospitalisation and is an intensive and long-term approach. Case managers have caseloads of about 20 patients or less, direct contact with patients¹³⁴ and are clinicians in charge of providing comprehensive treatment, rehabilitation and support services¹⁴⁰ together with their CM responsibilities¹⁴¹. ICM aims to maintain patient contact with services, decrease hospital admissions and enhance results¹⁴². Non ICM refers to a package of care that includes most of the features of ICM but a caseload size of over 20 patients.

Regarding CM models, it is worth highlighting the Flexible Assertive Community Treatment model or FACT¹⁴³, which is a rehabilitation-based CCM. FACT is an adaptation of the American ACT¹³⁶ to the Dutch community-based mental health services¹⁴⁴. FACT is composed of a multidisciplinary team that can operate individually or by means of a team approach, depending on patient's needs. That is, patients who are more stable receive individual CM coordinated by the multidisciplinary team, while less stable patients receive shared CM and assertive outreach from the same multidisciplinary team which is integrated by case managers (i.e. psychiatric nurses,

psychiatric community nurses, social workers and substance abuse counsellors), psychiatrists, psychologists and individual placement and support workers. These teams coordinate care, provide evidence-based medical interventions and recovery-based rehabilitation for people suffering from SMI. See Table 9 for more details regarding the features of FACT.

1.4.2. The effects of Case Management through metaanalyses

When considering the efficacy/effectiveness of CM, two relevant Cochrane reviews^{129,130} have had a clear impact. This may be related to the fact that they used a meta-analytical approach, which has been considered to provide a more objective assessment of evidence than literature reviews, a more accurate estimate of treatment effect, and may help to better explain inconsistencies between outcomes of individual studies¹⁴⁵. Together with the above-mentioned Cochrane reviews, there are some other reviews that use the same approach in an effort to establish CM efficacy/effectiveness and, moreover, the Cochrane group has updated its two meta-analytic reviews¹⁴².

The first meta-analytic review regarding the effects of CM was conducted by Bond in 1995¹⁴⁶. This review involved the effectiveness of ACT and included 9 studies with pre-post, quasi-experimental and experimental designs. The results of this review showed that 84% of patients who received ACT kept in contact with services in comparison to only 54% of patients who received standard care. Moreover, data showed that ACT significantly reduced inpatient days after one year. There was only limited evidence regarding the effectiveness of ACT in quality of life and general functioning.

Three years later, Gorey et al¹⁴⁷ conducted another review of this type and included, as Bond et al¹⁴⁶, pre-post, quasi-experimental and experimental studies. This review involved 24 studies, which doubles the number of studies included in the previous review¹⁴⁶. This may be related not only to the increase in CM studies over time, but also to the fact that the scope of this review was broader and included ACT and other models of CM (i.e. strength, rehabilitation and generalist). The results of this review showed that 75% of patients in CM were doing better than patients without CM, and that the more intense the CM, the greater the preventive fraction patients displayed.

Table 8. Models of Case Management

Thornicroft (1991): Axes											
<i>Patient responsibility</i>	<i>Level of contact</i>	<i>Intensity</i>	<i>Budgetary control</i>	<i>Health/social service staff</i>	<i>Status</i>	<i>Specialty</i>	<i>Staff/patient</i>	<i>Patient participation</i>	<i>Point of contact</i>	<i>Level of intervention</i>	<i>Target population</i>
Individual or team-based patient responsibility	Level of direct or indirect contact of case manager with patient	Frequency and intensity of contact with patient	Case manager control over budget	Professional areas involved in patient care	Training of case managers	Specialty of case managers	Size of caseload	Emphasis placed on patient participation	Setting where contact takes place	Individual, network or system	Degree of catchment population definition
Solomon (1992): Models											
<i>Generalist</i>	<i>SCM</i>			<i>RCM</i>			<i>ACT</i>				
Includes assessment, planning, linking and advocacy	Based on patients' strengths and includes the identification/development of resources/situations for patients' success			Includes the assessment of living skills and a rehabilitation plan. It provides ongoing interpersonal support, assistance in crises and access to resources			Includes skills training, clinical management and support. Provided by multidisciplinary teams 24h /7 days a week in the community				
Mueser et al (1998): Features											
<i>Models</i>	<i>Caseload</i>	<i>Outreach</i>	<i>Shared caseload</i>	<i>24-hour coverage</i>	<i>Patient input</i>	<i>Skills training</i>	<i>Contact frequency</i>	<i>Contact place</i>	<i>Treatment integration</i>	<i>Direct care</i>	<i>Target population</i>
<i>BCM</i>	1:50	Low	No	No	No	No	Low	Office	Low	Low	SMI
<i>CCM</i>	1:30	Low	No	No	Low	Low	Moderate	Office	Moderate	Moderate	SMI
<i>SCM</i>	1:20-30	Moderate	No	No	High	Moderate	Moderate	Community	Low	Low	SMI
<i>RCM</i>	1:20-30	Moderate	No	No	High	High	Moderate	Office Community	Low	Low	SMI
<i>ACT</i>	1:10	High	Yes	Yes (often)	Low	Moderate	High	Community	High	High	SMI high users
<i>ICM</i>	1:10	High	No	Yes (often)	Low	Moderate	High	Community	High	High	SMI high users

SCM = Strength Case Management; RCM: Rehabilitation Case Management; ACT = Assertive Community Treatment; BCM = Broker Case Management; SMI = Severe Mental Illness; CCM = Clinical Case Management;; ICM = Intensive Case Management

The two reviews previously described, along with that of Ziguras and Stuart¹⁴⁸, are the only ones that include other studies besides those with experimental designs (i.e. randomized, controlled trials). The inclusion of only this type of studies seems to improve the reliability of the meta-analysis results since it may help to differentiate between changes arising from CM and changes arising from other factors not related to CM¹⁴⁸. The aforementioned Cochrane reviews were also published in 1998^{129,130}. The first¹³⁰ aimed to establish the efficacy of CM, not including ACT, compared to standard care. It involved 8 randomized controlled trials and the outcomes regarding use of services and clinical and psychosocial functioning. Compared to standard care, CM increased contact with services, but also psychiatric hospital admissions. In addition, CM was not associated to improvements in patients' clinical and psychosocial functioning. The second review conducted by the Cochrane group¹²⁹ aimed to establish the efficacy of ACT in comparison to standard care, hospital-based rehabilitation and any other form of CM. It included 20 randomized controlled trials and involved the same type of outcomes as the first Cochrane review¹³⁰ together with costs. When ACT was compared to standard care, the former seemed to be related to a greater probability of maintaining contact with services, a lower probability of hospital admissions, less time in the hospital, better accommodation, a better job, greater satisfaction and a reduction in hospital resource costs. No ACT effect was observed in psychiatric symptoms or social functioning. When ACT was compared to hospital-based rehabilitation, ACT did not show any advantage with regard to retention, but seemed to decrease hospital admission and length of hospitalization, and to increase the probability of living independently. When ACT was compared to any other form of CM, there were no differences regarding retention and ACT seemed to decrease hospital stay and hospital resource costs.

In 1999, another meta-analytic review was conducted¹⁴⁹ and, as in the review conducted by Marshall et al¹²⁹, it aimed to establish the efficacy of ACT versus standard care. The study included 19 randomized controlled trials and showed ACT efficacy in decreasing hospital admissions, length of hospital stay, psychiatric symptoms and costs, and in increasing social functioning and patient satisfaction. According to the authors¹⁴⁹, the results should be accepted with caution, except in the case of patient satisfaction, because the relationship between outcomes and treatment was not completely clear as shown by the analyses of attrition effects and treatment variance. Subsequently, Ziguras

and Stuart¹⁴⁸ conducted another meta-analytic review. This review was a replication of the meta-analyses conducted by Marshall et al¹⁵⁰ and Marshall and Lockwood¹⁴¹, but with an expansion in its inclusion criteria. Thus, Ziguras and Stuart¹⁴⁸ included 44 studies, which was a significant increase in the number of studies included in the reviews conducted by Marshall et al¹⁵⁰ and Marshall and Lockwood¹²⁹. This review showed that CCM and ACT were better than standard care in terms of family burden, family satisfaction and costs of care. When compared to standard care, ACT seemed to reduce the total number of hospital admissions and the proportion of patients hospitalized, while CCM seemed to increase both outcomes. Even so, the length of hospital admission was shorter in CCM than in standard care. Both ACT and CCM reduced the number of hospital days, but ACT was significantly superior. No differences were observed between ACT and CCM in symptoms, patient contact with services, drop-out rates, social functioning and patient satisfaction.

The most recent meta-analytic reviews carried out to establish the efficacy of CM were conducted by Burns et al¹³⁴ and Dieterich et al¹⁴². The first review¹³⁴ aimed to establish the efficacy of ICM compared to standard care. It involved 29 randomized controlled trials and used hospital days as the only outcome. The results showed that ICM worked best for patients who already used a number of hospital resources, and that fidelity to ACT increased the probability of reducing hospital care in ICM. The second review¹⁴² is the updated version of the two Cochrane reviews already described^{129,130}. It aimed to establish the efficacy of ICM compared to standard care and also to non ICM and involved 38 randomized controlled trials. When comparing ICM to standard care, ICM showed efficacy in length of hospitalization, maintaining contact with services, overall functioning, accommodation, living independently and satisfaction. There were no differences between ICM and standard care with regard to mortality rates, contact with the legal system, employment status or quality of life. When comparing ICM to non ICM, ICM was better only with regard to drop-out rates at follow-up. There were no differences between ICM and non ICM in terms of length of hospitalization, service use, mortality, social functioning, mental state, behaviour, quality of life, satisfaction or costs. The analyses were also carried out taking into account fidelity to ACT and use of hospital resources at baseline. Fidelity to ACT and a high use of hospital resources at baseline were independently linked to a higher reduction of hospital time in ICM. When

both variables were combined, only high use of hospital resources at baseline was significantly associated to a higher reduction of hospital time in ICM.

In sum, CM and ACT are complementary rather than different models of CM in clinical practice . They have converged into two models of care for patients with SMI that differ with regard to intensity (i.e. ICM and non ICM). A most recent model is the FACT which integrates CM and ACT and its intensity depends on patients' needs. Efficacy results suggest that CM could be reconfigured by offering intensity of care according to patient characteristics. In other words, CM could be organized to tailor to patients' needs, which might help to improve patients' conditions but also enhance clinical decision-making and management of care by optimizing the use of resources.

1.4.3. Case management in Spain and in Catalonia

The deinstitutionalization movement in Spain also conducted to a shift from a hospital-based to a community-based mental health care delivery system that nowadays it is characterized by a network integrated by community mental health and psychosocial rehabilitation services¹⁵¹. The Mental Health Strategy of the Spanish National Health System¹⁵² emphasises the use of CM programs in order to coordinate the access to mental health resources and, thus, optimize their use. Even so, CM programs are not widely implemented in Spain¹⁵¹ and there are differences among Spanish autonomous communities such as Catalonia, where the state mental health care resources are provided by contracting private services.

In Catalonia, the public mental health network is integrated into the national health system and organised into health care sectors of about 100,000 inhabitants. This network is based on the principles of community mental health care and, specifically, on Adult Mental Health Centres (AMHCs) and other community services such as day hospitals or community rehabilitation centres. They all aim to provide specialized care by means of multidisciplinary teams.

AMHCs consist of multidisciplinary teams (including psychiatrists, psychologists, nurses and social workers) that offer specialist care for patients with mental disorders through the programmes and interventions included in the care service they provide. Since their set up, AMHCs have offered care to patients with SMI through a standard

treatment programme (STP) which is a low-intensity program run mainly by the intervention of psychiatrists as professionals in charge of patients. The main elements of the STP are the following: 1) general clinical and psychosocial assessment; and 2) medical interventions and follow-ups (basically psychopharmacologic).

Progressively, AMHCs increased the number of patients with SMI they were taking care of and the STP resources were not the proper ones for those patients with SMI who are more prone to drop-out, clinical relapses and frequent hospitalisations. Therefore, in 1997 the Health Department of Catalonia developed a specific type of CM programme for those patients¹⁵: The Severe Mental Disorder Specific Care Program.

The main elements of the CM programme are those described by Ruggeri and Tansella¹⁵³: 1) assignment of a community mental health nurse as a case manager to monitor and coordinate patient care; 2) comprehensive assessment of medical and psychosocial needs; 3) preparation of a personalised therapeutic plan based on individual needs; and 4) periodic reviews and updates of the therapeutic plan. Moreover, the CM programme meets the criteria of the clinical CM model¹⁵⁴ including the direct provision of the following interventions: 1) set-up and follow-up of medical interventions; 2) psychoeducation; 3) family intervention; 4) daily-life activity support; and 5) crisis intervention according to patients' needs and resource availability. It also meets the criteria of a non-intensive CM programme, since the caseload size is over 20 patients¹⁴².

Even so, frequently, the aforementioned CM programme is a deficient resource for a specific group of patients with SMI, especially for those not in contact with the public mental health network. For this group of patient there is another variant of CM programme called: Individualized Service Plan¹⁵⁵.

Table 9. Features of Flexible Assertive Community Treatment as described by van Veldhuizen (2007) and Drukker (2008)

Feature	Description	
Model service	Rehabilitation-based CCM	
Program caseload size	200-220 patients with SMI/50,000 inhabitants	
Staff	Multidisciplinary team: 7-8 FTE case managers; 0.8 psychiatrist; 0.6 psychologist; and 0.5 supported employment worker	
Tasks	Coordinate care Provide evidence-based medical interventions Provide recovery-oriented rehabilitation	
Approach	Individual CM for stable patients	Shared CM and AO for non stable patients
Description of FACT activities according to approach	2-4 visits per month at home	Assertive outreach
	Provide individual care	Shared case load
	Development of treatment plan: Goals of rehabilitation, Organization of social support, Organization of work and Crisis plan	The psychiatrist must see the patient within two days: Update crisis plan and Set crisis plan into motion
	Update of treatment plan once a year	Team goals: Prevent readmission and Shorten crisis
	Regular appointments with the psychiatrist - Medication management - Evaluation	Patient status is reviewed daily in the team routine: - Appointments for home visits - Appointments for other actions
	Regular appointments with the psychologist - Psychoeducation - Cognitive Behavior Therapy	If crisis decreases, gradual switch from shared caseload to individual care
Family interventions and supported employment if necessary	If crisis remits, update crisis plan and individual CM	

CCM = Clinical Case Management; SMI = Severe Mental Illness; FTE = Full Time Equivalent; CM = Case Management; AO = Assertive Outreach;

It has been also developed from 1997 and, unlike the Severe Mental Disorder Specific Care Program, it is not offered in AMHCCs. Rather, it is an autonomous resource that operates in the community alongside the rest of resources of the public mental health network such as AMHCCs, day hospitals, community rehabilitation centres, hospital units and other health, social and judicial services. This CM program aims to hold and link patients with SMI in the community and guarantee their functioning from their setting and their competences. It is based on the principles of intensive CM¹⁵⁴ and it includes as main elements: 1) assignment of a case manager as responsible for each case (i.e. a nurse, a social worker or a social educator); 2) assessment of patients' needs and competences; 3) assertive follow-up; 4) link of patients with services and coordination of the care required. It is a variant of high-intensity CM program since the patient-professional ratio is lower than 20¹⁴².

It is worth noting that medical and all other interventions included in either the STP or both CM programmes follow the Clinical Practice Guideline for Schizophrenia issued by the Spanish Ministry of Health and Consumer Affairs¹⁶. See Table 10 for a general comparison of the three community treatment programs available in Catalonia for the care of persons with SMI.

Table 10. Main characteristics of the community treatment programs for patients with severe mental illness in Catalonia

	Standard treatment	Severe Mental Disorder Specific Care Program	Individualized Care Plan
<i>It is provided by</i>	Adult Mental Health Center	Adult Mental Health Centre	Autonomous program
<i>Place where it is provided</i>	Adult Mental Health Center facilities	Adult Mental Health Centre facilities and, rarely, at home or hospital units	Community
<i>Clinician in charge</i>	Psychiatrist	Psychiatrist	Case manager
<i>Case manager</i>		Community mental health nurse	Community mental health nurse, social worker, social educator or occupational therapist
<i>Assessment</i>	Global assessment including medical and psychosocial aspects	Systematic assessment: <ul style="list-style-type: none"> - Medical assessment - Psychosocial assessment 	Systematic assessment: <ul style="list-style-type: none"> - Psychosocial needs - Clinical and social functioning
<i>Therapeutic plan</i>		Development of an individualized therapeutic plan <ul style="list-style-type: none"> - Regularly reviewed and updated - Modified if necessary 	Development of an individualized therapeutic plan <ul style="list-style-type: none"> - Regularly reviewed and updated - Modified if necessary
<i>Treatment</i>	Medical intervention : <ul style="list-style-type: none"> - pharmacological treatment set up 	Medical intervention : <ul style="list-style-type: none"> - pharmacological treatment set up Specific psychosocial interventions: <ul style="list-style-type: none"> - Psychoeducation - Family Therapy - Assistance in Daily Living - Crisis interventions (assertive outreach) 	Intervention aimed to adhere to the program and other services required
<i>Follow-up</i>	Medical follow-up: 4-6 visits per year	Medical follow-up: 4-6 visits per year Nursing follow-up: 12 visits per year	Weekly assertive follow-up according to patients' needs

2. APPROACH TO WORK

The shift from hospital-based to community-based care has been a challenge that has required the development of specific resources and strategies such as CM programs for the care of patients with SMI. This challenge has been also present in Catalonia where AMHCCs have developed a CM program called the Severe Mental Disorder Specific Care Program.

Initially, the aim of the present PhD thesis was to establish the effectiveness of the aforementioned CM program in a sample of patients with schizophrenia. To our knowledge, this had not been conducted so far, which is relevant since it involves the care of a great number of outpatients with SMI in Catalonia. Even so, we had to deal with some specific issues that, at the same time, turn into objectives of the present work.

Firstly, we conducted a literature review of CM for the writing of its background (i.e. definition, characteristics, models and effects). During that review, we realized that CM has undergone major changes over time especially regarding its models and effects. Specifically, there seem not to exist anymore the traditional distinction between CM models, which also affects the analysis of effects of CM. Taking into account all the above mentioned, we decided to conduct a more extensive literature review about CM, which would help to better understand the development and performance of CM programs at an international and national level.

Secondly, we also realized that some of the instruments we had choose to use for the evaluation of the CM program were not specifically validated in patients with schizophrenia. Those instruments had been frequently used although no specific validation was available in patients with schizophrenia because of their feasibility, some of the aspects they cover and their psychometric properties in other sample populations. Namely, these instruments were the following:

- The World Health Organization Quality of Life Scale Brief Version (WHOQOL-BREF)^{156,157}
- The Disability Assessment Schedule Short Form (DAS-s)¹⁵⁸
- The DUKE-UNC Functional Social Support Questionnaire (FSSQ)^{159,160}

The validation of the above-mentioned psychometric instruments was a requirement for the analyses of the effectiveness of the CM program. It is worth noting that the use of instruments that are valid and reliable is considered a key piece for quality research¹⁶¹ or, in other words:

“Science rests on the adequacy of its measurement. Poor measures provide a weak foundation for research and clinical endeavours” (Foster and Cone¹⁶², 1995, p. 258).

The literature review about CM highlighted that the elements and intensity of CM may be established according to patients’ needs. Therefore, it is important to improve the knowledge of the needs of patients receiving CM intervention such that described in our study. The validation of the psychometric instruments made a reliable ground for it. So, we aimed to establish the socio-demographic, clinical and psychosocial variables that were significantly associated with the assignment of a patient with schizophrenia in the Severe Mental Disorder Specific Care Program. Our results may provide a better understanding of the needs of patients with schizophrenia receiving CM services in that setting, which may help to tailor CM practices into patients’ needs. It may also help to provide a context for improving the definition of SMI at a regional level but, in view of the fact that the outcomes used are common to clinical practice and research, our results may also be easily replicated at other levels.

Finally, we proceeded to the evaluation of the effectiveness of the Severe Mental Disorder Specific Care Program in comparison with a STP and with regard to socio-demographic, clinical and psychosocial variables. This is important at a local level, as already said, but also at a national level. Studies on the effectiveness of CM in Spain with experimental designs and large sample sizes are scarce and restricted to specific type of outcomes^{151,163,164}, which makes it important to evaluate it, since it is known that there is country-culture influence on CM implementation¹⁶.

3. OBJECTIVES

The main objective of the present PhD thesis is to establish the effectiveness of a CM program (i.e. the Severe Mental Disorder Specific Care Program) operating at the State Mental Health Network of the Catalan Health Service in a sample of patients with schizophrenia.

To reach the main objective, it has been necessary to operationalize it in three consecutive objectives as shown in Figure 3.

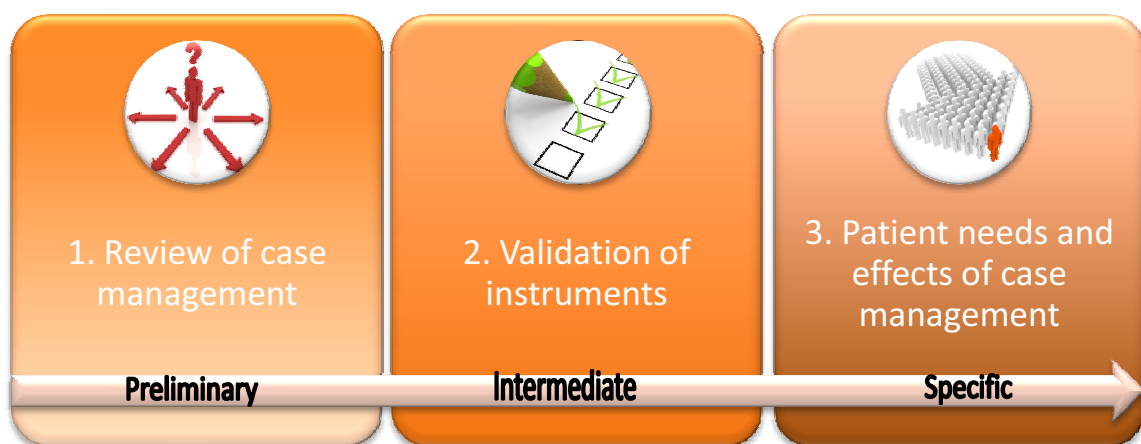


Figure 3. Objectives of the present PhD thesis

- *Preliminary objective:*

To review the literature about CM regarding its definition, characteristics, models and effects

- *Intermediate objective:*

To validate different psychometric instruments in patients with schizophrenia. It includes three sub-objectives:

- To validate the WHOQOL-BREF^{156,157} in patients with schizophrenia
- To validate the DAS-s¹⁵⁸ in patients with schizophrenia
- To validate the FSSQ^{159,160} in patients with schizophrenia

- *Specific objective:*

To improve the knowledge about the patients' needs and effects of the CM program (i.e. The Severe Mental Disorder Specific Care Program). It involves:

- To establish the socio-demographic, clinical and psychosocial variables significantly associated with the inclusion of patients in the CM program
- To establish the effectiveness of the CM program in comparison with a STP in a sample of patients with schizophrenia and with regard to socio-demographic, clinical and psychosocial variables.

4. RESULTS

4.1. Organization

As already stated, the main objective of the present PhD thesis is to establish the effectiveness of a CM program. In order to do so, it was necessary to operationalize it in three consecutive objectives (i.e. preliminary, intermediate and specific) which are linked to one or more studies, papers or paper proposals, as shown in Figure 4.

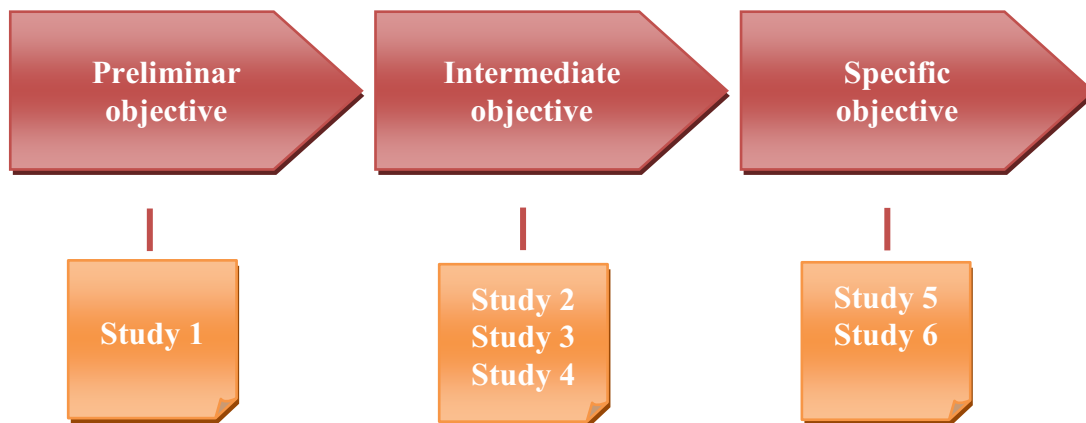


Figure 4. Linking objectives and studies

The first objective is the so called **preliminary objective** which aims to review the literature about CM regarding its definition, characteristics, models and effects. It is linked to our first study conducted (i.e. Study 1). Study 1 is entitled *Current case management models* and it is a review article that assesses and updates the literature regarding CM categorizations and models and their effects. It aims to better understand the current role of CM as a key component of mental health services.

The **intermediate objective** turns into three studies that involve the validation of psychometric instruments in patients with schizophrenia. Study 2 is entitled *The World Health Organization Quality of Life Scale Brief Version: a validation study in patients with schizophrenia*. It is an original article that shows the psychometric properties of the WHOQOL-BREF^{156,157} in patients with schizophrenia. It assesses the following aspects of validity and reliability of the instrument: internal consistency, evidence validity, sensitivity to change and changes over time. Study 3 is entitled *The World Health Organization Disability Assessment Schedule Short Form: a validation study in patients*

with schizophrenia. It is an original article that shows the psychometric properties of the DAS-s¹⁵⁸ in patients with schizophrenia. It assesses the following aspects of validity and reliability of the instrument: factor structure, internal consistency, evidence validity, sensitivity to change and changes over time. Study 4 is entitled *Validation of the modified DUKE-UNC Functional Social Support Questionnaire in patients with schizophrenia* and it is an original article that shows the psychometric properties of the FSSQ^{159,160} in patients with schizophrenia. It assesses the following aspects of validity and reliability of the instrument: factor structure, internal consistency, evidence validity, sensitivity to change and changes over time.

The last of the three consecutive objectives is the so-called **specific objective** and it involves two studies that aim to improve the knowledge of a CM program regarding the sample population it is aimed for (Study 5) and its effects (Study 6). Study 5 is entitled *Considering variables for the assignment of patients with schizophrenia to a case management programme*. It is an original article that analyses variables associated with the assignment of a patient with schizophrenia to CM services (i.e. the Severe Mental Disorder Specific Care Program) rather than to the STP services from 10 AMHCCs from Barcelona. It takes into account socio-demographic, use of service, clinical and psychosocial variables. Finally, there is Study 6 which is the most specific of the objectives of the present PhD thesis. Study 6 is entitled *Clinical case management for patients with schizophrenia with high care needs*. It is an original paper that shows the effectiveness of a CM program (i.e. the Severe Mental Disorder Specific Care Program) versus STP in a sample of patients with schizophrenia from 10 AMHCCs from Barcelona. It assesses their effectiveness with regard to use of service, clinical and psychosocial variables.

4.2. Publication Compendium

Following, there are further details about the studies that involve the present PhD thesis. They are presented according to its objectives.

- **Preliminary objective**

Study 1 → “*Current case management models*”

Authors: Mas-Expósito L, Amador-Campos JA, Gómez-Benito J and Lalucat-Jo L.

Journal: Journal of Social Work, accepted for publication.

- > Impact factor: 1.000
- > Journal Rank in Social Work: Q2

- **Intermediate objective**

Study 2 → “*The World Health Organization Quality of Life Scale Brief Version: a validation study in patients with schizophrenia*”

Authors: Mas-Expósito L, Amador-Campos JA, Gómez-Benito J and Lalucat-Jo L.

Journal: Quality of Life Research, 2011, 20(7):1079-1089.

- > Impact factor: 2.300
- > Journal Rank in Health Care Sciences and Services: Q2
- > Journal Rank in Public, Environmental and Occupational Health: Q2

Study 3 → “*The World Health Organization Disability Assessment Schedule Short Form: a validation study in patients with schizophrenia*”

Authors: Mas-Expósito L, Amador-Campos JA, Gómez-Benito J and Lalucat-Jo L.

Journal: Comprehensive Psychiatry, 2012, 53(2):208-216.

- > Impact factor: 2.257
- > Journal Rank in Psychiatry: Q3

Study 4 → “*Validation of the modified DUKE-UNC Functional Social Support Questionnaire in patients with schizophrenia*”

Authors: Mas-Expósito L, Amador-Campos JA, Gómez-Benito J and Lalucat-Jo L.

Journal: Social Psychiatry and Psychiatric Epidemiology, 2012, DOI 10.1007/s00127-012-0633-3

- > Impact factor: 2.696
- > Journal Rank in Psychiatry: Q2

- Specific objective:

Study 5 → “*Considering variables for the assignment of patients with schizophrenia to a case management programme*”

Authors: Mas-Expósito L, Amador-Campos JA, Gómez-Benito J and Lalucat-Jo L.

Journal: Community Mental Health Journal, under second review after the inclusion in the manuscript of the reviewer’s comments.

> Impact factor: 1.030

> Journal Rank in Health Policy and Services: Q3

> Journal Rank in Psychiatry: Q3

> Journal Rank in Public, Environmental and Occupational Health: Q3

Study 6 → “*Clinical case management for patients with schizophrenia with high care needs*”

Authors: Mas-Expósito L, Amador-Campos JA, Gómez-Benito J, Lluís Mauri-Mas and Lalucat-Jo L.

Journal: International Journal of Clinical and Health Psychology, under review.

> Impact factor: 2.787

> Journal Rank in Psychology Clinical: Q1

4.2.1. Study 1

This paper reviews and updates the literature conducted about CM at an international level. Its final aim is to set the proper background that may help to understand CM nowadays as a key component for the care of persons with SMI in mental health services (See Annex 1).

First, this paper reviews the literature of CM with regard to its origins, principles and tasks. Then, it reviews and updates the forms that CM has evolved in over time taking into account traditional models but also new models that are currently in practice. Finally, it examines and brings up to date the effectiveness or efficacy of CM through meta-analytic studies.

Overall, the present paper shows that CM has undergone major changes over time. On the one hand, the traditional models of CM seem to be out of date and not used anymore in clinical practice as evidenced by the most recent models of CM. On the other hand, the effects of CM have been mainly restricted to specific meta-analyses and are not homogeneous across studies. The most recent studies suggest that some variables (i.e. patients' characteristics and program fidelity) may be associated to CM efficacy or effectiveness.

This paper suggests the development of CM interventions that could offer various levels of intensity depending on the needs of patients. It may have implications for both patients and mental health professionals but also for mental health administrators. Namely, these kinds of CM interventions may help out to better improve patients' functioning, boost the decision making of mental health professionals and, at the same time, guarantee an optimal use of the resources available for the care of persons with SMI.

4.2.2. Study 2

The review of the literature of CM shows that it has undergone major changes over time but it also shows the use of non validated scales as one of the weak points of CM studies as well as some of the key components of CM. One of these key elements is the availability of assessment models integrated of valid and reliable instruments, which facilitates the follow-up of individuals' progression as well as the study of overall effects of CM programs (See Annex 2).

This study, as well as Studies 3 and 4, aims to validate an instrument for the assessment of patients with schizophrenia. Specifically, the objective of Study 2 is to validate the WHOQOL-BREF^{156,157} and show whether it is a suitable instrument to assess quality of life in this sample population.

Firstly, the paper deals with the overall internal consistency and the internal consistency associated with the domains of the instrument. Then, it addresses the validity evidence of the instrument 1) association with clinical and psychosocial variables and 2) differences in quality of life between groups of patients with schizophrenia. Finally, the paper focuses on the changes over time in quality of life as well as in other considered variables.

Overall, this paper shows that the WHOQOL-BREF^{156,157} has good psychometric properties in patients with schizophrenia. Specifically, it shows good internal consistency and the expected associations with clinical and psychosocial variables as well as the expected differences in quality of life between groups of patients with schizophrenia. That is, it shows good validity evidence. Finally, it shows sensitivity to change.

This study concludes that the WHOQOL-BREF^{156,157} has good reliability and validity, and suggests that it is suitable for the assessment of quality of life in patients with schizophrenia by mental health professionals for clinical practice or research purposes. More specifically, the WHOQOL-BREF^{156,157} may be a suitable instrument for use in CM programs as part of their assessment models.

4.2.3. Study 3

As stated in Study 2, one of the key components of CM is the availability of assessment models integrated by valid and reliable instruments. Study 3 aims to validate a psychometric instrument in a clinical sample of patients with schizophrenia. Namely, it deals with the psychometric properties of the DAS-s¹⁵⁸ in order to show its suitability for the assessment of disability in this patient population (See Annex 3).

This study assesses the validity and reliability of the aforementioned instrument. First, it deals with the factor structure of the instrument as well as its internal consistency. Then, it assesses its validity evidence (i.e. association with other variables and differences in disability between groups of patients with schizophrenia). In the end, Study 3 tests the capacity of the DAS-s¹⁵⁸ to detect changes over time and its sensitivity to change taking into account use of services, clinical and psychosocial variables.

In general terms, this study provides evidence about the psychometric properties of the DAS-s¹⁵⁸ in patients with schizophrenia. It has good reliability and validity as revealed by its proper values of internal consistency, its theoretically-supported factor structure, its validity evidence, its capacity to detect changes over time and its sensitivity to change.

The conclusion of this study is that the DAS-s¹⁵⁸ is a suitable instrument for the assessment of disability in patients with schizophrenia in clinical practice or research purposes. As the WHOQOL-BREF^{156,157}, it could be one of the instruments considered in assessment models of community treatment programs, such as CM programs, for the care of persons with schizophrenia.

4.2.4. Study 4

Study 2 and Study 3 have already highlighted the idea that one of the key components of community treatment programs, such as CM, is the availability of an assessment model integrated by valid and reliable instruments. As Study 2 and 3, Study 4 aims to validate a psychometric instrument in a clinical sample of patients with schizophrenia. Namely, it proves the psychometric properties of the FSSQ^{159,160} in order to show its suitability for the assessment of social support in this patient population (See Annex 4).

This study deals with the validity and reliability of the above mentioned questionnaire. Firstly, it evaluates its validity evidence: 1) the factor structure of the scale; 2) its internal consistency; 3) its associations with other variables; and 3) differences in social support in groups of patients with schizophrenia. Secondly, it deals with the capacity of the FSSQ^{159,160} to detect changes over time and its sensitivity to change considering use of services, clinical and psychosocial variables.

Study 4 shows good psychometric properties for the FSSQ^{159,160} in a sample of persons with schizophrenia. Specifically, it shows a factor structure that is theoretically-supported, adequate internal consistency, and good validity evidence as well as capacity to detect changes over time and sensitivity to change.

The Study 4 findings suggest that the FSSQ^{159,160} could be used for the assessment of perceived social support in patients with schizophrenia in research or clinical practice. More specifically, it could be part of the instruments that integrate the assessment models of community treatment programs as for example CM programs.

4.2.5. Study 5

The literature review conducted for the first study showed that the elements and intensity of CM practices should be established according to patients' needs. So, it highlighted the relevance of improving the knowledge of the needs of patients in such a community-based intervention. Study 2, 3 and 4 showed good psychometric properties of the aforementioned instruments in persons with schizophrenia. Study 5 aims to improve the knowledge of patients' needs assigned to a CM programme (See Annex 5).

First, this paper compares the profile of patients included in a CM program (i.e., the Severe Mental Disorder Specific Care Program) versus the profile of patients included in a STP in 10 AMHCCs from Barcelona (Catalonia, Spain). Then, it analyses which socio-demographic variables, clinical and psychosocial outcomes and use of health care service variables are significantly associated with the assignment of a patient to the CM programme. It showed that patients in CM services had higher use of health care services, poorer clinical and psychosocial functioning and more health care needs than patients in the STP. The variables significantly associated with the assignment of a patient to CM services were the following: 1) educational level; 2) needs; 3) physical health; 4) positive psychiatric symptoms; 5) social services visits; and 6) community psychiatric nursing visits.

The characterization of patients with schizophrenia according to treatment programme and the knowledge of patients' characteristics associated with the provision CM practices in the Catalan Health Service provide a better understanding of the needs of patients with schizophrenia receiving CM services. It may help to tailor the CM programme practices into patients' needs by considering other interventions such as CBT, strategies that target patients' social cognition or aimed at improving patients' physical health, besides those described in the Introduction section. In addition, our findings highlight other variables, besides those stated by NIMH (1987), which may be considered in the definition of SMI in the Catalan Health Service.

4.2.6. Study 6

The literature review conducted on CM showed some gaps in evidence regarding CM. Specifically, Study 1 showed that, to date, studies on CM in Spain are scarce and restricted to specific outcomes and that none study had been developed in Catalonia, which is important since there are differences in the provision of health services among Spanish autonomous communities. Studies 2, 3 and 4 were a guarantee for the reliability and validity of the scores of the psychometric instruments and, therefore, of data quality; while Study 5 was a necessary first step towards evaluating the effectiveness of the CM programme over the STP, which is the aim of Study 6 (See Annex 6).

This is a quasi-experimental study of one year of duration that compares the profile of a group of patients with schizophrenia in a CM programme from 10 AMHCCs in Barcelona (Spain) versus the profile of patients with schizophrenia in a STP. Patients were evaluated at baseline and at one year follow-up with a battery of instruments including socio-demographic data, clinical and psychosocial variables and use of services.

As already known, the CM programme group showed poorer clinical and psychosocial functioning and more health care needs at baseline. At one year follow-up, both treatment programmes were effective in maintaining contact with services and the group of patients in the CM programme improved, achieving a similar level to that of the STP group at baseline, regarding most outcomes included.

Hence, the results of this study highlight the effectiveness of a clinical CM programme implemented in Spain that could be directed at patients with more health care needs. The clinical CM programme and the STP could be provided consecutively in the care of schizophrenia, and responds to the importance of establishing CM on the basis of patients' needs.

5. DISCUSSION

The psychiatric deinstitutionalization supported the treatment of persons with SMI in the community rather than in psychiatric hospitals and, as a consequence, there was a clear need to develop community-based resources and interventions for this sample population. There was a growth of resources such as community mental health centres or day hospitals along with the development of community interventions such as CM. CM was originally defined as a way of coordinating, integrating and allocating individualized care within limited resources by means of continuous contact with at least one key worker¹¹⁶. However, the scope of the activities CM may involve has widened over time as revealed by the existing modalities of CM. CM is widely considered a major component of the services provided to persons with SMI, which points out the need of data supporting its efficacy and effectiveness in different settings since it is known that there is country influence on CM practices implementation¹⁶. Only a few initiatives have taken place in Spain^{151,165,166} but none specifically in Catalonia. Catalonia is a Spanish autonomous community where the state mental health resources are provided by private institutions by means of the public mental health network¹⁶⁷ in contrast to rest of Spanish autonomous communities. In this context emerged this PhD thesis to study the effectiveness of a clinical CM programme, so-called Severe Mental Disorder Specific Care Program¹⁵, for the care of patients with SMI in the Catalan Health System regarding patients' clinical and psychosocial functioning as well as health service use. In order to do so, a literature review was conducted showing that for the assessment of community interventions are necessary valid, reliable and context-adapted instruments. That is, instruments with valid and reliable scores for the assessment of the study population. Sometimes instruments are well-established as a part of the assessment resources available in mental health care services but, in contrary, have been never been validated in specific sample populations. The literature review also pointed out the relevance of improving the knowledge of the needs of patients with schizophrenia receiving care from such community-based modality of care as a key element interacting with its efficacy and effectiveness.

The conducted literature review (i.e., Study 1) highlighted the importance of considering patients' needs for the reconfiguration of CM services. This is consistent with the existing literature and initiatives that are being carried out. For instance, it has

been emphasized the importance of exploring how ACT teams address the physical health needs of persons suffering from SMI and learning more about their challenges. It is worth noting that this sample population suffers from high physical morbidity and mortality levels¹⁶⁸. Such suggested approach is thought to be revealing for active and novel ACT teams and could make possible a better integration of one of the greatest needs of patients with schizophrenia and mental health among other mental health services and settings^{169,170}. It has also been stressed the relevance¹⁷¹ of tackling the social needs of older patients with SMI that are being case managed¹⁷¹. Another example is the FACT, an adaptation of the American ACT¹³⁶ to the Dutch community-based mental health services¹⁴⁴ that is composed of a multidisciplinary team that can operate individually or by means of a team approach, depending on patient's needs. This new approach has shown promising results from its beginning. A preliminary evaluation of the FACT, showed that this community-based modality of care was associated to a decrease of the number of hospital days and personal costs when compared with treatment as usual¹⁷². A more recent study conducted by Bak et al¹⁷³ showed, by means of a real-life pre-post trial, a significant increase of the proportion of patients in clinical remission one year after the inclusion of the FACT in a specific geographic area.

The literature review conducted for Study 1 brings to view that CM models have undergone major changes over time and it seems there are no differences between the traditional CM and ACT in clinical practice¹³⁰. Actually, CM and ACT have evolved into two new models so-called "ICM and non-ICM" that share the same exact principles derived from CM and ACT but differ in intensity of care^{134,142}. Their effectiveness and efficacy is associated with patients' needs in terms that the higher the need, the more probabilities CM is effective.

In sum, Study 1 provides a better understanding of the development of CM from its beginning till nowadays. This information could be used to develop and put into practice new CM initiatives as well as adapt the existing ones. This should be made keeping in mind patients' needs and in order to optimize use of resources. The optimization of use of resources is nowadays a priority of mental health care policies especially in times of scarce resources.

The assessment of the efficacy or effectiveness of a treatment programme requires the collection and assessment of relevant outcomes. To do so, psychometric instruments that are valid, reliable and context-adapted are necessary. The validation studies of the WHOQOL-BREF^{156,157}, the DAS-s¹⁵⁸ and the FSSQ^{159,160} (i.e., Study 2, 3 and 4) support the appropriate psychometric properties shown in the original validation studies of such instruments. Moreover, these three validation studies sustain their use in the assessment of psychiatric patients and, especially, in outpatients with schizophrenia. This is of significance because studies about the validity and reliability of these three scales in psychiatric samples are scarce or lacking. As for the WHOQOL-BREF^{156,157}, it has been validated in patients suffering from major depression¹⁷⁴ and psychiatric outpatients^{175,176} in general terms. In addition, there is a validation study carried out in our setting and including patients with schizophrenia¹⁵⁶. In that study the WHOQOL-BREF^{156,157} showed satisfactory acceptability (i.e., whether the person taking the psychometric instrument finds it adequate), internal consistency, and evidence of convergent and discriminant validity. Even so, those analyses were based on a sample that included at the same time patients with schizophrenia, general patients and companions of those patients. In contrast, in our study, there is an extensive psychometric analysis of a sample solely composed of patients with schizophrenia, with follow-up at one year. To our knowledge, there are no specific validations of the DAS-s¹⁵⁸ and the FSSQ^{159,160} in psychiatric patients although they are instruments in use for the assessment of these patients such as those suffering from schizophrenia¹⁷⁷⁻¹⁷⁹ or recommended to be used as a psychosocial measure for the assessment of persons with SMI in the community¹⁸⁰.

In sum, the validation studies of the WHOQOL-BREF^{156,157}, the DAS-s¹⁵⁸ and the FSSQ^{159,160} showed that the three assessment scales have appropriate psychometric properties in outpatients with schizophrenia. Specifically, their scores were reliable and valid, which suggests that they are suitable psychometric instruments for the assessment of perceived quality of life, disability and perceived social support in outpatients with schizophrenia.

They could be used in clinical practice or research studies as outcome measures for the assessment of community interventions. We suggest that the use of three instruments provides a comprehensive assessment of the psychosocial functioning of patients with

schizophrenia in the community by means of the combination of clinician-rated and patient-rated outcomes.

We have also studied in detail the characteristics of patients with schizophrenia receiving a CM programme (i.e., Study 5), which has provided a comprehensive view of their needs. The improvement of the knowledge of patients needs is important since unmet needs have been considered to be good predictors of lower quality of life in persons suffering from SMI¹⁸¹. Our study is consistent with the view of some authors that suggest that needs are changeable and should be considered as outcomes in the assessment of mental health service systems¹⁸¹. As Drukker et al¹⁸², we suggest that rehabilitation interventions should be tailored to patients' needs. This is the way to raise long-term and favourable outcomes at the individual level and, at a local level, allows examinations that may help to elaborate relevant information for the management of specific groups of patients¹⁸². Some initiatives that tailor rehabilitation interventions to patient needs have been carried out. For example, Weinstein et al¹⁶⁹ have considered turning ACTs into an integrated health care system through the establishment of nursing and primary care alliances in order to be able to deal with the high prevalence of co-morbid physical health problems in persons suffering from SMI. Physical health has been seen as one of the parameters to consider in the reconfiguration of the CM programme evaluated in this PhD thesis.

The study of the needs of patients receiving care from the CM programme suggest its reconfiguration (i.e., Study 5). It takes into account that use of community psychiatric nursing services, use of social services, educational level, quality of life related to physical health, psychosocial needs and positive psychiatric symptoms are patients' characteristics significantly associated with the provision of CM practices in Catalonia and suggests such a reconfiguration by means of the addition of new elements that are evidence-based. Those elements may be, for example, CBT, social cognition strategies and physical health interventions. Additionally, the study of the variables significantly associated with the provision of CM practices in the aforementioned setting may be a preliminary further definition of SMI at a local level (i.e., the Catalan Health Service).

In these times of financial crisis and, consequently, of cuts in health care resources, it is important to carry out local initiatives to optimize the use of specific mental health care

resources such as CM programmes. Study 5 offers a deep insight into the needs of patients with schizophrenia receiving two community-based modalities of care aimed for the care of most persons with SMI in the Catalan Health Service (i.e., the Severe Mental Disorder Specific Care Program and the STP). This study provides a better understanding of the characteristics of specific groups of patients with whom these two modalities of care operate and suggests how could they be improved as well. The addition of new and evidence-based elements into the CM programme may turn into an enhanced version of it and, consequently, the complex needs of the sample population may be better fulfilled. That is the first step to optimize the use of the two community-based interventions analysed in this PhD thesis.

The evaluation of the effectiveness of the CM program versus the STP in 10 AMHCC in Barcelona (Spain) was the objective of Study 6. In Spain, the development of community teams to offer care for patients with SMI is quite irregular¹⁶⁷ and the literature regarding its effects is quite scarce. For instance, there is a descriptive study¹⁶⁵ about the Individualized Service Plan¹⁵⁵ which is a variant of high-intensity CM program^{134,142} functioning in Catalonia. It compares a group of patients receiving care from this CM program versus a group of patients receiving care from the Severe Mental Disorder Specific Care Program and shows that these two groups differ in terms of use of hospital and community services, disability level, clinical status, unmet needs and some of aspects of family burden and social support. Besides this descriptive approach, there are, to our knowledge, two analytical studies regarding the effects of CM in patients with SMI^{151,166}. The first one focuses on a variant of clinical CM and shows a significant reduction in use of hospital and emergency services that maintains over three years¹⁵¹. The most recent study focuses on the modality of CM called ACT and shows a significant decrease of hospital admissions and inpatient days as well as emergency room visits¹⁶⁶. In this PhD thesis we have analysed a variant of clinical CM and, thus, our results about the effects of CM are closer to those of the most recent study¹⁵¹. So, our study increases the evidence in favour of the use of CM for the care of persons with SMI in Spain. Namely, it strengthens the evidence of the effectiveness of the clinical CM model in use of service outcomes, which seems to contradict CM studies conducted in other settings where CM has been associated with increasing hospitalisation^{130,148}. Even so, one should note that there is country-influence on CM implementation¹⁶ and, therefore, those contradictory results may be related to differences between settings.

The reviews of Marshall et al¹³⁰ and Ziguras and Stuart¹⁴⁸ included studies only from the USA and the UK so their conclusions may not be transferrable to the Spanish setting. While in the USA the CM resources for persons with SMI are mainly private; in the UK they are integrated in the National Health Service and offered by specialized teams (e.g., community mental health teams or assertive outreach teams). In Catalonia, those resources are run by private institutions and offered by the public mental health network through AMHCCs that offer specific treatment programmes according to patients needs. This PhD thesis also adds new evidence including the study of the effects of the clinical CM model in clinical and psychosocial outcomes.

Overall, Study 6 showed that the clinical CM programme and the STP were effective in maintaining contact with mental health care services. The clinical CM programme was effective in improving the clinical and psychosocial functioning of patients with schizophrenia. After the follow-up, patients in the clinical CM group showed a similar profile to that of patients in the STP group regarding clinical functioning, quality of life and needs. It should be highlighted that, at baseline, the clinical CM group showed poorer levels of clinical and psychosocial functioning. The clinical CM programme was also effective in terms of health care service use. Again, after the follow-up, there was a decrease of the number of hospitalised patients as well as in the proportion of visits to emergency rooms.

As already said, it is relevant to carry out local initiatives to optimize the use of specific mental health care resources. The present study offers a deeper insight into the two community-based modalities of care aimed for the care of most persons with SMI in the Public Mental Health Network of the Catalan Health Service. It establishes its effectiveness showing that they both are effective and that may be offered consecutively according to patients' needs. It helps to improve the knowledge about how these community-based modality of care operate. Study 6 is then the second step in the way to optimize their use.

There are some limitations that should be considered in the development of this PhD thesis. At a general level, one of the limitations that should be mentioned is the fact that we did not used a structured interview to establish patient psychiatric diagnoses. Although this might have affected its reliability, we should mention that they were

conducted by experienced research psychiatrists and following the research diagnostic criteria established by the ICD-10¹³ as well as considered self-reports and caregiver reports. Another limitation is the fact that patients' assessments were not conducted by independent assessors, which might have biased the results. Even so, the consistency of our results with the literature gives us some confidence that assessor bias did not affect outcomes.

There are as well some limitations concerning the specific objectives of this PhD thesis and, thus, affecting Study 5 and 6 at the same time. The group of patients of the CM programme were matched to the group of patients of the STP considering a score in GAF¹⁸³ scale of +/- 10 points. The results showed lower GAF¹⁸³ scores in the CM group than in the STP group, which may be related to the aforementioned matching process.

Some limitations should also be considered for Study 6. First of all, the design of the study was not that of a randomized controlled trial which is considered a rigorous method for establishing a cause-effect relationship between interventions and results¹⁸⁴. It was a quasi-experiment that is considered to be an appropriate design in clinical and ordinary settings¹⁸⁵, such as that in this study. One of the strengths of our study design in comparison with the study design of the previous studies on CM effects in Spain is the inclusion of a control group, which strengthens the study of the relationship between CM effects and outcomes.

Some of the above limitation showed recommendations for future work. Further research might use a more systematic approach for the literature review and statistical procedures to establish the efficacy and effectiveness of CM. Intermediate outcomes, such as case manager variables, that may be associated with the efficacy and effectiveness of CM may also be bear in mind. More work will need to be done to determine if the three instruments validated show appropriate psychometric properties in persons with schizophrenia from other settings and different clinical stability as well as other sample of psychiatric patients. For instance, one should consider that schizophrenia is just one of the diagnoses included in the definition of SMI in the Catalan Health Service but, in daily clinical practice, AMHCCs deal with the full diagnosis range of persons with SMI (e.g., bipolar disorder, recurrent depressive disorder or obsessive compulsive disorder). Specific validation studies involving those

patient populations are needed. Further studies may be carried out to strengthen the validity and reliability of the psychometric instruments validated. Specifically, these studies may include psychometric aspects such as concomitant validity, agreement between assessors, differences between group of patients established by means of diagnostic interviews and the factor structure of the WHOQOL-BREF^{156,157}. It would be interesting consider a shorter GAF¹⁸³ range when matching groups of patients as well as more specific and objective measures regarding physical health. If, as suggested by Study 5, there is a reconfiguration of the CM programme then a study about its efficacy/effectiveness should be conducted. This could be done by comparing outcomes in a group of patients with schizophrenia receiving the reconfigured CM programme with outcomes in a group of patients with schizophrenia receiving the original CM programme. Further investigation into the effects of the CM programme at the medium and long-term is strongly recommended. A one year follow-up may not have been long enough to see if the positive outcomes achieved are maintained or if new positive outcomes arise at the medium or long-term. Some authors support that outcomes associated to CM appear over time but not in a short term perspective¹⁸⁶. At the moment, we are working on the 3 year follow-up of the study. Also the study of the effectiveness and efficacy of specific interventions included in the CM programme should be carried out.

This PhD has focused on the study of two community-based interventions for the care of persons with schizophrenia and in functioning in the Public Mental Health Network of the Catalan Health Service. Even so, this network is integrated, by primary care, hospital, social services besides those of mental health care. Its organization aims to provide a comprehensive care of the patient. Therefore, the interaction of all those services in the care of patients should be a key element in further research.

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ANNEXES

Annex 1

Study 1:

Mas-Expósito L, Amador-Campos JA, Gómez-Benito J and Lalucat-Jo L. Current case management models. *Journal of Social Work*. 2012.

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Enviado el: martes, 14 de agosto de 2012 13:09
Para: Laia Mas
Asunto: Journal of Social Work - Decision on Manuscript ID JSW-11-0046.R1

14-Aug-2012

Dear Ms. Mas-Expósito:

It is a pleasure to accept your manuscript entitled "Depicting current case management models" in its current form for publication in Journal of Social Work. The comments of the reviewer(s) who reviewed your manuscript are included at the foot of this letter.

Thank you for contribution to the Journal of Social Work.

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Sincerely,
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Editor in Chief, Journal of Social Work
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Reviewer(s)' Comments to Author:

To whom it may concern:

This is to certify that the paper entitled:

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written by: L. Mas-Expósito, J.A. Amador-Campos, J. Gómez-Benito and L. Lalucat-Jo

has been accepted for publication in the Journal of Social Work.

This certification is issued to the authors of this paper upon their request for whatever purposes it may serve.

Issued this 12th of November 2012 at Salford (United Kingdom).

A handwritten signature in black ink that reads "S.M. Shardlow". The signature is written in a cursive style and is underlined with a single horizontal stroke.

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CURRENT CASE MANAGEMENT MODELS

Depicting Current Case Management Models

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CURRENT CASE MANAGEMENT MODELS

Abstract

Case management is one of the principal components of service delivery in mental health services. Over time, it has evolved into new models, and various meta-analytic studies have been carried out to establish its effects. Those studies have yielded non-homogeneous results, which might be related in part to the progress of case management models. Therefore, there is a need to understand the relationship between CM models and CM effects. This paper deals with this issue by reviewing and updating the literature regarding case management models and effects in order to help understand its current role and suggest how CM could be reorganized. Assertive community treatment and any other case management model seem to have fused and turned into two models that differ mainly with regard to the intensity of care provided to patients. The results of the meta-analyses on the efficacy/effectiveness of case management are not homogeneous across all studies, which seems to be related to the case management model used and the strictness of the methodology followed. When the model of case management used is congruent with clinical practice, the results favor case management over standard care and show that intensive and non-intensive case management may be provided depending on the previous use of hospital resources. Our paper suggests that case management models could be reconfigured by offering an intensity of care based on patients' needs.

Keywords: community treatment, case management, assertive community treatment, intensive case management, severe mental illness.

CURRENT CASE MANAGEMENT MODELS

Depicting Current Case Management Models

Case Management (CM) is widely considered to be a major component of the services provided to patients with severe mental illness (SMI) (Rubin, 1992). Namely, CM has been defined as a way of coordinating, integrating and allocating individualized care within limited resources by means of continuous contact with one or more key professionals (Thornicroft, 1991).

The origins of CM are related to the deinstitutionalization movement that supported the care of patients with SMI in the community instead of in psychiatric hospitals. Therefore, patients with SMI started receiving outpatient care from community mental health centers or day hospitals in the community and the interventions provided there increased in order to fulfill patients' needs. Even so, a considerable number of these patients experienced problems in accessing the services required because those services were multiple, complex (Mueser, Bond, Drake and Resnick, 1998) and fragmented (Intagliata, 1982). These facts led to an increase in hospital admissions (Rössler, Löffler, Fätkenheuer and Reicher-Rössler, 1992), loss of patient contact with community services and, subsequently, the failure of community services to fulfill patients' needs (Audit Commission, 1986; Melzer, Hale, Malik, Hogman and Wood, 1991). CM emerged to deal with the above-mentioned problems.

Characteristics of Case Management

The different models of CM share a set of principles that derive mainly from social work (Thornicroft, 1991) and support a type of intervention aimed at enhancing patient adaptation in the community and at improving their functional ability. The principles most commonly reported as the basis of CM were described by Thornicroft (1991) and include: 1) Continuity, 2) Accessibility, 3) Staff-patient relationship, 4) Tailoring

CURRENT CASE MANAGEMENT MODELS

support to need, 4) Facilitating independence, 5) Patient advocacy and 6) Advocacy for services.

The above principles are put into practice by way of tasks that have been discussed to varying degrees by a range of authors (Chamberlain and Rapp, 1991; Charnley and Davies, 1987; Dincin, 1990; Draine, 1997; Drake et al., 1998; Modrcin, Raw and Chamberlain, 1985; Renshaw, 1987; Rothman, 1991; Stein and Diamond, 1985). These tasks may range from the detection/identification of patients to the coordination of service provision or the direct provision of clinical care. Table 1 shows an overview of tasks that have mainly been linked to CM.

INSERT TABLE 1 AROUND HERE

Although the origins, definition, principles and tasks of CM seem to be well-established, CM has had to adapt over time, thus evolving from more traditional models to new ones (Bachrach, 1980; Hargreaves et al., 1984; Lamb, 1980; Marshall, Lockwood and Green, 1998; Marshall and Lockwood, 1998; Mueser et al., 1998; Solomon, 1992; Thornicroft, 1991). Moreover, the efficacy of CM has primarily been understood through two Cochrane reviews (Marshall et al., 1998; Marshall and Lockwood, 1998); however, in actual fact, eight meta-analytic reviews have been conducted on the topic. Those reviews have yielded non-homogeneous results, which might be related in part to the progress of case management models. Thus, there is a need to understand the relationship between the evolution of CM models and the study of CM effects as well as establish other factors that may have played a role in the latter. This paper deals with these issues by looking at CM models and discussing the reviews of CM effects. It aims to suggest how CM models could be organized to help fulfill patients' needs while improving clinical decision making and optimizing use of resources.

CURRENT CASE MANAGEMENT MODELS

Case Management Models

Although the principles and tasks already mentioned seem to prevail as the foundation of CM, the scope of activities of case managers has widened, including, for example, other populations besides SMI (MacFarlane, 2006; Rapp, 2007). The increase in the case managers' scope of activities is revealed through various CM models. A conventional way of categorizing CM models involves differentiating between direct care and service broker according to the frequency of patient contact and intervention intensity (Bachrach, 1980; Hargreaves et al., 1984; Lamb, 1980). CM models has become progressively more complex and comprehensive. For instance, Thornicroft (1991) describes CM models according to their position in 12 axes. It may be one of the most useful categorizations of CM since it may reflect its complexity in practice. Solomon (1992) and Mueser et al. (1998), suggest a different way of categorizing CM models. According to Solomon (1992), there are four types of CM: 1) Assertive Community Treatment (ACT), 2) Strength CM, 3) Rehabilitation and 4) Generalist. Meanwhile, Mueser et al. (1998) describe the following six models: 1) Broker CM, 2) Clinical Case Management (CCM), 3) Strength CM, 4) Rehabilitation, 5) ACT and 6) Intensive Case Management (ICM). There has also traditionally been a broader categorization that differentiates between ACT and any other CM model (Marshall et al., 1998; Marshall and Lockwood, 1998). In this categorization, ACT has distinguished elements when compared to any other model of CM. Specifically, it includes lower caseloads, a team approach rather than an individual approach, assertive outreach and direct provision of care.

With regard to new categorizations, Burns et al. (2007) differentiates between ICM and non ICM models. The term ICM is applied to different conceptual models (Intagliata, 1982; McGrew and Bond, 1995; Stein and Test, 1980; Witheridge, Dincin and Appelby,

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1982; Witheridge, 1991), which shows a convergence of ACT with any other CM model. ICM pertains to the local service organization and it is considered to be a way of organizing teams (Johnson, 2008). ICM addresses the social and health needs of people with SMI at high risk of rehospitalization and is an intensive and long-term approach. Case managers have caseloads of about 20 patients or less, direct contact with patients (Burns et al., 2007) and are clinicians in charge of providing comprehensive treatment, rehabilitation and support services (Scott and Dixon, 1995) together with their CM responsibilities (Marshall, 2008). ICM models aim to maintain patient contact with services, decrease hospital admissions and enhance results (Dieterich, Irving, Park and Marshall, 2010). Non ICM models include most of the features of ICM models but a caseload size of over 20 patients.

It is worth highlighting the Flexible Assertive Community Treatment model or FACT (van Veldhuizen, 2007), which is a rehabilitation-based CCM. FACT is an adaptation of the American ACT model (Stein and Test, 1980) to the Dutch community-based mental health services (Drukker et al., 2008). FACT is composed of a multidisciplinary team that can operate individually or by means of a team approach, depending on patient's needs. That is, patients who are more stable receive individual CM coordinated by the multidisciplinary team, while less stable patients receive shared CM and assertive outreach from the same multidisciplinary team which is integrated by case managers (i.e. psychiatric nurses, psychiatric community nurses, social workers and substance abuse counselors), psychiatrists, psychologists and individual placement and support workers. These teams coordinate care, and provide evidence-based medical interventions and recovery-based rehabilitation for people suffering from SMI.

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The Effects of CM through Meta-Analytic Analyses

When considering the efficacy/effectiveness of CM, two relevant Cochrane reviews (Marshall, 1998a; Marshall, 1998b) have had a clear impact. This may be related to the fact that they used a meta-analytical approach, which has been considered to provide a more objective assessment of evidence than literature reviews, a more accurate estimate of treatment effect, and may help to better explain inconsistencies between outcomes of individual studies (Egger, Smith and Phillips, 1997). Together with the above-mentioned Cochrane reviews, there are other reviews that use the same approach in an effort to establish CM efficacy/effectiveness and, moreover, the Cochrane group has updated its two meta-analytic reviews (Dieterich et al., 2010). Below, there is a description of the main characteristics and results of the meta-analytic reviews conducted to establish the efficacy of CM from 1995 to 2010 (see Table 2).

INSERT TABLE 2 AROUND HERE

To our knowledge, the first meta-analytic review regarding the effects of CM was conducted by Bond in 1995 (Bond, McGrew and Fekete, 1995). This review involved the effectiveness of ACT and included 9 studies with pre-post, quasi-experimental and experimental designs. The results of this review showed that 84% of patients who received ACT kept in contact with services in comparison to only 54% of patients who received standard care. Moreover, data showed that ACT significantly reduced inpatient days after one year. There was only limited evidence regarding the effectiveness of ACT in quality of life and general functioning. Three years later, Gorey et al. (1998) conducted another review of this type and included, as Bond et al. (1995), pre-post, quasi-experimental and experimental studies. This review involved 24 studies, which doubles the number of studies included in the previous review (Bond et al., 1995). This may be related not only to the increase in CM studies, but also to the fact that the scope

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of this review was broader and included ACT and other models of CM (i.e. strength, rehabilitation and generalist). The results of this review showed that 75% of patients in CM were doing better than patients without CM, and that the more intense the CM, the greater the preventive fraction patients displayed. The two reviews previously described, along with that of Ziguras and Stuart (2000), are the only ones that include other studies besides those with experimental designs (i.e. randomized, controlled trials). The inclusion of only this type of studies seems to improve the reliability of the meta-analysis results since it may help to differentiate between changes arising from CM and changes arising from other factors not related to CM (Ziguras and Stuart, 2000). The aforementioned Cochrane reviews were also published in 1998 (Marshall et al., 1998; Marshall and Lockwood, 1998). The first (Marshall et al., 1998) aimed to establish the efficacy of CM, not including ACT, compared to standard care. It involved 8 randomized controlled trials and the outcomes regarding use of services and clinical and psychosocial functioning. Compared to standard care, CM increased contact with services, but also psychiatric hospital admissions. In addition, CM was not associated to improvements in patients' clinical and psychosocial functioning. The second review conducted by the Cochrane group (Marshall and Lockwood, 1998) aimed to establish the efficacy of ACT in comparison to standard care, hospital-based rehabilitation and any other CM model. It included 20 randomized controlled trials and involved the same type of outcomes as the first Cochrane review (Marshall et al., 1998) together with costs. When ACT was compared to standard care, the former seemed to be related to a greater probability of maintaining contact with services, a lower probability of hospital admissions, less time in the hospital, better accommodation, a better job, greater satisfaction and a reduction in hospital resource costs. No ACT effect was observed in psychiatric symptoms or social functioning. When ACT was compared to hospital-

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based rehabilitation, ACT did not show any advantage with regard to retention, but seemed to decrease hospital admission and length of hospitalization, and to increase the probability of living independently. When ACT was compared to any other model of CM, there were no differences regarding retention and ACT seemed to decrease hospital stay and hospital resource costs. In 1999, another meta-analytic review was conducted (Herdelin and Scott, 1999) and, as in the review conducted by Marshall et al. (1998), it aimed to establish the efficacy of ACT versus standard care. The study included 19 randomized controlled trials and showed ACT efficacy in decreasing hospital admissions, length of hospital stay, psychiatric symptoms and costs, and in increasing social functioning and patient satisfaction. According to the authors (Herdelin and Scott, 1999), the results should be accepted with caution, except in the case of patient satisfaction, because the relationship between outcomes and treatment was not completely clear as shown by the analyses of attrition effects and treatment variance. Subsequently, Ziguras and Stuart (2000) conducted another meta-analytic review. This review was a replication of the meta-analyses conducted by Marshall et al. (1998) and Marshall and Lockwood (1998), but with an expansion in its inclusion criteria. Thus, Ziguras and Stuart (2000) included 44 studies, which was a significant increase in the number of studies included in the reviews conducted by Marshall et al. (1998) and Marshall and Lockwood (1998). This review showed that CCM and ACT were better than standard care in terms of family burden, family satisfaction and costs of care. When compared to standard care, ACT seemed to reduce the total number of hospital admissions and the proportion of patients hospitalized, while CCM seemed to increase both outcomes. Even so, the length of hospital admission was shorter in CCM than in standard care. Both ACT and CCM reduced the number of hospital days, but ACT was significantly superior. No differences were observed between ACT and CCM in

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symptoms, patient contact with services, drop-out rates, social functioning and patient satisfaction. The most recent meta-analytic reviews carried out to establish the efficacy of CM were conducted by Burns et al. (2007) and Dieterich et al. (2010). The first review (Burns et al., 2007) aimed to establish the efficacy of ICM compared to standard care. It involved 29 randomized controlled trials and used hospital days as the only outcome. The results showed that ICM worked best for patients who already used a number of hospital resources, and that fidelity to ACT increased the probability of reducing hospital care in ICM. The second review (Dieterich et al., 2010) is the updated version of the two Cochrane reviews already described (Marshall et al., 1998; Marshall and Lockwood, 1998). It aimed to establish the efficacy of ICM compared to standard care and also to non ICM and involved 38 randomized controlled trials. When comparing ICM to standard care, ICM showed efficacy in length of hospitalization, maintaining contact with services, overall functioning, accommodation, living independently and satisfaction. There were no differences between ICM and standard care with regard to mortality rates, contact with the legal system, employment status or quality of life. When comparing ICM to non ICM, ICM was better only with regard to drop-out rates at follow-up. There were no differences between ICM and non ICM in terms of length of hospitalization, service use, mortality, social functioning, mental state, behavior, quality of life, satisfaction or costs. The analyses were also carried out taking into account fidelity to ACT and use of hospital resources at baseline. Fidelity to ACT and a high use of hospital resources at baseline were independently linked to a higher reduction of hospital time in ICM. When both variables were combined, only high use of hospital resources at baseline was significantly associated to a higher reduction of hospital time in ICM.

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Discussion

We analyzed CM models and its effects in order to study its evolution. CM goes beyond the initial definition of CM as a broker service (Moore, 1990) in the sense that it aims to coordinate and monitor the provision of social, medical, educational and other services for patients with SMI, but also to provide direct services to this population.

Although the definition and main objectives of CM seem to be well-established, new CM models have been developed. The most traditional categorization of CM models is that which differentiates between ACT and any other model of CM (Marshall et al., 1998). However, the current differences in clinical practice between ACT and CM are not so clear since they both seem to have turned into two models (Dieterich et al., 2010). These new models are known as ICM and non ICM (Burns et al., 2007; Dieterich et al., 2010). Their conceptual roots combine the same CM and ACT principles (Intagliata, 1982; McGrew and Bond, 1995; Stein and Test, 1980; Witheridge et al., 1982; Witheridge, 1991), but they differ mainly in terms of intensity of care. ICM models have caseloads of up to 20 patients, while non ICM models have over 20. It is worth highlighting FACT, which is an adaptation of the ACT model (Stein and Test, 1980) to the community-based mental health system of the Netherlands where it is considered to be the basic structure for the care of patients with SMI (Van Veldhuizen, 2007). Again, FACT represents the convergence of ACT and CM since the main features of both are included in the same model of care, which prioritizes features of the former or the latter depending on patients' needs. Taking into account all that mentioned above, it seems that ACT and CM models are presently considered to be complementary rather than different models.

We identified eight meta-analytic reviews with regard to CM efficacy. The results are not homogeneous across the different reviews. Two of them show positive results in

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favor of CM regarding all outcomes included (Gorey et al., 1998; Burns et al., 2007), while four of them show that CM is more effective than or as effective as standard care (Bond et al., 1995; Dieterich et al., 2010; Herdelin and Scott, 1999; Marshall et al., 1998; Ziguras and Stuart, 2000). Moreover, one review yielded negative results regarding CM efficacy (Marshall et al., 1998). This lack of homogeneity regarding CM efficacy might be related to the use of different categorizations of CM models and the strictness of the methodology of the reviews. With regard to the categorizations of CM models, one should note that three different categorizations are used in the reviews as shown in Table 3: 1) CM as a general model regardless of specific models (Gorey et al., 1998); 2) CM and ACT as different models (Bond et al., 1995; Herdelin and Scott, 1999; Marshall et al., 1998; Marshall and Lockwood, 1998; Ziguras and Stuart, 2000); and 3) ICM and non ICM as two models integrating ACT and any other model of CM and differing in intensity of care (Burns et al., 2007; Dieterich et al., 2010). Table 3 also shows that these categorizations lead to six different comparisons of CM models in the reviews: 1) CM in general terms versus standard care (Gorey et al., 1998); 2) CM (not including ACT) versus standard care (Marshall et al., 1998; Ziguras and Stuart, 2000); 3) ACT versus standard care (Bond et al., 1995; Herdelin and Scott, 1999; Marshall and Lockwood, 1998; Ziguras and Stuart, 2000); 4) CM (not including ACT) versus ACT (Marshall and Lockwood, 1998; Ziguras, 2000 and Stuart, 2000); 5) ICM versus standard treatment (Burns et al., 2007; Dieterich et al., 2010); and 6) ICM versus non ICM (Burns et al., 2007; Dieterich et al., 2010). Therefore, the results of the different meta-analyses could not be directly compared. Another possible reason for lack of homogeneity between studies even within the same comparison of CM model might be the strictness of the methodology of the reviews. For example, the strictness of the methodology used has been explained (Ziguras et al., 2002) as the main reason for the

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inconsistencies between the results of Marshall et al. (1998) and Marshall and Lockwood (1998), and Ziguras and Stuart (2000) when comparing the effects of CM or ACT versus standard care. Unlike Marshall et al. (1998) and Marshall and Lockwood (1998), Ziguras and Stuart (2000) included non-experimental designs in their review and skewed and non-normally distributed data. This may also be related to the negative efficacy results shown by Marshall et al. (1998). The strictness of the methodology used may also help to understand the inconsistency of the results regarding the efficacy of ACT compared to standard care if only high-quality reviews (i.e. based on a systematic literature review and only experimental designs) are considered. Specifically, the results shown by Herdelin and Scott (1999) are less promising than those observed in the review by Marshall and Lockwood (1998). This could be related to the fact that the former study (Herdelin and Scott, 1999) used broader patient inclusion criteria (i.e. patients with more than one diagnosis of SMI) and outpatient and inpatient care were both considered to be standard care together.

INSERT ABOUT HERE TABLE 3

When the ICM and non ICM are considered, the results shows that ICM is better than standard care regarding service use, clinical variables and psychosocial variables, although it seems to be comparable to non ICM in most of these variables (Dieterich et al., 2010). Moreover, previous use of hospital resources and fidelity to ACT model seem to be independently associated to CM efficacy. The higher the patient use of hospital resources at baseline or the closer ICM is to the ACT model, the greater the reduction of patient stay in hospital (Burns et al., 2007; Dieterich et al., 2010). Considering the above-mentioned results, further research should help to clarify the efficacy of ICM vs. non ICM and evaluate the effects of non ICM compared to standard care. Also, further research should include the effects of specific variables on CM

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efficacy, such as previous patient use of hospital resources, fidelity to ACT or other relevant variables. For example, recently it has been argued that high fidelity to ACT model might be related to positive outcomes, a decrease in economic costs and, consequently, an increase in the economic resources available for the development of other interventions for SMI patients (Randall, Wakefield and Richards, 2010). It has also been shown that case managers could prompt or strengthen the effects of perceived self-stigma on patients with SMI (Konradt and Early, 2010) and that their expectations are associated to positive patient progress on employment (O'Connell and Stein, 2011). In sum, CM and ACT are complementary rather than different models of CM in clinical practice . They have converged into two models of care for patients with SMI that differ with regard to intensity (i.e. ICM and non ICM). A most recent model is the FACT which integrates CM and ACT and its intensity depends on patients' needs. Efficacy results suggest that CM could be reconfigured by offering intensity of care according to patient characteristics. In other words, CM could be organized to tailor to patients' needs, which might help to improve patients' conditions but also enhance clinical decision-making and management of care by optimizing the use of resources.

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Table 1. Summary of Case Management Tasks

Case management tasks
Detection of patients
Establishment and maintenance of a therapeutic alliance
Advocacy
Needs assessment
Design of an individualized care plan
Continuous monitoring of the care plan
Monitoring of client's mental functioning
Compliance with medication and side effects
Supportive counseling
Coordination of service delivery: referral and linking to services
Monitoring and evaluating the effectiveness of service provision
<u>Modifying provision of services</u>

This summary is based on the works of Chamberlain and Rapp (1991); Charney and Davies (1987); Dincin et al. (1990); Drainie (1997); Drake et al. (1998); Modrcin et al. (1985); Renshaw (1987); Rothman (1991, and Stein and Diamond (1985).

Table 2. Review of the Meta-analytical Studies on CM

Author	Year	CM model	Period of review	Type of study included	Inclusion criteria	No. of studies included	Sample characteristics	Types of variables included
Bond et al.	1995	ACT	1978-1989*	Pre-post design Quasi-experimental Experimental	ACT Programs developed by Thresholds Bridge and adopted in programs elsewhere	9	N = 550 100% SMI	Clinical Psychosocial Use of services
Gorey et al.	1998	ACT Rehabilitation Strength Generalist	1980-1996	Pre-experimental Quasi-experimental Experimental	CM practice Patients with SMI	24	N = 70 (median) 100% SMI	Clinical Costs Psychosocial Use of services
Marshall et al.	1998a	CM vs. SC	1966-1997	Experimental	18-65 years old Diagnosis of SMI - Schizophrenia - Bipolar mania - Depression with psychotic characteristics	8	N = 644 45% schizophrenia Mean age: 55 years old F (%): 52	Clinical Psychosocial Use of services
Marshall and Lockwood	1998b	ACT vs. SC ACT vs. HBR ACT vs. CM	1974-1987	Experimental	18-65 years old Diagnosis of SMI - Schizophrenia - Bipolar mania - Depression with psychotic characteristics	20	N = 1165 34% schizophrenia Mean age: 37 F (%): 34	Clinical Costs Psychosocial Use of services
Herdlin and Scott	1999	ACT vs. SC	1973-1997	Experimental	Randomized controlled trials More than one diagnosis of SMI Comparison of ACT vs. outpatient care Works published in peer	19	N _{range} = 35 to 873 Ages 18-65 Both genders Racial & ethnic diversity All psychiatric diagnoses except organic brain	Clinical Costs Psychosocial Use of services

				review journals	dysfunction, mental retardation and primary diagnosis of substance abuse
Ziguras and Stuart	2000	CCM vs. SC ACT vs. SC CCM vs. ACT	1980-1998	Adults Diagnosis of SMI: - Psychosis - Affective disorders - Anxiety disorders	44 CM vs. SC ($n_{study}=35$) N = 6365 61.6% schizophrenia Mean age: 37 F (%): 44
Burns et al.	2007	ICM vs. SC	Till 2007	Diagnosis of SMI: - Schizophrenia - Schizophrenia-like disorder - Bipolar disorder - Depression with psychotic features Community care setting	29 N = 5809 66% schizophrenia or schizophrenia-like disorder Mean age: 37.9 years F (%): 37
Dieterich et al.	2010	ICM vs. SC ICM vs. non ICM	Till 2009	18-65 years old Diagnosis of SMI of the NIMH or Diagnosis of SMI - Schizophrenia - Bipolar mania - Depression with psychotic characteristics - Personality disorders Community care setting	38 N = 7328 100% SMI Mean age: 38 years F (%): 30

*Non systematic literature review

ACT = Assertive Community Treatment; CM = Case Management; SC = Standard Care; SMI = Severe Mental Illness; F = female; HBR = Hospital based Rehabilitation; CCM = Clinical Case Management; ICM = Intensive Case Management; NIMH = National Institute of Mental Health;

Table 3. Case Management model categorizations in the meta-analytic studies and the Case Management model comparisons derived

Model categorization	Model comparison	Author
CM including ACT	CM vs. standard care	Gorey et al. (1998)
CM & ACT	CM vs. standard care	Marshall et al. (1998); Ziguras & Stuart (2000)
	ACT vs. standard care	Bond et al. (1995); Herdalin & Scott (1999); Marshall and Lockwood (1998); Ziguras & Stuart (2000)
	CM vs. ACT	Marshall and Lockwood (1998); Ziguras & Stuart (2000)
ICM & non ICM	ICM vs. standard care	Burns et al. (2007); Dieterich et al. (2010)
	ICM vs. non ICM	Burns et al. (2007); Dieterich et al. (2010)

CM = Case Management; ACT = Assertive Community Treatment; ICM = Intensive Case Management

Annex 2

Study 2:

Mas-Expósito L, Amador-Campos JA, Gómez-Benito J and Lalucat-Jo L. The World Health Organization Quality of Life Scale Brief Version: a validation study in patients with schizophrenia. *Quality of Life Research*. 2011; 20(7):1079-1089.

The World Health Organization Quality of Life Scale Brief Version: a validation study in patients with schizophrenia

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The World Health Organization Quality of Life Scale Brief Version: a validation study in patients with schizophrenia

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Abstract

Purpose The World Health Organization Quality of Life Scale Brief Version (WHOQOL-BREF) is used for patients with schizophrenia although no validation is available. This work addresses this issue by dealing with its psychometric properties in a clinical sample of patients with schizophrenia.

This study is conducted for the Research Group on Severe Mental Disorder.

Please refer the Appendix section for the members of Research Group on Severe Mental Disorder.

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Methods Two hundred forty-one patients from 10 Adult Mental Health Care Centers (AMHCC) meeting the following inclusion criteria were included: (1) International Classification of Diseases-10 or ICD-10 diagnosis of schizophrenia, (2) Global Assessment of Functioning scores or GAF ≤ 50 , (3) Illness duration of more than 2 years and (4) Clinical stability at assessment time. Patients were evaluated at baseline and at one-year follow-up regarding quality of life (QOL), clinical variables and other psychosocial measures.

Results Internal consistency was excellent for the total WHOQOL-BREF (0.88 at baseline and 0.89 at follow-up) and adequate (0.65–0.78 at baseline; 0.66–0.79 at one-year follow-up) for the WHOQOL-BREF domains. Correlations between WHOQOL-BREF scores and those of global functioning, psychiatric symptoms, disability and social support ranged between small and large. There were significant differences between groups of patients with schizophrenia in the WHOQOL-BREF. Patients who were anxious, disabled, lacked social support and used more social services scored significantly lower in some or all WHOQOL-BREF domains. Changes in WHOQOL-BREF scores were positively associated with changes over time in global functioning, social support and use of health services, and negatively with psychiatric symptoms and disability (correlation coefficients between small and moderate). After one-year follow-up, patients improved in overall functioning and there was a decrease in psychiatric symptoms.

Conclusions This study shows that the WHOQOL-BREF has good reliability and validity, and suggests that it is suitable for the assessment of QOL in patients with schizophrenia.

Keywords WHOQOL-BREF · Quality of life · Schizophrenia · Reliability · Validity

Abbreviations

QOL	Quality of life
WHOQOL-100	World Health Organization Quality of Life Scale
WHOQOL-BREF	World Health Organization Quality of Life Scale Brief Version
AMHCC	Adult Mental Health Care Centers
GAF	Global Assessment of Functioning
ICD-10	International Classification of Diseases-10
PH	Physical health
P	Psychological
SR	Social Relationships
E	Environment
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders Fourth Edition
PANSS	The Positive and Negative Syndrome Scale
DAS-s	The World Health Organization Short Disability Assessment Schedule
FSSQ	The Functional Social Support Questionnaire

Introduction

Quality of life (QOL) in patients with schizophrenia is an area of increasing significance because it is an essential component for clinical trials and patient management. The assessment of QOL takes into account patients' rights, autonomy and opinions during the processes involving diagnosis and care [1]. Although it is not clear whether patients with schizophrenia are good at evaluating their QOL because they might show cognitive and insight deficits, there is evidence that support the validity of the assessment made by these patients [2].

Valid and reliable instruments to assess QOL have been developed for use with various target populations. Those instruments are grouped into specific and generic [3]. Specific instruments aim to assess QOL in particular target populations, while generic instruments aim to assess QOL across a variety of disease indications as well as healthy population. These types of instruments are complementary and wherever possible it is preferable to use them together. The Quality of Life Scale [4], the Quality of Life Interview [5], or the Lancashire Quality of Life Profile [6] are specific instruments for patients with schizophrenia. The World Health Organization Quality of Life Scale [7] or WHOQOL-100, the 36-Item Short Form Survey [8] and the EUROQOL instrument [9] are generic instruments.

The World Health Organization Quality of Life Scale Brief Version [10] or WHOQOL-BREF is a short version of the WHOQOL-100 [7], and it was developed to deal with time restrictions, minimize respondent burden and for use in situations where facet-level detail is unnecessary [11]. Both scales support a characterization of QOL defined as "individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns [12]" (p. 28). They allow a comprehensive assessment of QOL and can be used in different settings such as medical practice, research, or audit. The WHOQOL-BREF is an international cross-culturally analogous QOL evaluation tool [13] which contains aspects regarding social relations and environment not covered by other instruments.

The WHOQOL-BREF has been adapted and validated in the general population [14–17], adolescents [18], older people [19–21], smokers [22], alcoholics [23], patients with HIV/AIDS [24], traumatic injuries [25, 26] and psychiatric outpatients [27–29].

The suitability of the scale, the aspects it covers, its reliability and validity in other populations make it promising for the assessment of patients with schizophrenia [30–34] although no validation is available. This work addresses this issue by validating this instrument in a sample of patients with schizophrenia. Firstly, we aim to establish its overall internal consistency and the internal consistency associated with its domains. Secondly, we address WHOQOL-BREF validity evidence: associations with clinical and psychosocial variables, and QOL differences between groups of patients with schizophrenia, established according to socio-demographic variables, psychiatric symptoms, disability, social support and use of health services. The association between subjective QOL and socio-demographic variables is controversial, and it is currently considered that socio-demographic variables are not significantly associated with QOL [35–37]. We do not expect significant differences in QOL between groups of patients established according to socio-demographic variables. It is thought that perceived social support has a positive relationship with subjective QOL, while disability, the severity of depression, anxiety, and negative symptoms as well as use of services have a negative one [38]. Consequently, we expect that disabled, depressed and anxious patients, as well as those lacking social support and those with higher health service use show poorer levels of subjective QOL. Finally, we aim to test changes in QOL, along with other variables, after one-year follow-up. As a result of the treatment provided to patients, we expect significant improvements in global functioning, psychiatric symptoms, disability, social support, and QOL.

Method

Sample

Patients came from 10 Adult Mental Health Care Centers (AMHCC) in Barcelona (Spain). These AMHCC are run by the Catalan Department of Health and share similar characteristics regarding the care provided to patients. They offer a care package to patients with schizophrenia by means of multidisciplinary community mental health teams (i.e. a psychiatrist, a psychologist, a community mental health nurse and a social worker). This care package involves medical and psychosocial interventions of varying intensity depending on patients' needs and is coordinated by one of the members of the mental health teams (i.e. a community mental health nurse).

From December 2006 to January 2008, these AMHCC participated in a study consisting of a 1-year follow-up of patients in contact with services who met the following inclusion criteria: (1) Global Assessment of Functioning or GAF [39] scores of 50 or lower, (2) Illness length greater than 2 years, (3) International Classification of Diseases-10 or ICD-10 [40] diagnosis of schizophrenia, and (4) Clinical stability at assessment time. Patients were excluded if they had dementia, organic brain injury, or mental retardation. Patients who visited consecutively and who met study inclusion criteria were asked to participate. Specifically, 260 patients met these inclusion criteria but 19 did not consent to participate. Data from this study were used for the present work.

The final sample comprised 241 (67.6% men) patients, their mean age was 41.7 years (SD = 11.6), and 72.6% of them had illness duration greater than 10 years; 70.5% of patients had a diagnosis of paranoid schizophrenia and 29.5% of other schizophrenias (i.e. 10.8% undifferentiated, 9.1% residual, 6.2% hebephrenic, 1.2% simple and 2.1% other). Other socio-demographic characteristics of patients are described in Table 1.

A total of 219 patients (90.9%) were successfully evaluated at one-year follow-up. Sixteen people (out of 22) were not evaluated following their psychiatrist's instructions because they were not clinically stable at assessment time or did not have contact with services, three died (one from terminal illness and two by suicide), two did not properly complete the evaluation and one dropped out of the study.

Instrument

The WHOQOL-BREF is composed of 26 items taken from the 100 items in the WHOQOL-100. It contains one item for each of the 24 facets included in the WHOQOL-100 and two items (not considered in the scoring) regarding overall QOL and general health. It requires 10 min to

Table 1 Socio-demographic characteristics of the sample at baseline

Variable	N	%
Age*		
≤42 years	133	42.8
>42 years	178	57.2
Gender		
Females	78	32.4
Males	163	67.6
Illness duration		
≤10 years	66	27.4
>10 years	175	72.6
Marital status		
Single	181	75.1
Living with partner or married	32	13.3
Divorced or separated or widow	28	11.6
Educational level		
≤Primary school	113	46.9
>Primary school	128	53.1
Living arrangement		
Family Property	166	68.9
Others	45	31.1
Employment status		
Active	53	22
Non-active	188	78
Schizophrenia type		
Paranoid	170	70.5
Other	71	29.5

* The two groups have been established taking into account the mean

administer and assesses subjective QOL in four domains: (1) Physical Health (PH; e.g. "How satisfied are you with your sleep?"; theoretical range: 7–35), (2) Psychological (P; e.g. "How much do you enjoy life?"; theoretical range: 6–30), (3) Social Relationships (SR; e.g. "How satisfied are you with your personal relationships?"; theoretical range: 3–15), and (4) Environment (E; e.g. "How satisfied are you with your access to health services?"; theoretical range: 8–40), and provides an overall QOL measure (theoretical range: 26–130). Each item is rated on a five-point Likert Scale, ranging from 1 (Not at all, Very dissatisfied, Very poor) to 5 (An extreme amount, Very satisfied, Very good). The higher the score, the better the QOL reported by the patient except for items 3, 4 and 26 that, therefore, need to be reversed for the scoring.

The development of the WHOQOL-BREF involved: (1) review of QOL cultural concepts, (2) definition of WHOQOL-BREF domains and (3) development and translation of WHOQOL-BREF questions [41]. The WHOQOL-BREF showed good psychometric properties. Internal consistency values ranged from 0.66 to 0.84; and correlations with the WHOQOL-100 subscales ranged from 0.89 to 0.95.

Skevington et al. [42] confirmed and extended information about its properties and showed good to excellent psychometric properties in adults recruited from in-patient and outpatient health care facilities, regardless of diagnosis or severity, and from the general population.

Procedure

The study was approved by the Ethics Committee of the Catalan Union of Hospitals in accordance with the ethical standards of the 1964 Declaration of Helsinki. The procedures and assessments were described to each patient who then provided informed consent.

The community mental health teams performed patients' assessments. The diagnosis was established by the psychiatrist by means of a non-structured interview following ICD-10 [40] research diagnosis criteria and considered self-reports and caregiver reports. The psychiatrist also carried out the assessment of psychiatric symptoms, while the rest of the assessments were performed by the other members of the community mental health teams under the psychiatrist's supervision. The psychiatrist was in charge of setting up the assessment agenda, supervising its development and sending the sheet scores to the psychologist in charge of the design and analyses of the study database.

To ensure the quality of assessment data, all psychiatrists participated in a schizophrenia diagnostic agreement workshop comprising two case studies. All researchers were trained in the administration of the instruments in a 4-hour session run by a psychologist with experience in psychological assessment of psychiatric patients. Systematic reviews of data coding and registration were taken, and patient information was contrasted with data from the AMHCC responsible for each patient.

Patients were evaluated at baseline and at one-year follow-up with the following assessment tools:

The WHOQOL-BREF [43]

The GAF [39]: This is a reliable and valid measure of global psychological functioning in patients with severe mental disorder. Its theoretical range is 1–100, where 100 denotes best possible functioning. It is included in the *Diagnostic and Statistical Manual of Mental Disorders Fourth Edition* [39] or DSM-IV.

The Positive and Negative Syndrome Scale or PANSS [44]

This instrument is used for assessing symptom severity in patients with schizophrenia and it is translated and validated in Spanish [45]. It assesses psychiatric symptoms in three domains: positive (theoretical range: 7–49 where 49

denotes higher levels of positive psychiatric symptoms), negative (theoretical range: 7–49 where 49 represents higher levels of negative psychiatric symptoms), general (theoretical range: 16–112; where 112 denotes higher levels of general psychiatric symptoms), and provides an overall measure of psychiatric symptoms (theoretical range: 30–210, where 210 means higher levels of psychiatric symptoms). Internal consistency values of its subscales range between medium and high and its convergent validity with other measures of psychiatric symptoms is high and ranges from 0.70 to 0.81 [45].

The World Health Organization Short Disability Assessment Schedule or DAS-s [46]

This is a seven-item scale developed by the World Health Organization and its theoretical range is between 0 and 30, where 30 corresponds to higher levels of disability. It is a valid measure of global functioning in patients with mental disorders included in the *ICD-10* [40].

The Functional Social Support Questionnaire or FSSQ [47]

This is an eight-item questionnaire that measures the strength of the patient's social network. It assesses perceived social support in two domains: confidential social support (theoretical range: 6–30, where 30 denotes higher levels of confidential social support) and affective social support (theoretical range: 5–25, where 25 represents higher levels of affective social support), and provides an overall measure of social support (theoretical range: 11–55, where 55 shows higher levels of social support). It is also translated and validated in Spanish [48], and the reliability indexes are of 0.80 and 0.92 for hetero-report and self-report, respectively. The concurrent validity with other health measures ranges from 0.20 to 0.21 and from –0.13 to –0.81 [48].

First, the psychiatrist conducted the assessment of global functioning and psychiatric symptoms with the GAF and the PANSS to check if patients meet inclusion criteria. Then, the other members of the community mental health teams administered the rest of assessment tools in the following order: (1) DAS-s, (2) the WHOQOL-BREF, and (3) the FSSQ.

After each evaluation, systematic reviews of data coding and registration were taken and patient information was contrasted with family interviews and AMHCC registered data.

Data analysis

Data were analyzed using the *Statistical Package for the Social Sciences* v.15.

Internal consistency was evaluated by means of Cronbach's α and the contribution of WHOQOL-BREF items to the overall α , and the α associated with their domains. The internal consistency was calculated at baseline and at one-year follow-up. Cronbach's α values were considered as follows: $0.60 \leq \alpha < 0.80$ adequate, $0.80 \leq \alpha < 0.85$ good and $\alpha \geq 0.85$ excellent [49].

To assess validity evidence [50], Pearson's correlations between WHOQOL-BREF scores at baseline and the GAF, PANSS, DAS-s, and FSSQ scores at baseline were calculated. Correlation values were considered as follows: (1) < 0.3 = small, (2) 0.3 – 0.5 = moderate and (3) ≥ 0.5 large [51]. *T*-tests and analysis of variance were used to analyze differences in WHOQOL-BREF scores between groups of patients with schizophrenia. Patient groups were defined according to socio-demographic variables, the presence of anxiety symptoms [44] (item 2 of PANSS general ≥ 4), depressive symptoms [44] (item 6 of PANSS general ≥ 4), lack of social support [48] (FSSQ ≤ 32), and disability (DAS-s total mean score ≥ 4). For the DAS-s, a cutoff score of ≥ 4 was considered because an item score ≥ 4 indicates the presence of disability even with assistance [46]. Moreover, patient groups were defined according to use of health services during the year prior to baseline assessment.

T-tests for dependent samples were used to assess change over time between baseline and at one-year follow-up for WHOQOL-BREF, GAF, PANSS, DAS-s and FSSQ scores, and use of community mental health services (i.e. community psychiatric visits and community nursing visits). We compared the number of patient visits during the year prior to baseline assessment and the number of patient visits during the year following this assessment. The Bonferroni correction for multiple comparisons was applied [52], and a *P* value ≤ 0.003 was considered significant. The effect size was also estimated [53] and its values were considered as follows: (1) < 0.3 = small, (2) 0.3 – 0.5 = moderate and (3) ≥ 0.5 large [51].

Differences between scores at baseline and at one-year follow-up were calculated for WHOQOL-BREF scores, GAF, PANSS, DAS-s, FSSQ scores and use of community services. Sensitivity to change was determined by Pearson's correlation coefficients between WHOQOL-BREF score differences and the other score differences.

Results

Internal consistency

Internal consistency coefficients at baseline for WHOQOL-BREF total score was 0.88 and 0.89 at 1-year follow-up. For the WHOQOL-BREF domains, coefficients ranged

between 0.65 and 0.78 at baseline and between 0.66 and 0.79 at one-year follow-up. We also tested the change in Cronbach's alpha values when items are suppressed. Only the suppression of item 4 (i.e. "How much do you need any medical treatment to function in your daily life?") increased the level of internal consistency of the total WHOQOL-BREF by 0.01, at baseline and at one-year follow-up. The suppression of any other items maintained or decreased internal consistency coefficients by 0.01 at baseline and at one-year follow-up. Similar results have been reported regarding the WHOQOL-BREF domains. Specifically, item suppression increases or decreases Cronbach's alpha values by 0.01, which may be considered negligible.

Validity evidence

Pearson's correlations between WHOQOL-BREF scores and GAF, PANSS, DAS-s and FSSQ scores at baseline were mostly significant, and ranged from -0.04 to 0.55 (see Table 2). Specifically, correlations between WHOQOL-BREF and GAF scores were small; correlations between WHOQOL-BREF and PANSS scores were negative and small; correlations between WHOQOL-BREF and DAS-s scores were also negative but moderate, and correlations between WHOQOL-BREF and FSSQ scores ranged between small and large.

Table 2 shows the differences in groups of patients with schizophrenia in WHOQOL-BREF scores. There were no statistically significant differences in WHOQOL-BREF scores between groups established according to socio-demographic variables. There were significant differences between groups of patients with schizophrenia based on psychiatric symptoms, social functioning and use of health services. In particular, there were significant differences between anxious and non-anxious patients in WHOQOL-PH and WHOQOL-P. Anxious patients scored significantly lower in those domains. Disabled patients and patients without social support scored significantly lower in almost all WHOQOL-BREF domains.

Regarding social health service use, there were significant differences between groups in WHOQOL-E. Patients that used those services scored lower in this domain than those patients that did not use those services. No other differences were observed regarding use of health services.

Changes over time

There were statistically significant changes over time regarding PANSS positive, PANSS negative, PANSS general, PANSS total, GAF clinical, and GAF social scores. To be precise, there was a decrease in psychiatric symptoms as shown by changes in PANSS scores over time

Table 2 Validity evidence of the WHOQOL-BREF^a for patients with schizophrenia

	WHOQOL physical	WHOQOL psychological	WHOQOL social relations	WHOQOL environment	WHOQOL total
<i>Association with clinical and psychosocial variables:</i>					
	<i>[r (P value)] (n = 241)</i>				
GAF ^b clinical	0.17 (P = 0.010)	0.25 (P < 0.001)	ns	0.21 (P = 0.001)	0.23 (P < 0.001)
GAF social	0.20 (P = 0.002)	0.20 (P = 0.002)	ns	0.23 (P < 0.001)	0.23 (P < 0.001)
PANSS ^c positive	ns	-0.18 (P = 0.005)	-0.13 (P = 0.048)	-0.14 (P = 0.025)	-0.17 (P = 0.009)
PANSS negative	ns	ns	-0.14 (P = 0.033)	ns	ns
PANSS general	-0.17 (P = 0.008)	-0.25 (P < 0.001)	-0.19 (P = 0.004)	-0.19 (P = 0.002)	-0.24 (P < 0.001)
PANSS total	-0.13 (P = 0.038)	-0.21 (P = 0.001)	-0.18 (P = 0.004)	-0.17 (P = 0.008)	-0.21 (P = 0.001)
DAS- ^{s,d}	-0.30 (P < 0.001)	-0.31 (P < 0.001)	-0.31 (P < 0.001)	-0.36 (P < 0.001)	-0.40 (P < 0.001)
FSSQ ^e total social support	0.35 (P < 0.001)	0.35 (P < 0.001)	0.55 (P < 0.001)	0.51 (P < 0.001)	0.52 (P < 0.001)
FSSQ confidential support	0.34 (P < 0.001)	0.34 (P < 0.001)	0.53 (P < 0.001)	0.49 (P < 0.001)	0.50 (P < 0.001)
FSSQ affective support	0.25 (P < 0.001)	0.29 (P < 0.001)	0.41 (P < 0.001)	0.40 (P < 0.001)	0.42 (P < 0.001)
<i>Group differences: [t test(P value)] (n = 241)</i>					
Age (≤42 years old: >42 years old)	ns	ns	ns	ns	ns
Gender (male: female)	ns	ns	ns	ns	ns
Illness length (≤10 years: >10 years)	ns	ns	ns	ns	ns
Education (≤primary school: >primary school)	ns	ns	ns	ns	ns
Employment status (active: non-active)	ns	ns	ns	ns	ns
Diagnosis (paranoid schizophrenia: other schizophrenias)	ns	ns	ns	ns	ns
Living arrangement (family property: others) [F (P value)]	ns	ns	ns	ns	ns
Marital status (single: married or living with partner: divorced or separated or widow) [t test (P value)]	ns	ns	ns	ns	ns
Depressed vs. non-depressed (PANSS general: item number 6 ≥ 4 vs. item number 6 < 4)	ns	ns	ns	ns	ns
Anxious vs. no anxious (PANSS general: item number 2 ≥ 4 vs. item number 2 < 4)	3.23 (P = 0.001)	3.76 (P < 0.001)	ns	ns	ns
Disabled vs. non-disabled (DAS-s ≥ 4 vs. DAS-s < 4)	ns	3.14 (P = 0.001)	2.72 (P = 0.003)	4.30 (P < 0.001)	3.92 (P < 0.001)
Lacking social support vs. having social support (FSSQ ≤ 32 vs. FSSQ > 32)	-4.45 (P < 0.001)	-4.28 (P < 0.001)	-7.37 (P < 0.001)	-6.62 (P < 0.001)	-6.94 (P < 0.001)
Use of social services vs. no use of social services ^Y	ns	ns	ns	-2.96 (P = 0.003)	ns
Use of emergency calls vs. no use of emergency calls ^Y	ns	ns	ns	ns	ns

n: Simple size at baseline; ns: non-significant; Y: Time frame: patient visits during the year previous to the first assessment versus patients visits during a year after the first assessment
^a WHOQOL-BREF: World Health Organization Quality of Life Brief Version; ^b GAF: Global Assessment of Functioning; ^c PANSS: Positive and Negative Syndrome Scale; ^d DAS-s: The World Health Organization Short Disability Assessment Schedule; ^e FSSQ: Functional Social Support Questionnaire

Table 3 Clinical and psychosocial variables and use of health services at baseline and at 1-year follow-up (*n* = 219)

Measure	Baseline		1 year follow-up		Differences over time		
	Mean	SD	Mean	SD	<i>t</i>	<i>P</i>	ES
PANSS ^a positive	16.67	6.26	15.22	6.10	5.02	<0.001	0.32
PANSS negative	24.07	6.99	22.34	6.90	5.08	<0.001	0.33
PANSS general	42.35	12.73	39.22	12.30	5.30	<0.001	0.34
PANSS total	83.10	22.47	76.79	21.96	6.14	<0.001	0.38
GAF ^b clinic	47.07	9.69	49.58	11.01	−4.94	<0.001	0.32
GAF social	44.29	10.00	46.26	10.36	−3.45	<0.001	0.23
DAS-s ^c	9.09	4.46	8.59	4.46	2.37	ns	0.16
WHOQOL-BREF ^d physical health	13.25	2.42	13.27	2.54	−0.95	ns	0.01
WHOQOL-BREF psychological health	12.18	2.86	12.19	2.81	−0.01	ns	0.00
WHOQOL-BREF social relationships	10.54	3.26	10.50	3.24	0.23	ns	0.02
WHOQOL-BREF environment	13.24	2.26	13.31	2.36	−0.51	ns	0.04
WHOQOL-BREF general	81.82	13.94	81.95	14.11	−0.18	ns	0.01
FSSQ ^e total social support	36.68	9.47	36.57	9.72	0.22	ns	0.02
FSSQ confidant support	16.55	4.99	16.37	5.17	0.63	ns	0.00
FSSQ affective support	10.90	3.14	10.78	3.22	0.68	ns	0.00
Community psychiatric visits ^Y	5.76	4.22	6.28	4.43	−1.75	ns	0.12
Community nursing visits ^Y	5.92	7.13	8.38	9.03	−4.35	<0.001	0.28

SD: Standard deviation; ns: non-significant; Y: Time frame: patient visits during the year previous to the first assessment versus patients visits during a year after the first assessment

^a PANSS: Positive and Negative Syndrome Scale; ^b GAF: Global Assessment of Functioning; ^c DAS-s: The World Health Organization Short Disability Assessment Schedule; ^d WHOQOL-BREF: World Health Organization Quality of Life Scale Brief Version; and ^e FSSQ: Functional Social Support Questionnaire

and an improvement in overall functioning as indicated by changes in GAF scores over time. Effect sizes were medium for most scores but small for GAF social scores. DAS-s scores decreased over time but not significantly and WHOQOL-BREF scores and FSSQ scores remained about the same over time. With regard to use of health services, there were statistically significant changes over time in community nursing visits. Specifically, there was an increase in community nursing visits with a small effect size. No other statistically significant differences over time were observed (See Table 3).

Sensitivity to change

Firstly, score differences between baseline and one-year follow-up were calculated for WHOQOL-BREF domains, WHOQOL-BREF total score, the other assessment tools and community service visits. Secondly, Pearson's correlation coefficients between WHOQOL-BREF score differences and all other score differences were calculated. Table 4 shows that Pearson's correlations between changes in WHOQOL-BREF scores and changes in GAF, PANSS, DAS-s, FSSQ scores and community service visits were mostly significant. Those coefficients ranged from −0.00 to 0.36. In particular, correlations between the change in

WHOQOL-BREF and the change in GAF scores were small; correlations between changes in WHOQOL-BREF and changes in PANSS and DAS-s scores were negative and small; correlations between changes in WHOQOL-BREF and changes in FSSQ scores ranged between small and moderate. As for use of health services, only community nursing visits showed statistically significant correlations. Specifically, correlations between changes in WHOQOL-BREF scores and changes in community nursing visits were small.

Discussion

The aim of this study was to validate the WHOQOL-BREF in patients with schizophrenia. The WHOQOL-BREF showed suitable psychometric properties in this patient population.

Internal consistency values at baseline and at 1-year follow-up were excellent for the total WHOQOL-BREF and adequate for WHOQOL-BREF domains. These findings are in agreement with the evidence about the psychometric properties of the WHOQOL-BREF. During the development of the WHOQOL-BREF [41], Cronbach's α values of the WHOQOL-BREF domains ranged between

Table 4 Sensitivity to change of the WHOQOL-BREF^a for patients with schizophrenia

	WHOQOL physical r(P)	WHOQOL psychological r(P)	WHOQOL social relations r(P)	WHOQOL environment r(P)	WHOQOL total r(P)
Sensitivity to change (n = 219)					
GAF ^b clinical	0.11 (P = 0.092)	0.14 (P = 0.035)	0.09 (P = 0.198)	0.04 (P = 0.539)	0.14 (P = 0.035)
GAF social	0.23 (P = 0.001)	0.18 (P = 0.008)	0.07 (P = 0.283)	0.14 (P = 0.035)	0.23 (P = 0.001)
PANSS ^c positive	-0.10 (P = 0.132)	0.10 (P = 0.145)	-0.15 (P = 0.029)	-0.02 (P = 0.803)	-0.13 (P = 0.065)
PANSS negative	-0.16 (P = 0.017)	-0.19 (P = 0.005)	-0.16 (P = 0.019)	-0.08 (P = 0.236)	-0.20 (P = 0.003)
PANSS general	-0.14 (P = 0.038)	-0.19 (P = 0.004)	-0.20 (P = 0.003)	-0.05 (P = 0.448)	-0.19 (P = 0.004)
PANSS total	-0.16 (P = 0.016)	-0.20 (P = 0.003)	-0.21 (P = 0.002)	-0.06 (P = 0.368)	-0.21 (P = 0.001)
DAS-s ^d	-0.15 (P = 0.030)	-0.19 (P = 0.006)	-0.16 (P = 0.020)	-0.11 (P = 0.112)	-0.21 (P = 0.001)
FSSQ ^e total social support	0.24 (P < 0.001)	0.27 (P < 0.001)	0.28 (P < 0.001)	0.27 (P < 0.001)	0.36 (P < 0.001)
FSSQ confidential support	0.25 (P < 0.001)	0.27 (P < 0.001)	0.31 (P < 0.001)	0.26 (P < 0.001)	0.36 (P < 0.001)
FSSQ affective support	0.17 (P = 0.014)	0.21 (P = 0.002)	0.07 (P = 0.299)	0.21 (P = 0.002)	0.25 (P < 0.001)
Nursing community visits (n = 218) ^Y	0.12 (P = 0.075)	0.09 (P = 0.190)	0.18 (P = 0.007)	0.01 (P = 0.892)	0.11 (P = 0.096)
Psychiatric community visits (n = 218) ^Y	0.03 (P = 0.699)	0.01 (P = 0.888)	-0.06 (P = 0.392)	0.00 (P = 0.989)	0.00 (P = 0.947)

n: Sample size; Y: Time frame: patient visits during the year previous after first assessment versus patient visits during the year after the second assessment

^a WHOQOL-BREF: World Health Organization Quality of Life Scale Brief Version; ^bGAF: Global Assessment of Functioning; ^cPANSS: Positive and Negative Syndrome Scale; ^dDAS-s: The World Health Organization Short Disability Assessment Schedule; ^eFSSQ: Functional Social Support Questionnaire

0.66 and 0.84. In 2002, the WHOQOL group participated in a field trial held in 23 countries, which intended to confirm and extend information on WHOQOL-BREF psychometric properties. Cronbach's α values of the WHOQOL-BREF domains observed ranged between 0.55 and 0.88 for the PH domain, between 0.73 and 0.89 for the P domain, between 0.55 and 0.77 for the SR domain and between 0.65 and 0.87 for the E domain [42]. In a study with adult psychiatric outpatients, the internal consistency of the WHOQOL-BREF four domains ranged from 0.66 to 0.80 [29].

We expected to find that global functioning and perceived social support had a positive relationship with subjective QOL, while the severity of depression, anxiety and negative symptoms as well as disability and use of services had a negative one [38]. Those were the directional relationships of the present findings, which also have been found in other studies. Some authors have found similar associations between the domains of the WHOQOL-BREF and measures of psychopathological symptoms, social support [24, 29] and functioning [54]. One should note that the correlation coefficients of QOL with those variables ranged between small and large, with disability and social support showing the largest coefficients. This might suggest that disability and social support are more closely related to QOL than psychiatric symptoms and global functioning. However, it should be emphasized that psychiatric symptoms and functioning were assessed by clinicians, while

QOL and social support were self-rated by patients. Those results suggest that patients' perceptions of mental health do not correspond with clinicians' perceptions [55–57]. Some authors have even argued that those perceptions might be independent [58–60]. This lack of agreement between informants might be related to higher associations between measures provided by the same informant than between measures provided by different informants [61].

There were no differences in WHOQOL-BREF domains between groups of patients established according to socio-demographic variables. The present findings have been observed in other studies. Skantze et al. [62] showed that QOL had no association with gender, marital status, and standard of living, while in a multicentre study [63], no differences in subjective QOL between men and women with schizophrenia were observed. Young [64] found no associations between perceived QOL and sex, age, education, and marital status. Although some studies have reported significant associations between subjective QOL and socio-demographic factors [29, 55, 65], it is agreed that the relationship between socio-demographic factors and subjective QOL is controversial, weak, or non-existent [38]. Therefore, socio-demographic variables are still not considered to be significantly associated with QOL in patients with schizophrenia, which is consistent with our results.

There were significant differences between patient groups. Disabled patients and patients lacking social

support showed poorer levels of QOL in almost all WHOQOL-BREF domains, while anxious patients scored lower in the PH and P domains of the WHOQOL-BREF. Although one should note that group differences may be unreliable since they were made according to established cut-offs of single scale items rather than through diagnostic interviews, our results are consistent with findings which show that QOL is associated with disability, social support, and psychiatric symptoms [30]. Patients who used social services more showed poorer levels of QOL related to environment. In other words, patients with more care needs at a social level appeared to show poorer levels of QOL. The association between care needs and QOL in patients with schizophrenia has been widely investigated [38], and it has been shown that there is a relationship between high numbers of unmet needs and low QOL, which is consistent with the present findings.

There are differences in QOL when comparing patients with schizophrenia with healthy subjects or other clinical groups [38]. Patients with schizophrenia are significantly impaired in both the general and all specific QOL domains compared with healthy subjects but only in some domains when compared with other clinical groups. At baseline, WHOQOL-BREF scores in our study sample differed from those of healthy people. For example, in the development of the WHOQOL-BREF [41], mean scores in healthy people were 16.2 for the PH, 15 for the P, 14.3 for the S and 13.5 for the E domain, which were higher than those in our sample. Akvardar et al. [66] showed similar WHOQOL-BREF scores to those obtained in our study and found that patients with schizophrenia scored significantly lower than healthy subjects in all WHOQOL-BREF domains. They also showed lower scores in the P and SR domains when compared to patients with diabetes and bipolar disorder.

At one-year follow-up, we expected, as a consequence of the role of AMHCC in the provision of care to patients with schizophrenia, a decrease in levels of psychiatric symptoms and disability and an increase in levels of global functioning, QOL and social support. There were only improvements regarding psychiatric symptoms and global functioning together with an increase in community psychiatric nursing visits. We observed a decrease in disability but non-significant, and we did not observe improvements regarding QOL and social support as perceived by patients. Although WHOQOL-BREF was sensitive to changes over time, the associations between changes in WHOQOL-BREF scores and changes in the rest of variables were mostly small except for changes in social support that ranged between small and moderate. Again, those results might show lack of agreement between patients' and clinicians' assessments. Moreover, the lack of improvements regarding QOL could be explained by the fact that

impairment in QOL appears to be relatively stable across the course of the illness [38].

To date, the WHOQOL-BREF has been used for the assessment of patients with schizophrenia although no validation of the scale is available. The present findings provide evidence regarding the psychometric properties of the WHOQOL-BREF in patients with schizophrenia, which supports its use in this patient population. It shows that the WHOQOL-BREF has good reliability and validity, and suggests that it is a suitable scale for the assessment of QOL in patients with schizophrenia. Taking all the above into account, the WHOQOL-BREF could be used in patients with schizophrenia as an assessment tool for purposes such as research or routine practice.

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Conflicts of interest The authors declare no conflict of interest.

Appendix

The Work Group on Severe Mental Disorder is composed of the following members from Adult Mental Health Care Centers in Barcelona: M^a Antonia Argany, Francesca Asensio, Marta Berruezo, Carlos Blecua, Ignasi Bros, Ana Isabel Cerrillo, Ana del Cuerpo, Amparo Escudero, Judit Farré, Clara Fort, Marisa García, M^a Carmen González, Eva Leno, Lluís Mauri, Isabel Mitjà, Mónica Montoro, Montserrat Nicolás, Rosa Ordoñez, Carmen Pinedo, Montserrat Prats, M^a Joaquina Redín, M^a Teresa Romero, Francesc Segarra, Juan Carlos Valdearcos, Immaculada Zafra, Matías Zamora y Antonio Zúñiga.

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Annex 3

Study 3:

Mas-Expósito L, Amador-Campos JA, Gómez-Benito J and Lalucat-Jo L. The World Health Organization Disability Assessment Schedule Short Form: a validation study in patients with schizophrenia. *Comprehensive Psychiatry*. 2012; 53(2):208-216.

The World Health Organization Short Disability Assessment Schedule: a validation study in patients with schizophrenia

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Abstract

Purpose: The World Health Organization Short Disability Assessment Schedule (DAS-s) is used for patients with schizophrenia, although no validation is available. This manuscript addresses this issue by dealing with its psychometric properties in a clinical sample of patients with schizophrenia.

Methods: Two hundred forty-one patients from 10 Adult Mental Health Care Centers meeting the following inclusion criteria were included: (1) *International Classification of Diseases, 10th Revision*, diagnosis of schizophrenia; (2) Global Assessment of Functioning scores 50 or less; (3) illness duration of more than 2 years; and (4) clinical stability at assessment time. Patients were evaluated at baseline and at 1-year follow-up regarding disability, sociodemographic and clinical variables, psychosocial measures, and use of mental health services.

Results: The factor analysis revealed a single factor that explained 60.57% of the variance. Internal consistency values were appropriate for the DAS-s total (0.78 at baseline and 0.78 at 1-year follow-up). Correlations between DAS-s scores and those of global functioning, psychiatric symptoms, social support, and quality of life ranged between small and moderate (range, 0.13-0.39). There were significant differences between groups of patients with schizophrenia in the DAS-s. Patients who were unemployed, with lower global functioning, with cognitive impairment, and lacking social support scored significantly lower in DAS-s scores. After 1-year follow-up, there was a nonsignificant decrease in DAS-s scores; and patients improved significantly in overall functioning and psychiatric symptoms.

Discussion: This study shows that the DAS-s has good reliability and validity and suggests that it is suitable for the assessment of disability in patients with schizophrenia.

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Conflict of interest: The authors declare no conflict of interest.

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1. Introduction

Disability is seen in impairments on daily life activities involving, for example, personal care, occupation, and family and social relationships. Disability is present in mental health disorders and, particularly, in persons with schizophrenia who, due to disability, may show difficulties in having a major life activity [1,2]. Taking into account these consequences, it is justified that disability would be an essential element of investigation and practice in the context of rehabilitation in patients with schizophrenia [3].

The assessment of disability in rehabilitation is limited by the following factors [4]: (1) several measurement methods (ie, self-report, hetero-report, performance-based report, etc), (2) ambiguity between disability and other related terms (ie, functioning, living skills, incapacity, etc), and (3) lack of

agreement on the scope of its meaning. The World Health Organization (WHO) developed the Short Disability Assessment Schedule (DAS-s) [5] that is an instrument to assess disability in mental disorders that deals with the aforementioned limitations. It takes into account different sources of information, and it provides a concise and cross-culturally agreed upon definition of disability based on the *International Classification of Impairments, Disabilities and Handicaps* [6].

The DAS-s [5] is derived from the WHO Psychiatric Disability Assessment Schedule (DAS) [7] that is a semistructured interview developed for the assessment of disability of patients with mental disorders and, specifically, psychotic patients. It was developed in two international field trials of the multiaxial presentation of the *International Classification of Diseases, 10th Revision (ICD-10)* [8] and assesses problems in personal care, occupational tasks, and functioning with regard to the social setting of the patient. It can be used in different settings such as medical practice, research, or audit and is an international disability evaluation tool applicable across different cultures [5].

Although no validation is available in patients with schizophrenia, the DAS-s has been used for the assessment of this patient population [9–12] because of its suitability, the aspects it covers, and its psychometric properties with psychiatric patients [5]. This manuscript addresses the issue by validating this instrument in a clinical sample of outpatients with schizophrenia.

Firstly, we aim to establish its factor structure. The results of the dimensionality of the test will guide the rest of psychometric analyses. Secondly, we address the internal consistency of this scale. Thirdly, we deal with its convergent validity. Namely, we study DAS-s associations with clinical and psychosocial variables and disability differences between groups of patients with schizophrenia, established according to sociodemographic variables, global functioning, psychiatric symptoms, and social support. As observed in previous studies, we expect to find a positive relationship between disability and psychiatric symptoms [13–17] while finding a negative one between disability and social support [18], quality of life [19], and measures of global functioning. McKibbin et al [4] found, in general terms, no associations between disability and sociodemographic variables, whereas Alptekin et al [17] only found significant associations between disability and employment. We do not expect there to be significant differences between groups of patients with schizophrenia based on socio-demographic variables. Taking into account the aforementioned expected relationships, we expect to find disability differences between groups of patients with schizophrenia established according to global functioning, psychiatric symptoms, and social support. Specifically, we expect to find that patients with higher global functioning, lower levels of psychiatric symptoms (ie, depression, anxiety, insight, and cognition), and higher social support will show lower levels of disability.

Finally, we aim to test the capacity of the DAS-s to detect changes over time and to establish its sensitivity to change after 1-year follow-up. We anticipate significant improvements in perceived social support, global functioning, psychiatric symptoms, disability, and quality of life in relation to community treatment provided to patients [20].

2. Methods

2.1. Sample

Patients came from 10 Adult Mental Health Care Centers (AMHCC) in Barcelona (Spain). These AMHCC are run by the Catalan Department of Health and share similar characteristics regarding the care provided to patients. They offer a care package to patients with schizophrenia by means of multidisciplinary community mental health teams (ie, a psychiatrist, a psychologist, a community mental health nurse, and a social worker). This care package involves medical and psychosocial interventions of varying intensity depending on patients' needs and is coordinated by one of the members of the mental health teams (ie, a community mental health nurse).

From December 2006 to January 2008, these AMHCC participated in a study consisting of a 1-year follow-up of patients in contact with services who met the following inclusion criteria: (1) Global Assessment of Functioning (GAF) [21] scores of 50 or lower, (2) illness length greater than 2 years, (3) *ICD-10* [8] diagnosis of schizophrenia, and (4) clinical stability at assessment time. Patients were excluded if they had dementia, organic brain injury, or mental retardation. Patients who visited consecutively and who met study inclusion criteria were asked to participate. Specifically, 260 patients met these inclusion criteria; but 19 did not consent to participate. Data from this study were used in this manuscript.

The final sample comprised 241 patients (67.6% men). Their mean age was 41.7 years (SD, 11.6), and 72.6% of them had illness duration greater than 10 years; 70.5% of patients had a diagnosis of paranoid schizophrenia; and 29.5% of other schizophrenias (ie, 10.8% undifferentiated, 9.1% residual, 6.2% hebephrenic, 1.2% simple, and 2.1% other). Other sociodemographic characteristics of patients are described in Table 1.

A total of 219 patients (90.9%) were successfully evaluated at 1-year follow-up. Sixteen people (of 22) were not evaluated following their psychiatrist's instructions because they were not clinically stable at assessment time or did not have contact with services; 3 died (1 from terminal illness and 2 by suicide), 2 did not properly complete the evaluation, and 1 dropped out of the study.

2.2. Instruments

Patients were evaluated at baseline and at 1-year follow-up with the following assessment tools.

Table 1
Sociodemographic characteristics of the sample at baseline

Variable	n	(%)
Age, mean (SD)	41.71 (11.60)	
Sex		
Female	78	32.4
Male	163	67.6
Illness duration		
<5 years	24	10.0
5-10 years	42	17.4
>10 years	175	72.6
Marital status		
Single	181	75.1
Living with a partner or married	32	13.3
Divorced, separated, or widowed	28	11.6
Educational level		
≤Primary school	113	46.9
>Primary school	128	53.1
Living arrangement		
Family property	166	68.9
Other	45	31.1
Employment status		
Active	53	22
Nonactive	188	78
Schizophrenia type		
Paranoid	170	70.5
Other	71	29.5

2.2.1. The Short Disability Assessment Schedule [5]

It is a semistructured interview based on the clinician's assessment of the information obtained from the patient, caregivers, family, case notes, and other records. It is derived from the DAS [7] and is composed of the following items [5]: (1) personal care, which refers to personal hygiene, dressing, feeding, and other; (2) occupation, which refers to expected functioning in paid activities, studying, homemaking, and other; (3) family and household members, which refers to expected interaction with partner, parents, children, and other; and (4) broader social context, which refers to expected performance in relation to community members, participation in social activities, and other. Each item is rated on a 6-point scale with the following anchor points: 0 = no disability at any time; 1 = deviation from the norms in the performance of 1 or more of the tasks or roles expected to be carried out by the patient in his or her cultural setting; 2 = deviation from the norms is conspicuous, and dysfunction interferes with social adjustment (ie, slightly disabled most of the time or moderately disabled some of the time); 3 = deviation from the norms in most of the expected tasks and roles; 4 = deviation from the norms in all of the expected tasks and roles; and 5 = deviation from the norms has reached a crisis point (ie, the patient is severely disabled all of the time). The addition of all item scores provides an overall measure of disability [9,11,12]. The higher the score, the greater the disability perceived by the clinician. Besides the aforementioned items, there are also 3 other items not included in the scoring but which the clinician needs to take into account when rating with the DAS-s. First, time covered by the rating (ie, current, last

month, last year, etc). Second, total duration of disability (ie, <1 year, ≥1 year, and unknown). Finally, specific abilities of the patient (ie, presence and description).

The DAS-s was developed in the framework of the multiaxial presentation of the *ICD-10* [5]. It involved (1) elaboration of a draft version by an international expert advisory group; (2) revision of the draft version by participants in the development of different versions of the *ICD-10* [8], heads of WHO centers, the World Psychiatric Association, and other; and (3) elaboration of the final version of the DAS-s based on the DAS [7]. During its development [5], the DAS-s showed good psychometric properties. The DAS-s intraclass correlation coefficients ranged from 0.40 for disability in family and household activities to 0.74 for disability in personal care. Moreover, 50% of specific disability categories had κ values higher than 0.50.

In this study, the time covered in the rating was the last month.

2.2.2. The Global Assessment of Functioning [21]

This is a reliable and valid measure of global psychological functioning in patients with severe mental disorder. Its theoretical range is 1 to 100, where 100 denotes best possible functioning. It is included in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* [21].

2.2.3. The Positive and Negative Syndrome Scale [22]

This instrument, the Positive and Negative Syndrome Scale (PANSS), is used for assessing symptom severity in patients with schizophrenia; and it has been translated into and is validated in Spanish [23]. It assesses psychiatric symptoms in 3 domains: positive (theoretical range, 7-49, where 49 denotes higher levels of positive psychiatric symptoms), negative (theoretical range, 7-49, where 49 represents higher levels of negative psychiatric symptoms), general (theoretical range, 16-112, where 112 denotes higher levels of general psychiatric symptoms) and provides an overall measure of psychiatric symptoms (theoretical range, 30-210, where 210 means higher levels of psychiatric symptoms). Internal consistency values of its subscales range between medium and high, and its convergent validity with other measures of psychiatric symptoms is high and ranges from 0.70 to 0.81 [23].

2.2.4. The Functional Social Support Questionnaire [24]

The Functional Social Support Questionnaire (FSSQ) is an 11-item questionnaire that measures the strength of the patient's social network. It assesses perceived social support in 2 domains: confidential social support (theoretical range, 6-30, where 30 denotes higher levels of confidential social support) and affective social support (theoretical range, 5-25, where 25 represents higher levels of affective social support) and provides an overall measure of social support (theoretical range, 11-55, where 55 shows higher levels of social support). It has also been translated into and validated in Spanish [25], and the reliability indexes are 0.80 and 0.92 for

hetero-report and self-report, respectively. The concurrent validity with other health measures ranges in absolute values from 0.13 to 0.81 [25].

2.2.5. The World Health Organization Quality of Life Scale Brief Version [26]

The World Health Organization Quality of Life Scale Brief Version (WHOQOL-BREF) is a short version of the World Health Organization Quality of Life Scale or WHOQOL-100 that is considered an international, cross-culturally analogous quality of life evaluation tool [27]. During its development, internal consistency values ranged from 0.66 to 0.84; and correlations with the WHOQOL-100 subscales ranged from 0.89 to 0.95 [27]. Skevington et al [28] confirmed and extended information about its properties and showed good to excellent psychometric properties. There is a Spanish version [29] that shows good psychometric properties in patients with schizophrenia [30].

2.3. Procedure

The study was approved by the Ethics Committee of the Catalan Union of Hospitals in accordance with the ethical standards of the 1964 Declaration of Helsinki. The procedures and assessments were described to each patient who then provided informed consent.

The community mental health teams performed patient assessments. The diagnosis was established by the psychiatrist by means of a nonstructured interview following *ICD-10* [8] research diagnosis criteria and considered self-reports and caregiver reports. The psychiatrist also carried out the assessment of psychiatric symptoms while the rest of the assessments were performed by the other members of the community mental health teams under the psychiatrist's supervision. The psychiatrist was in charge of setting up the assessment agenda, supervising its development, and sending the score sheets to the psychologist in charge of the design and analyses of the study database.

To ensure the quality of data assessment, all psychiatrists participated in a schizophrenia diagnostic agreement workshop comprising two case vignettes. All researchers were trained in the administration of the instruments in a 4-hour session run by a psychologist with experience in psychological assessment of psychiatric patients. Systematic reviews of data coding and registration were taken, and patient information was contrasted with data from the AMHCC responsible for each patient.

First, the psychiatrist conducted the assessment of global functioning and psychiatric symptoms with the GAF and the PANSS to check if the patients met the inclusion criteria, then the other members of the community mental health teams administered the rest of assessment tools in the following order: (1) DAS-s, (2) the WHOQOL-BREF, and (3) the FSSQ.

After each evaluation, systematic reviews of data coding and registration were taken; and patient information was contrasted with family interviews and AMHCC registered data.

2.4. Data analysis

Exploratory factor analysis was performed using principal axis factoring. Factors were selected taking into account the following criteria: eigenvalues more than 1, the coefficient between the variance explained for the first factor and the second one, and the analysis of the scree plot [31,32].

Internal consistency was evaluated by means of Cronbach α and the contribution of DAS-s items to the overall α . The internal consistency was calculated at baseline and at 1-year follow-up. Cronbach α values were considered as follows: $0.60 \leq \alpha < 0.80$ adequate, $0.80 \leq \alpha < 0.85$ good and $\alpha \geq 0.85$ excellent. [33].

To assess convergent validity [34], Pearson correlations between DAS-s scores at baseline and the GAF, PANSS, FSSQ, and WHOQOL-BREF scores at baseline were calculated. Correlation values were considered as follows: (1) < 0.3 = small, (2) 0.3 to 0.5 = moderate, and (3) ≥ 0.5 = large [35]. *t* Tests and analysis of variance were used to analyze differences in DAS-s scores between groups of patients with schizophrenia. Patient groups were defined according to sociodemographic variables, low global functioning [21] (GAF scores ≤ 50), the presence of anxiety symptoms [22] (item 2 of PANSS general ≥ 4), depressive symptoms [22] (item 6 of PANSS general ≥ 4), lack of insight [22] (item 12 of PANSS general ≥ 4), cognitive impairment [22] (item 5 of PANSS negative ≥ 4), and lack of social support [25] (FSSQ ≤ 32).

t Tests for dependent samples were used to assess change over time between baseline and at 1-year follow-up for DAS-s, GAF, PANSS, FSSQ, and WHOQOL-BREF scores and AMHCC visits. The Bonferroni correction for multiple comparisons was applied [35], and a *P* value $\leq .003$ was considered significant. The effect size was also estimated [36], and its values were considered as follows: (1) < 0.3 = small, (2) 0.3 to 0.5 = moderate, and (3) ≥ 0.5 large [37].

Differences between scores at baseline and at 1-year follow-up were calculated for DAS-s, GAF, PANSS, FSSQ, and WHOQOL-BREF scores and AMHCC visits. Sensitivity to change was determined by Pearson correlation coefficients between DAS-s score differences and the other score differences.

Data were analyzed using the Statistical Package for the Social Sciences v.15 (SPSS, Chicago, IL).

3. Results

3.1. Factor analysis

The analysis of the correlation and anti-image matrices and the results of the Kaiser-Meyer-Olkin measure of sampling adequacy (Kaiser-Meyer-Olkin, 0.77; Bartlett's test of sphericity; $\chi^2 = 264.58$; *df* = 6; *P* < .0001) showed that DAS-s data were appropriate to run the factor analysis. The exploratory factor analysis revealed a 1-factor structure with an eigenvalue of 2.42, which explained 60.57% of the

variance. Loadings of items from 1 to 4 were 0.71, 0.80, 0.84, and 0.76, respectively.

3.2. Internal consistency

Internal consistency coefficients for DAS-s were 0.78 at baseline and 0.78 at 1-year follow-up. We also tested the change in Cronbach α values when items are suppressed. The suppression of any of the items decreased internal consistency coefficients at baseline and at 1-year follow-up (range, 0.01–0.09). Item suppression decreased Cronbach α values by 0.09 as maximum, which may be considered negligible.

3.3. Convergent validity

Pearson correlations between DAS-s scores and GAF, PANSS, FSSQ, and WHOQOL-BREF scores at baseline were mostly significant and ranged from 0.13 to 0.39 in absolute values (Table 2). Specifically, correlations between DAS-s and GAF scores were negative and mainly small, correlations between DAS-s and PANSS scores were positive and ranged between small and moderate, correlations between DAS-s scores and FSSQ were negative and ranged between small and moderate, and correlations between DAS-s and WHOQOL-BREF scores were negative and ranged between small and moderate.

Table 2 shows the differences in DAS-s scores for groups of patients with schizophrenia. There were no statistically significant differences in DAS-s scores between groups established according to sociodemographic variables except for employment status. Namely, active patients scored significantly lower than nonactive patients in all DAS-s scores [DAS-s personal care: $t(101.06) = -3.082$ ($P=.003$); DAS-s occupation: $t(239) = -6.575$ ($P<.001$); DAS-s family and household: $t(104.79) = -3.623$ ($P<.001$); DAS-s broader social context: $t(239) = -3.427$ ($P=.001$); DAS-s total: $t(239) = -5.220$ ($P<.001$)]. There were significant differences in DAS-s scores between groups of patients with schizophrenia established according to clinical functioning, social functioning, cognitive impairment, and social support. In particular, patients with higher clinical functioning, higher social functioning, without cognitive impairment, and higher social support scored significantly lower in almost all DAS-s scores.

3.4. Changes over time

As shown in Table 3, DAS-s scores decreased over time but not significantly. There were statistically significant changes over time regarding PANSS positive, PANSS negative, PANSS general, PANSS total, GAF clinical, and

Table 2
Validity evidence of the DAS-s for patients with schizophrenia

	DAS-s				
	Personal care	Occupation	Family and household	Broader social context	Total
<i>Association with clinical and psychosocial variables (n = 241) (r [P value])</i>					
GAF clinical	-0.264 ($P < .001$)	-0.306 ($P < .001$)	-0.295 ($P < .001$)	-0.308 ($P < .001$)	-0.377 ($P < .001$)
GAF social	-0.217 ($P < .001$)	-0.323 ($P < .001$)	-0.320 ($P < .001$)	-0.351 ($P < .001$)	-0.390 ($P < .001$)
PANSS positive	0.223 ($P < .001$)	0.128 ($P = .047$)	0.290 ($P < .001$)	0.166 ($P = .010$)	0.259 ($P < .001$)
PANSS negative	0.169 ($P = .008$)	0.260 ($P < .001$)	0.204 ($P = .010$)	0.341 ($P < .001$)	0.312 ($P < .001$)
PANSS general	0.166 ($P = .010$)	0.155 ($P = .060$)	0.236 ($P < .001$)	0.252 ($P < .001$)	0.259 ($P < .001$)
PANSS total	0.209 ($P = .001$)	0.204 ($P = .001$)	0.278 ($P < .001$)	0.295 ($P < .001$)	0.316 ($P < .001$)
FSSQ total social support	-0.308 ($P < .001$)	-0.223 ($P < .001$)	-0.340 ($P < .001$)	-0.264 ($P < .001$)	-0.364 ($P < .001$)
FSSQ confidential support	-0.261 ($P < .001$)	-0.184 ($P = .004$)	-0.299 ($P < .001$)	-0.270 ($P < .001$)	-0.324 ($P < .001$)
FSSQ affective support	-0.295 ($P < .001$)	-0.193 ($P < .001$)	-0.307 ($P < .001$)	-0.179 ($P < .001$)	-0.313 ($P < .001$)
WHOQOL-BREF physical	-0.231 ($P < .001$)	-0.267 ($P < .001$)	-0.149 ($P = .021$)	-0.303 ($P < .001$)	-0.304 ($P < .001$)
WHOQOL-BREF psychological	-0.231 ($P < .001$)	-0.202 ($P < .001$)	-0.216 ($P = .001$)	-0.330 ($P < .001$)	-0.312 ($P < .001$)
WHOQOL-BREF social relations	-0.221 ($P = .001$)	-0.186 ($P = .004$)	-0.249 ($P < .001$)	-0.307 ($P < .001$)	-0.307 ($P < .001$)
WHOQOL-BREF environment	-0.261 ($P = .001$)	-0.253 ($P = .001$)	-0.277 ($P = .001$)	-0.321 ($P = .001$)	-0.356 ($P = .001$)
WHOQOL-BREF total	-0.295 ($P < .001$)	-0.288 ($P < .001$)	-0.274 ($P < .001$)	-0.388 ($P < .001$)	-0.398 ($P < .001$)
<i>Group differences (n = 241) (t test [P value])</i>					
Low clinical functioning vs high clinical functioning	4.062 ($P < .001$)	4.079 ($P < .001$)	3.455 ($P < .001$)	3.929 ($P < .001$)	4.963 ($P < .001$)
Low social functioning vs high social functioning	2.802 ($P = .006$)	4.718 ($P < .001$)	3.788 ($P < .001$)	4.320 ($P < .001$)	5.018 ($P < .001$)
Depressed vs nondepressed	-0.117 ($P = .907$)	-0.537 ($P = .591$)	-0.600 ($P = .549$)	-2.282 ($P = .023$)	-1.106 ($P = .270$)
Anxious vs nonanxious	0.109 ($P = .913$)	0.811 ($P = .420$)	1.058 ($P = .291$)	1.231 ($P = .222$)	1.049 ($P = .362$)
Insight impairment vs noninsight impairment	-1.485 ($P = .139$)	-2.761 ($P = .006$)	-2.216 ($P = .028$)	-2.564 ($P = .011$)	-2.931 ($P = .004$)
Cognitive impairment vs noncognitive impairment	-1.840 ($P = .067$)	-3.055 ($P = .003$)	-1.495 ($P = .136$)	-3.473 ($P = .001$)	-3.192 ($P = .002$)
Lacking social support vs having social support	-4.127 ($P < .001$)	-3.410 ($P = .001$)	-4.355 ($P < .001$)	-3.633 ($P < .001$)	-5.010 ($P < .001$)

n = sample size at baseline.

Table 3
Clinical and psychosocial variables and use of health services at baseline and at 1-year follow-up (n = 219)

Measure	Baseline		1-year follow-up		Differences over time		ES
	Mean	SD	Mean	SD	<i>t</i>	<i>P</i>	
DAS-s personal care	1.32	1.35	1.18	1.26	2.18	.031	0.15
DAS-s occupation	2.72	1.54	2.59	1.58	-1.37	.172	0.09
DAS-s family and household	2.05	1.48	2.01	1.45	0.56	.579	0.04
DAS-s broader social context	3.00	1.37	2.81	1.45	-2.26	.025	0.15
DAS-s total	9.09	4.46	8.59	4.46	2.37	.018	0.16
PANSS positive	16.67	6.26	15.22	6.10	5.02	<.001	0.32
PANSS negative	24.07	6.99	22.34	6.90	5.08	<.001	0.33
PANSS general	42.35	12.73	39.22	12.30	5.30	<.001	0.34
PANSS total	83.10	22.47	76.79	21.96	6.14	<.001	0.38
GAF clinic	47.07	9.69	49.58	11.01	-4.94	<.001	0.32
GAF social	44.29	10.00	46.26	10.36	-3.45	<.001	0.23
FSSQ confidant support	16.55	4.99	16.37	5.17	0.63	.531	0.00
FSSQ affective support	10.90	3.14	10.78	3.22	0.68	.500	0.00
FSSQ total social support	36.68	9.47	36.57	9.72	0.22	.823	0.02
WHOQOL-BREF physical health	13.25	2.42	13.27	2.54	-0.95	.924	0.01
WHOQOL-BREF psychological health	12.18	2.86	12.19	2.81	-0.01	.990	0.00
WHOQOL-BREF social relationships	10.54	3.26	10.50	3.24	0.23	.816	0.02
WHOQOL-BREF environment	13.24	2.26	13.31	2.36	-0.51	.612	0.04
WHOQOL-BREF general	81.82	13.94	81.95	14.11	-0.18	.856	0.01
AMHCC psychiatric visits ^a	5.76	4.22	6.28	4.43	-1.75	.082	0.12
AMHCC nursing visits ^a	5.92	7.13	8.38	9.03	-4.35	<.001	0.28

^a Time frame of patient visits during the year before the first assessment vs patient visits during the year after the first assessment.

GAF social scores. To be precise, there was a decrease in psychiatric symptoms as shown by changes in PANSS scores over time and an improvement in overall functioning as indicated by changes in GAF scores over time. Effect sizes were medium for most scores but small for GAF social scores. Functional Social Support Questionnaire and WHOQOL-BREF scores remained about the same over time. With regard to AMHCC visits, there were statistically significant changes over time in nursing visits. Specifically, there was an increase in nursing visits with a small effect

size. No other statistically significant differences over time were observed (Table 3).

3.5. Sensitivity to change

Firstly, score differences between baseline and 1-year follow-up were calculated for DAS-s scores, the other assessment tools, and AMHCC visits. Secondly, Pearson correlation coefficients between DAS-s score differences and all other score differences were calculated. Table 4 shows that

Table 4
Sensitivity to change of the DAS-s for patients with schizophrenia

	DAS-s personal care	DAS-s occupation	DAS-s family and household	DAS-s broader social context	DAS-s total
<i>Sensitivity to change (n = 219) (r [P value])</i>					
GAF clinical	-0.18 (<i>P</i> = .008)	-0.09 (<i>P</i> = .202)	-0.27 (<i>P</i> < .001)	-0.15 (<i>P</i> < .001)	-0.25 (<i>P</i> < .001)
GAF social	-0.18 (<i>P</i> = .009)	-0.10 (<i>P</i> = .048)	-0.29 (<i>P</i> < .001)	-0.28 (<i>P</i> < .001)	-0.33 (<i>P</i> < .001)
PANSS positive	0.21 (<i>P</i> = .002)	0.03 (<i>P</i> = .702)	0.21 (<i>P</i> = .002)	0.13 (<i>P</i> = .050)	0.20 (<i>P</i> = .003)
PANSS negative	0.13 (<i>P</i> = .500)	-0.00 (<i>P</i> = .989)	0.17 (<i>P</i> = .012)	0.18 (<i>P</i> = .006)	0.17 (<i>P</i> = .010)
PANSS general	0.17 (<i>P</i> = .012)	-0.09 (<i>P</i> = .200)	0.15 (<i>P</i> = .024)	0.15 (<i>P</i> = .029)	0.13 (<i>P</i> = .062)
PANSS total	0.20 (<i>P</i> = .003)	-0.04 (<i>P</i> = .527)	0.20 (<i>P</i> = .003)	0.18 (<i>P</i> = .007)	0.19 (<i>P</i> = .006)
FSSQ total social support	-0.06 (<i>P</i> = .365)	-0.02 (<i>P</i> = .736)	-0.16 (<i>P</i> = .018)	-0.20 (<i>P</i> = .002)	-0.17 (<i>P</i> = .015)
FSSQ confidential support	-0.02 (<i>P</i> = .766)	-0.02 (<i>P</i> = .778)	-0.17 (<i>P</i> = .010)	-0.19 (<i>P</i> = .005)	-0.13 (<i>P</i> = .050)
FSSQ affective support	-0.07 (<i>P</i> = .297)	-0.08 (<i>P</i> = .226)	-0.11 (<i>P</i> = .100)	-0.13 (<i>P</i> = .056)	-0.15 (<i>P</i> = .028)
WHOQOL-BREF physical	-0.12 (<i>P</i> = .082)	-0.03 (<i>P</i> = .710)	-0.19 (<i>P</i> = .004)	-0.14 (<i>P</i> = .043)	-0.15 (<i>P</i> = .030)
WHOQOL-BREF psychological	-0.16 (<i>P</i> = .019)	0.00 (<i>P</i> = .949)	-0.18 (<i>P</i> = .009)	-0.19 (<i>P</i> = .004)	-0.19 (<i>P</i> = .006)
WHOQOL-BREF social relation	0.05 (<i>P</i> = .442)	-0.07 (<i>P</i> = .291)	-0.27 (<i>P</i> < .001)	-0.13 (<i>P</i> = .065)	-0.16 (<i>P</i> = .020)
WHOQOL-BREF environment	0.01 (<i>P</i> = .907)	-0.02 (<i>P</i> = .796)	-0.09 (<i>P</i> = .175)	-0.18 (<i>P</i> = .007)	-0.11 (<i>P</i> = .112)
WHOQOL-BREF total	-0.10 (<i>P</i> = .150)	-0.02 (<i>P</i> = .791)	-0.23 (<i>P</i> = .001)	-0.24 (<i>P</i> < .001)	-0.21 (<i>P</i> = .001)
AMHCC psychiatric visits ^a	0.11 (<i>P</i> = .099)	0.02 (<i>P</i> = .778)	0.13 (<i>P</i> = .065)	-0.04 (<i>P</i> = .579)	0.07 (<i>P</i> = .277)
AMHCC nursing visits ^a	0.00 (<i>P</i> = .950)	-0.06 (<i>P</i> = .395)	-0.08 (<i>P</i> = .273)	-0.07 (<i>P</i> = .341)	-0.08 (<i>P</i> = .266)

n = sample size.

^a Time frame of patient visits during the year before the first assessment vs patients visits during the year after the first assessment.

Pearson correlations between changes in DAS-s scores and changes in GAF, PANSS, FSSQ, and WHOQOL-BREF scores were mostly significant. Those coefficients ranged from 0.00 to 0.33 in absolute values. In particular, correlations between the change in DAS-s and the change in GAF scores were negative and ranged between small and moderate, correlations between changes in DAS-s and changes in PANSS scores were positive and small, correlations between changes in DAS-s and changes in FSSQ scores were negative and small, and correlations between changes in DAS-s and changes in WHOQOL-BREF scores were mainly negative and small. As for AMHCC visits, there were no statistically significant correlations.

4. Discussion

The aim of this study was to validate the DAS-s in patients with schizophrenia. The DAS-s showed suitable psychometric properties in this patient population.

The factor analysis revealed a single factor that explained a high percentage of variability. This supports the use of an overall measure as a sum of the 4 items of the DAS-s [9,11,12]. Janca et al [5] suggested that the DAS-s items be scored individually, taking into account a clinical criteria but not the factor structure of the scale. To our knowledge, this is the first study that aims to establish its factor structure.

Internal consistency values at baseline and at 1-year follow-up were adequate for the DAS-s total. During the development of the DAS-s [5], the study of its psychometric properties was conducted using case vignettes and a sample of psychiatric patients recruited consecutively and included content analyses and assessments of interrater reliability. The authors concluded that the DAS-s was useful, user-friendly, and reliable. Our findings are an extension regarding the adequacy of the psychometric properties of the DAS-s.

We expected to find a positive relationship between disability and psychiatric symptoms [13–17] while finding a negative one between disability and social support [18], quality of life [19], and global functioning. Those were the directional relationships of our findings that have been found in other studies. Findings regarding the relationship between disability and psychiatric symptoms are controversial. Most authors show that there is a significant and positive relationship between disability and psychiatric symptoms, although some of them show that disability is associated only with negative symptoms [13,16,15], some with both negative and positive symptoms [14], and others with psychiatric symptoms in general terms [17]. Our findings are consistent with the association between disability and psychiatric symptoms in general terms.

As observed in other studies [4], we found significant and negative associations between disability, functioning, and quality of life. In our study, we used the GAF for the assessment of functioning and the WHOQOL-BREF for quality of life. They both aim to measure the functioning of

persons in their own environment. This may explain why they show the greatest correlation coefficients with disability. With regard to perceived social support, the present study showed that perceived social support is related to community adaptation in the sense that the higher the social support perceived, the better the community adaptation [38]. One should think that the DAS-s is intended to measure patient adaptation in its own environment or community adaptation. It is worth noting that disability and functioning were clinician rated (DAS-s and GAF), whereas social support and quality of life were self-rated (FSSQ and WHOQOL-BREF). The fact that the raters are different may explain why the correlation coefficients of the latter variables were not as great as one would expect [39].

There were no differences in DAS-s scores between groups of patients established according to sociodemographic variables except for employment. Our findings have been observed in other studies. For instance, McKibbin et al [4] found no association between sociodemographic characteristics (ie, age, education, sex, and ethnicity) and overall disability scores. When examining disability domains, McKibbin et al [4] found some associations between disability and sociodemographic variables in a sample of older patients with schizophrenia. Our results are, in general terms, congruent with the aforementioned results; but we did not find associations between disability domains and sociodemographic variables. This could be related to the use of different tools to assess disability and to the specific characteristics of the samples included. For example, the mean age in the present study was lower than that in the research by McKibbin et al [4]. Our results are also congruent with the results of Alptekin et al [17] that showed no significant associations between disability and age, sex, and marital status but a significant association between disability and employment. Further research may involve the effects of employment/occupational programs in this sample population, which seem to lessen disability [40] and, in addition, extend the information about the relationship between disability and sociodemographic variables because other studies have found differences between DAS-s scores and sociodemographic variables such as sex [9].

There were significant differences between patient groups. As expected, patients with lower functioning, cognitive impairment, and lacking social support showed higher disability levels in almost all DAS-s scores. The findings about functioning and social support are congruent with the relationship stated for these variables with disability earlier in the discussion. As for cognitive impairment, our findings support a body of evidence that show a relationship between cognitive impairment and disability [41–43]. Although we also hypothesized disability differences between groups of patients established according to levels of depression [4,17], anxiety [44], and insight impairment [45–47], our study did not find such associations. Even so, one should note that group differences may be unreliable because they were made according to established cutoffs of

single-scale items rather than through diagnostic interviews. Further research is needed to clarify the relationship between psychiatric symptoms and disability because, as already mentioned, it is controversial.

At 1-year follow-up after the provision of care to patients through AMHCC [20], we expected a decrease in disability and psychiatric symptoms and an increase in levels of general functioning, social support, and quality of life. There were only improvements regarding psychiatric symptoms and global functioning together with an increase of community psychiatric nursing visits. We did not observe significant improvements regarding disability, social support, or quality of life. This might somehow reflect the need for more specific psychosocial interventions aimed to improve disability, social support, and quality of life [48]. The lack of changes in DAS-s scores at 1-year follow-up might be one of the reasons why there are only small significant associations between changes in DAS-s scores between baseline and 1-year follow-up and changes in the rest of tests scores and AMHCC visits between baseline and 1-year follow-up.

To date, the DAS-s has been used for the assessment of patients with schizophrenia, although no validation of the scale is available. This manuscript provides evidence regarding the psychometric properties of the DAS-s in patients with schizophrenia. The DAS-s has good reliability and validity that supports its use in this patient population. Taking all the above into account, it can be considered that the DAS-s could be used for the assessment of disability in patients with schizophrenia as an evaluation tool for purposes such as research or routine practice. Future research should involve psychometric properties in other sample populations, such as other mental disorders as well as other populations with disability.

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Annex 4

Study 4:

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Validation of the modified DUKE-UNC Functional Social Support Questionnaire in patients with schizophrenia

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Abstract

Purpose The modified DUKE-UNC Functional Social Support Questionnaire (FSSQ) is considered a psychometric instrument to assess the social support in patients with schizophrenia. However, it has not been validated in this patient population. This issue is addressed here by examining the tool's psychometric properties in a clinical sample of patients with schizophrenia.

Methods Two hundred and forty-one patients from ten Adult Mental Health Centres (AMHC) meeting the following inclusion criteria were included: (1) International Classification of Diseases-10 (ICD-10) diagnosis

of schizophrenia; (2) Global Assessment of Functioning (GAF) scores ≤ 50 ; (3) Illness duration of more than 2 years; and (4) Clinical stability. Patients were evaluated at baseline and at 1-year follow-up for clinical and psychosocial variables.

Results The factor analysis revealed two factors that explained 54.15 % of the variance. Internal consistency was excellent for the total FSSQ (0.87 at baseline and 0.88 at 1 year follow-up) and ranged between adequate and excellent for FSSQ domains. Correlations between FSSQ scores and those of global functioning, psychiatric symptoms, disability and quality of life ranged between small and large. There were significant differences between groups of patients with schizophrenia in FSSQ scores. Patients with higher levels of somatic complaints and patients who were disabled scored significantly lower in some or all FSSQ scores. After 1-year follow-up, patients improved in overall functioning and there was a decrease in psychiatric symptoms. There were mainly small significant associations between changes in FSSQ scores from baseline to 1-year follow-up and changes in the rest of the test scores, and AMHC visits between baseline and 1-year follow-up.

Conclusions The FSSQ scores are reliable and valid, which suggests that the instrument is appropriate for the assessment of perceived social support in patients with schizophrenia.

Keywords Modified Duke-UNC Functional Social Support Questionnaire · FSSQ · Factor structure · Reliability · Validity · Social support · Schizophrenia

For the Research Group on Severe Mental Disorder. The working group members are listed in "Appendix".

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Introduction

Social support was conceptualised by Walsh and Connelly [38] as any material, instrumental and emotional support

provided by a social network. Such a network usually involves family and friends but is not restricted to them [28]. Social networks in people with severe mental illness are smaller than those in people without [8, 25] and frequently, they are restricted to the immediate family [31]. In patients with severe mental illness, poor levels of social support have been associated with poor quality of life [34, 44], poor self-esteem [15], high levels of psychiatric symptoms and more frequent hospitalisations [10, 36]; while high levels of social support have been associated with increased activity [29] and, thus, as a critical component to facilitating their treatment and recovery.

In view of this relationship between poor social support and poor outcomes in patients with severe mental illness, it is important to have specific instruments for assessing social support and there are a number of such tools which can be used in this group of patients as for example the Social Network and Support Interview Tool [30], the Arizona Social Support Inventory [3], the Multidimensional Scale of Perceived Social Support [46] and the Social Support Questionnaire [35].

The modified Duke-UNC Functional Social Support Questionnaire or FSSQ [6] is another example of assessment instrument that aims to measure social support. More specifically, it aims to measure the person's satisfaction with the functional and affective aspects of his or her social support. It is a brief instrument composed of 11 items taken from a larger questionnaire that was derived from a literature review [6, 7] and includes quantitative and functional measures regarding affective support (i.e., the possibility of having people to communicate) and confidant support (i.e., expression of love, affection and empathy). The FSSQ was developed in English and validated in patients recruited from a family medical practice [6]. Further validations have involved patients attending primary care health centres [5, 13]. These validation studies have explored the factor

structure of the FSSQ [5, 6, 13] and have shown the following two factors (1) affective support and (2) confidant support. Table 1 summarises the results of these studies. As seen in Table 1, some of the items have been located in either of the two factors of the FSSQ and this has been explained by differences in the way that patients from different settings understand the meaning of the items [5, 13].

The FSSQ is also considered an instrument for use in patients with severe mental illness [19] but so far, it has not been validated in this sample population. This issue has been addressed here by studying the psychometric properties of the FSSQ in a clinical sample of outpatients with schizophrenia.

Firstly, we aimed to establish its factor structure, its overall internal consistency and the internal consistency associated with its domains. Secondly, we addressed FSSQ validity evidence: associations with clinical and psychosocial variables, and differences in perceived social support between groups of patients with schizophrenia, established according to socio-demographic variables, psychiatric symptoms, disability, and use of services. As in previous studies, we expected to find a positive relationship between perceived social support and functioning [12] and quality of life [34, 44], and a negative relationship between perceived social support and psychiatric symptoms [10, 36] and disability [9]. In the validation study of the FSSQ [6], most socio-demographic variables showed no significant associations with perceived social support. We did not expect significant differences between groups of patients with schizophrenia based on socio-demographic variables. Taking into account the above-mentioned relationships, we expected to find differences in perceived social support between groups of patients with schizophrenia, according to psychiatric symptoms and disability. Specifically, we expected to find that patients with lower levels of psychiatric symptoms (i.e., depression, anxiety and somatic

Table 1 Results of the studies including exploratory factor analyses regarding the FSSQ

Authors	Sample	Setting	Factors	Internal consistency	Items in each factor
Broadhead (1988)	401 patients	Family medicine practice	F1: Confidant Support	0.62 ^a	6,7,8,9,10
			F2: Affective Support	0.64 ^a	4,5,11
			Remaining single items		1,2,3
De La Revilla Ahumada (1991)	139 patients	Health centre in a socio-economically deprived area	F1: Confidant Support	0.82 ^b	1,4,6,7,8,10
			F2: Affective Support		2,3,5,9,11
Bellón-Saameño (1996)	656 patients	Urban health centre	F1: Confidant Support	0.88 ^c	1,2,6,7,8,9,10
			F2: Affective Support	0.79 ^c	3,4,5,11

FSSQ The modified DUKE-UNC Functional Social Support Questionnaire

^a Average item reminder correlations

^b Overall Cronbach's α coefficient of the FSSQ

^c Cronbach's α coefficient of the FSSQ domains

complaints) and lower disability levels would show higher levels of perceived social support. We also expected to find differences in perceived social support between groups of patients according to use of health services, i.e., that patients with lower levels of perceived social support would use health services more frequently [5, 6]. In a meta-analysis review, Ziguras and Stuart [45] showed that community treatment programs were effective in patients with severe mental illness in terms of clinical and psychosocial outcomes. We expected significant improvements in perceived social support, global functioning, psychiatric symptoms, disability and quality of life after 1-year follow-up linked to the effect of community treatment in patients.

Method

Sample

Patients were recruited from ten Adult Mental Health Centres (AMHC) in Barcelona (Spain). AMHC belong to the Catalan Department of Health and provide care to patients in a similar way. Multidisciplinary community mental health teams (including psychiatrists, psychologists, community mental health nurses and social workers) offer a comprehensive intervention to patients with schizophrenia. Such intervention is usually managed by a community mental health nurse, provides care at a medical and psychosocial level and its intensity depends on patients' needs. Patient data came from a study conducted in these AMHC from December 2006 to January 2008. That study consisted of a 1-year follow-up of patients in contact with services meeting the following inclusion criteria: (1) Global Assessment of Functioning (GAF) [2] scores of 50 or lower; (2) Illness duration greater than 2 years; (3) International Classification of Diseases-10 (ICD-10) [41] diagnosis of schizophrenia; and (4) Clinical stability at time of assessment. Clinical stability was defined as the patient condition that allows to treat her or him in an outpatient setting as that in our study. The following exclusion criteria were used: dementia, organic brain injury or mental retardation. Patients visited consecutively by one of the members of the community mental health teams and meeting the study inclusion criteria were asked to participate. Two hundred and sixty patients met the inclusion criteria but 19 did not consent to take part in the study.

The final sample included 241 patients (67.6 % men) with a mean age of 41.7 years ($SD = 11.6$). Moreover, 72.6 % of them had illness duration greater than 10 years, 70.5 % of them had been diagnosed of paranoid schizophrenia and 53.1 % had a primary school level. The

majority were single (75.1 %), had no employment (78 %) and lived with their families (68.9 %). Details of the clinical and socio-demographic characteristics of the final sample at baseline have been described elsewhere [27].

Two hundred and nineteen patients (90.9 %) were re-evaluated 1 year after the first assessment. Sixteen patients (out of 22) were not evaluated because they were not clinically stable at time of assessment (i.e., the patient condition did not allow to treat him or her in an outpatient setting) or had lost contact with services, three died (2 by suicide and 1 from terminal illness), two did not finish the assessments and one left the study.

Instruments

Patients were evaluated at baseline and at 1-year follow-up with the following assessment tools:

- The FSSQ [6]. It is composed of 11 items. Each item is rated on a five-point Likert scale, ranging from 1 ("Much less than I would like") to 5 ("As much as I would like"). The higher the score, the better the social support perceived. The FSSQ can be interviewer- or self-rated, requires 5 min to administer and assesses subjective social support in two domains: (1) Confidant support (e.g., "My family and friends visit me"; score range 6–30); and (2) Affective support (e.g., "I get love and affection"; score range 5–25); and provides an overall social support measure (score range: 11–55). The FSSQ scores showed test–retest reliability coefficient of 0.66 and internal consistency, evaluated by means of item-remainder correlations, ranged from 0.50 to 0.85 in family medicine outpatients [7]. Correlations with symptoms, emotional functioning and activities as measured by the DUKE-UNC Health Profile scores were statistically significant.

The FSSQ was translated and validated in Spanish [13] in a sample of patients attending a primary care health centre in a socio-economically deprived area. The internal consistency for the FFSQ total score was 0.82. Another Spanish validation in a sample of patients attending primary care health centres in a less socio-economically deprived area [5] showed reliability coefficients of 0.80 and 0.92 for hetero-report and self-report, respectively. Concurrent validity with other health measures ranged in absolute values from 0.13 to 0.81 [5].

- *The Positive and Negative Syndrome Scale* or PANSS [21]. This is an instrument used to assess the severity of symptoms in patients with schizophrenia and has been translated into and validated in Spanish [32]. It includes three domains: positive (score range 7–49); negative (score range 7–49); general (score range 16–112); and

provides a measure of psychiatric symptoms in general terms (score range 30–210). The higher the score, the higher level of psychiatric symptoms. Its subscale scores showed internal consistency values that ranged between medium and high and its convergent validity with other measures of psychiatric symptoms was high and ranged from 0.70 to 0.81 in a sample of persons with schizophrenia [32].

- The GAF from the *Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV)* [2]. Its scores are reliable and valid to measure global functioning in psychiatric patients. It is a single-item scale and its score range oscillates between 1 and 100. The higher the score, the better the global functioning of patient.
- *The World Health Organization Short Disability Assessment Schedule (DAS-s)* [18] from the *ICD-10* [41]. These instrument scores are valid to assess disability. It is composed of seven items and developed by the World Health Organization. Its score range is 0–30. The higher the score, the higher the patient disability. It showed good psychometric properties in Spanish outpatients with schizophrenia [26].
- *The World Health Organization Quality of Life Scale Brief Version (WHOQOL-BREF)* [42]. This is a short instrument to assess subjective quality of life that is derived from the World Health Organization Quality of Life Scale [42]. It includes three domains: (1) Physical Health (score range 7–35), (2) Psychological (score range 6–30), (3) Social Relationships (score range 3–15), and (4) Environment (score range 8–40), and provides an overall measure (score range 26–130). The higher the score, the better the quality of life reported. Its scores showed internal consistency values that ranged between 0.66 and 0.84; correlations with the WHOQOL-100 subscales ranged from 0.89 to 0.95 in 15 different settings world wide [42]. Its translation into Spanish [24] showed proper psychometric properties in outpatients suffering from schizophrenia [27].

Procedure

The Ethics Committee of the Catalan Union of Hospitals approved the study in accordance with the ethical standards of the 1964 Declaration of Helsinki. Patients provided informed consent after the procedures and assessments had been explained to them.

The AMHC community mental health teams performed the study assessments. Namely, the psychiatrists established patient diagnoses by an interview according to the ICD-10 [41] research diagnosis criteria and self and caregiver reports.

The psychiatrists also assessed psychiatric symptoms and global functioning, and the other members of the community mental health teams conducted the rest of the assessments under the psychiatrists' supervision. The psychiatrists were in charge of setting up the assessment agenda, managing its progress and sending the score sheets to the psychologist responsible for the study database.

Different measures were taken to ensure the quality of assessment data. Firstly, all psychiatrists participated in a schizophrenia diagnostic agreement workshop by means of two clinical vignettes. Secondly, all researchers received a 4-h training session on the use of assessment instruments run by a psychologist with experience in the assessment of psychiatric patients, especially those with psychosis. Moreover, patient data were contrasted with data from AMHC and systematic examinations of the coding and registration of data were run.

Patients were evaluated at baseline and at 1-year follow-up according to the following procedure. First, to check patient inclusion criteria, the psychiatrist assessed global functioning and psychiatric symptoms with the GAF and the PANSS, respectively. Second, the other community mental health team members conducted the other assessments in the following order: (1) DAS-s; (2) the WHOQOL-BREF; and (3) the FSSQ. Systematic reviews of data coding and registration were run after each assessment and patient information was contrasted with data from family interviews and data registered in AMHC.

Data analysis

Data were analysed using the *Statistical Package for the Social Sciences* v.15.

Exploratory factor analysis (EFA) was performed using principal axis factoring and varimax rotation. Factors were selected using the following criteria: (1) the analysis of the scree plot, and (2) eigenvalues >1 [17, 20].

Internal consistency was evaluated at baseline and at 1-year follow-up by means of Cronbach's α . We studied the contribution of FSSQ items to the overall α , and the α associated with their domains. Cronbach's α coefficients were established as follows: $0.60 \leq \alpha < 0.80$ adequate; $0.80 \leq \alpha < 0.85$ good; and $\alpha \geq 0.85$ excellent [16].

Pearson's correlations between FSSQ scores at baseline and the GAF, PANSS, DAS-s and WHOQOL-BREF scores at baseline were calculated to assess validity evidence [1]. We considered the correlation coefficients as follows: (1) <0.3 = small; (2) 0.3 to 0.5 = moderate; and (3) ≥ 0.5 large [11].

To test differences in FSSQ scores between groups of patients with schizophrenia, we used *T* tests and analysis of variance test. The groups of patients were classified according to socio-demographic variables, the existence of

psychiatric symptoms such as anxiety [21] (item 2 of PANSS general ≥ 4), depression [21] (item 6 of PANSS general ≥ 4) and somatic complaints [21] (item 1 of PANSS general ≥ 4) and disability (DAS-s total mean score ≥ 4). We considered a cut-off item score of ≥ 4 for the DAS-s since a score of ≥ 4 indicates disability, although with the presence of external help [18]. Groups of patients were also established in terms of whether patients have used health services or not (i.e., primary care services and social services) during the year prior to baseline assessment. We estimated the effect size by means of correlation coefficients [33] which was considered as follows: (1) < 0.3 = small; (2) 0.3 to 0.5 = moderate; and (3) ≥ 0.5 large [11].

To assess change in patient status between baseline and at 1-year follow-up, we used *T* tests for dependent samples. FSSQ, GAF, PANSS, DAS-s and WHOQOL-BREF scores and use of community mental health services (i.e., community psychiatric visits and community nursing visits) were considered for those analyses. For community mental health services, we compared the frequency of patient visits during the year prior to baseline assessment and the frequency of patient visits during the year following that assessment. We applied the Bonferroni correction for multiple comparisons [14] and we considered significant a *p* value ≤ 0.004 . We estimated the effect size by means of correlation coefficients [33] which was considered as follows: (1) < 0.3 = small; (2) 0.3 to 0.5 = moderate; and (3) ≥ 0.5 large [11].

We calculated differences between scores at baseline and at 1-year follow-up for FSSQ, GAF, PANSS, DAS-s, WHOQOL-BREF and use of community mental health services. Pearson's correlation coefficients were used to calculate sensitivity to change between FSSQ score differences and differences in the rest of the scores.

Results

Factor analysis

The EFA revealed a two-factor structure with eigenvalues greater than 1 which explained 54.15 % of the variance. Table 2 shows item loading on each factor and the explained variance. Factor 1 (Confidant Support) included six items relating to the possibilities of counting on someone to communicate; factor 2 (Affective Support) included five items relating to counting on someone for love, care and empathy. Items number 3 and 5 had almost identical loadings in factor 1 and 2. Taking their conceptual meaning into account, we considered them in Factor 2 for the subsequent analyses.

Table 2 Factor structure of the FSSQ ($n = 241$)

Items	Factor 1	Factor 2
1	0.025	<i>0.871</i>
2	0.226	<i>0.502</i>
3	0.431	<i>0.455</i>
4	<i>0.736</i>	0.208
5	0.500	<i>0.480</i>
6	<i>0.781</i>	0.221
7	<i>0.827</i>	0.139
8	<i>0.733</i>	0.227
9	0.220	<i>0.629</i>
10	<i>0.722</i>	0.255
11	<i>0.646</i>	0.197
Explained variance (%)	43.85	10.30
Measure of sampling adequacy	0.90	
Bartlett's test of sphericity (χ^2 ; <i>p</i>)	(967.64; $p < 0.001$)	
Cronbach's alpha	0.87	0.68

Items in factors highlighted in italics

FSSQ The modified DUKE-UNC Functional Social Support Questionnaire

Internal consistency

Internal consistency coefficient for FSSQ total score at baseline was 0.87 and 0.88 at 1-year follow-up. For the FSSQ domains according to Broadhead [6], coefficients were 0.66 for FSSQ affective and 0.83 for FSSQ confidant at baseline, while at 1-year follow-up, they were 0.69 for FSSQ affective and 0.86 for FSSQ confidant. We also tested the change in Cronbach's alpha values when items are suppressed. Only the suppression of item 2 (i.e., "Chances to talk to someone I trust about my personal and family problems") increased the level of internal consistency of the FSSQ total by 0.002 at baseline. The suppression of any other items maintained or decreased internal coefficients by 0.02 maximum, which may be considered negligible. Regarding the FSSQ domains, the suppression of item 1 (i.e., "Love and affection") increased internal consistency levels by 0.03 and 0.02 at baseline and at 1-year follow-up, respectively. The suppression of any other items maintained or decreased internal coefficients by 0.12 maximum.

Validity evidence

Pearson's correlations between FSSQ scores and GAF, PANSS, DAS-s and WHOQOL-BREF scores at baseline were mostly significant, and ranged from 0.00 to 0.55 (see Table 3). Table 3 also shows the differences in FSSQ scores in groups of patients with schizophrenia. There was no statistically significant difference in FSSQ scores

Table 3 Validity evidence of the FSSQ for patients with schizophrenia

	FSSQ total	FSSQ confidant	FSSQ affective
Association with clinical and psychosocial variables	[<i>r</i> (<i>p</i> value)] (<i>n</i> = 241)		
GAF clinical	0.14 (<i>p</i> = 0.037)	0.10 (<i>p</i> = 0.144)	0.11 (<i>p</i> = 0.080)
GAF social	0.14 (<i>p</i> = 0.032)	0.14 (<i>p</i> = 0.027)	0.10 (<i>p</i> = 0.132)
PANSS positive	-0.09 (<i>p</i> = 0.147)	-0.03 (<i>p</i> = 0.684)	-0.11 (<i>p</i> = 0.101)
PANSS negative	0.06 (<i>p</i> = 0.327)	0.03 (<i>p</i> = 0.679)	0.13 (<i>p</i> = 0.048)
PANSS general	-0.07 (<i>p</i> = 0.293)	-0.05 (<i>p</i> = 0.426)	-0.02 (<i>p</i> = 0.752)
PANSS total	-0.05 (<i>p</i> = 0.486)	-0.03 (<i>p</i> = 0.664)	0.00 (<i>p</i> = 0.975)
DAS-s	-0.36 (<i>p</i> < 0.001)	-0.32 (<i>p</i> < 0.001)	-0.31 (<i>p</i> < 0.001)
WHOQOL-BREF physical	0.35 (<i>p</i> < 0.001)	0.34 (<i>p</i> < 0.001)	0.25 (<i>p</i> < 0.001)
WHOQOL-BREF psychological	0.35 (<i>p</i> < 0.001)	0.34 (<i>p</i> < 0.001)	0.29 (<i>p</i> < 0.001)
WHOQOL-BREF social relations	0.55 (<i>p</i> < 0.001)	0.53 (<i>p</i> < 0.001)	0.41 (<i>p</i> < 0.001)
WHOQOL-BREF environment	0.51 (<i>p</i> < 0.001)	0.49 (<i>p</i> < 0.001)	0.40 (<i>p</i> < 0.001)
WHOQOL-BREF total	0.52 (<i>p</i> < 0.001)	0.50 (<i>p</i> < 0.001)	0.42 (<i>p</i> < 0.001)
Group differences	[<i>t</i> test; <i>p</i> value] (<i>n</i> = 241)		
≤42 years old vs. >42 years old	1.24; <i>p</i> = 0.218	1.42; <i>p</i> = 0.158	1.18; <i>p</i> = 0.239
Female vs. male	0.16; <i>p</i> = 0.875	1.00; <i>p</i> = 0.316	-0.04; <i>p</i> = 0.971
≤10 years illness duration vs. >10 years illness duration	-1.41; <i>p</i> = 0.162	-1.62; <i>p</i> = 0.108	-1.21; <i>p</i> = 0.230
Educational level ≤ primary school vs. educational level > primary school	-1.41; <i>p</i> = 0.161	-1.57; <i>p</i> = 0.118	-1.04; <i>p</i> = 0.300
Employment status active vs. employment status non active	0.26; <i>p</i> = 0.799	0.33; <i>p</i> = 0.741	-0.17; <i>p</i> = 0.868
Diagnosis of paranoid schizophrenia vs. diagnosis of other schizophrenias	1.19; <i>p</i> = 0.234	1.21; <i>p</i> = 0.230	0.97; <i>p</i> = 0.331
Living in a housing owned by family vs. not living in a housing owned by family	1.29; <i>p</i> = 0.198	0.20; <i>p</i> = 0.840	2.34; <i>p</i> = 0.020
Single vs. married or cohabiting vs. divorced or separated or widowed [F (<i>p</i> value)]	0.83; <i>p</i> = 0.438	1.13; <i>p</i> = 0.325	0.55; <i>p</i> = 0.581
Depressed vs. non depressed (PANSS general item 6 ≥ 4 vs. item 6 < 4)	0.31; <i>p</i> = 0.754	0.33; <i>p</i> = 0.746	0.42; <i>p</i> = 0.673
Anxious vs. no anxious (PANSS general: item 2 ≥ 4 vs. item 2 < 4)	-0.97; <i>p</i> = 0.336	-0.13; <i>p</i> = 0.897	-1.17; <i>p</i> = 0.249
Somatic complaint vs. no somatic complaint (PANSS general: item 1 ≥ 4 vs. item 1 < 4)	2.88; <i>p</i> = 0.004	2.46; <i>p</i> = 0.015	1.86; <i>p</i> = 0.064
Disabled vs. non disabled (DAS-s ≥ 4 vs. DAS-s < 4)	4.78; <i>p</i> < 0.001	4.47; <i>p</i> < 0.001	4.39; <i>p</i> < 0.001
Use of general practitioner services vs. no use of general practitioner services ^Y	0.41; <i>p</i> = 0.683	1.01; <i>p</i> = 0.316	0.36; <i>p</i> = 0.722
Use of primary care nurse services vs. no use of primary care nurse services ^Y	-0.13; <i>p</i> = 0.898	0.93; <i>p</i> = 0.356	-0.45; <i>p</i> = 0.657
Use of social services vs. no use of social services ^Y	0.33; <i>p</i> = 0.742	0.805; <i>p</i> = 0.422	-0.35; <i>p</i> = 0.731

FSSQ The modified DUKE-UNC Functional Social Support Questionnaire, GAF Global Assessment of Functioning, PANSS Positive and Negative Syndrome Scale, DAS-s The World Health Organization Short Disability Assessment Schedule, WHOQOL-BREF World Health Organization Quality of Life Brief Version

n sample size at baseline

^Y Time frame: patient visits during the year prior to the first assessment

between groups established according to socio-demographic variables. There were significant differences between groups of patients with schizophrenia based on levels of somatic complaints and levels of disability. In particular, patients with higher levels of somatic complaints scored significantly lower in FSSQ total (Mean = 31.96; SD = 8.99) than patient with lower levels of somatic complaints (FSSQ total: Mean = 37.42; SD = 9.15). The effect size was 0.18. Patients who were disabled scored significantly lower in FSSQ total (Mean = 31.69; SD = 9.80), FSSQ confidant (Mean = 14.32; SD = 5.39) and FSSQ

affective (Mean = 9.42; SD = 3.26) than patients non-disabled (FSSQ total: Mean = 38.50; SD = 8.46) (FSSQ confidant: Mean = 17.49; SD = 4.49) (FSSQ affective: Mean = 11.41; SD = 2.93). The effect sizes were 0.45 for FSSQ total, 0.40 for FSSQ confidant and 0.27 for FSSQ affective. No other differences were observed.

Changes over time

FSSQ scores remained about the same over time. There were statistically significant changes over time regarding

Table 4 Clinical and psychosocial variables and use of health services at baseline and at 1-year follow-up ($n = 219$)

Measure	Baseline		1 year follow-up		Differences over time		
	Mean	SD	Mean	SD	t	p	ES
FSSQ total social support	36.68	9.47	36.57	9.72	0.22	0.823	0.02
FSSQ confidant support	16.55	4.99	16.37	5.17	0.63	0.531	0.00
FSSQ affective support	10.90	3.14	10.78	3.22	0.68	0.500	0.00
PANSS positive	16.67	6.26	15.22	6.10	5.02	<0.001	0.32
PANSS negative	24.07	6.99	22.34	6.90	5.08	<0.001	0.33
PANSS general	42.35	12.73	39.22	12.30	5.30	<0.001	0.34
PANSS total	83.10	22.47	76.79	21.96	6.14	<0.001	0.38
GAF clinic	47.07	9.69	49.58	11.01	-4.94	<0.001	0.32
GAF social	44.29	10.00	46.26	10.36	-3.45	<0.001	0.23
DAS-s	9.09	4.46	8.59	4.46	2.37	0.018	0.16
WHOQOL-BREF physical health	13.25	2.42	13.27	2.54	-0.95	0.924	0.01
WHOQOL-BREF psychological health	12.18	2.86	12.19	2.81	-0.01	0.990	0.00
WHOQOL-BREF social relationships	10.54	3.26	10.50	3.24	0.23	0.816	0.02
WHOQOL-BREF environment	13.24	2.26	13.31	2.36	-0.51	0.612	0.04
WHOQOL-BREF general	81.82	13.94	81.95	14.11	-0.18	0.856	0.01
Community psychiatric visits ^Y	5.76	4.22	6.28	4.43	-1.75	0.082	0.12
Community nursing visits ^Y	5.92	7.13	8.38	9.03	-4.35	<0.001	0.28

FSSQ The modified DUKE-UNC Functional Social Support Questionnaire, *PANSS* Positive and Negative Syndrome Scale, *GAF* Global Assessment of Functioning, *DAS-s* The World Health Organization Short Disability Assessment Schedule, *WHOQOL-BREF* World Health Organization Quality of Life Scale Brief Version

SD standard deviation

^Y Time frame: patient visits during the year prior to the first assessment versus patient visits during the year after the first assessment

Table 5 Sensitivity to change of the FSSQ for patients with schizophrenia ($n = 219$)

	FSSQ total $r(p)$	FSSQ confidant $r(p)$	FSSQ affective $r(p)$
Sensitivity to change			
GAF clinical	0.08 ($p = 0.218$)	0.09 ($p = 0.168$)	0.04 ($p = 0.608$)
GAF social	0.09 ($p = 0.183$)	0.12 ($p = 0.066$)	0.02 ($p = 0.793$)
PANSS positive	-0.06 ($p = 0.364$)	-0.08 ($p = 0.250$)	0.05 ($p = 0.449$)
PANSS negative	-0.09 ($p = 0.187$)	-0.10 ($p = 0.140$)	-0.03 ($p = 0.654$)
PANSS general	-0.15 ($p = 0.024$)	-0.16 ($p = 0.019$)	0.01 ($p = 0.880$)
PANSS total	-0.13 ($p = 0.047$)	-0.15 ($p = 0.030$)	0.01 ($p = 0.880$)
DAS-s	-0.17 ($p = 0.015$)	-0.13 ($p = 0.050$)	-0.15 ($p = 0.028$)
WHOQOL-BREF physical	0.24 ($p < 0.001$)	0.25 ($p < 0.001$)	0.17 ($p = 0.014$)
WHOQOL-BREF psychological	0.27 ($p < 0.001$)	0.27 ($p < 0.001$)	0.21 ($p = 0.002$)
WHOQOL-BREF social relations	0.28 ($p < 0.001$)	0.31 ($p < 0.001$)	0.07 ($p = 0.299$)
WHOQOL-BREF environment	0.27 ($p < 0.001$)	0.26 ($p < 0.001$)	0.21 ($p = 0.002$)
WHOQOL-BREF total	0.36 ($p < 0.001$)	0.36 ($p < 0.001$)	0.25 ($p < 0.001$)
Community nursing visits ($n = 218$) ^Y	0.06 ($p = 0.363$)	-0.01 ($p = 0.922$)	0.10 ($p = 0.157$)
Community psychiatric visits ($n = 218$) ^Y	-0.10 ($p = 0.158$)	-0.09 ($p = 0.203$)	-0.12 ($p = 0.080$)

n sample size

FSSQ The modified DUKE-UNC Functional Social Support Questionnaire, *GAF* Global Assessment of Functioning, *PANSS* Positive and Negative Syndrome Scale, *DAS-s* The World Health Organization Short Disability Assessment Schedule, *WHOQOL-BREF* World Health Organization Quality of Life Brief Version

^Y Time frame: patient visits during the year after the first assessment versus patient visits during the year after the second assessment

all PANSS and GAF scores. There was a decrease in psychiatric symptoms as revealed by changes in PANSS scores over time and an improvement in overall functioning as shown by changes in GAF scores over time. Effect sizes were medium for most scores but small for GAF social scores. DAS-s scores decreased over time but not significantly and WHOQOL-BREF scores remained the same over time. With regard to use of health services, there were statistically significant changes over time in community nursing visits. Specifically, there was an increase in community nursing visits with a small effect size. No other statistically significant differences over time were observed (See Table 4).

Sensitivity to change

Firstly, score differences between baseline and 1-year follow-up were calculated for FSSQ scores, the other assessment instruments and community service visits. Secondly, Pearson's correlation coefficients between FSSQ score differences and all other score differences were calculated (see Table 5): Pearson's correlations between changes in FSSQ scores and changes in GAF were non-significant; Pearson's correlations between changes in FSSQ scores and changes in PANSS general and total scores were significant except for FSSQ affective scores; Pearson's correlations between changes in FSSQ scores and changes in DAS-s and WHOQOL-BREF scores were all significant; and Pearson's correlations between changes in FSSQ scores and community service visits were non-significant. Those coefficients ranged from -0.01 to 0.36 . In particular, correlations between the change in FSSQ and the change in GAF scores were positive and small; correlations between changes in FSSQ and changes in PANSS and DAS-s scores were mostly negative and small; correlations between changes in FSSQ and changes in WHOQOL-BREF scores were positive and ranged between small and moderate. As for use of health services, correlations were mostly negative and small.

Discussion

The aim of this study was to validate the FSSQ in patients with schizophrenia. The FSSQ showed suitable psychometric properties in this patient population.

The EFA of the FSSQ revealed the existence of two factors, Confidant Social Support and Affective Social Support, that gather information regarding the possibilities of counting on someone for communication and the possibilities of counting on someone for love, care and empathy, respectively. This factor structure is similar to that observed in other studies [5, 6, 13] in which items 6, 7,

8 and 10 load in the same factor 1, and item 5 loads in factor 2. Item 3 also loads in factor 2 in the studies conducted by De la Revilla Ahumada [13] and Bellón Saameño [5] and their results are consistent with ours. Items 1 and 11 loaded in factors 1 and 2, respectively [5, 13], while in our study it was the other way around. The differences regarding the loadings of items 1 and 11 across studies may be explained by differences in perceptions between patients with schizophrenia and other informants [37, 39, 43]. The loading of items 2, 4 and 9 in factor 2 is only consistent with the factor structure of de la Revilla Ahumada [13] which, in fact, is the most similar to that shown in the present study except for items 1 and 11. This could be related to similarities in the characteristics of the samples included. De la Revilla Ahumada [13] included patients from primary care services with a low socio-economical status, which might be similar to the status of patients included in our sample and the deprived socio-economic situation of patients with schizophrenia [22, 23].

Internal consistency values at baseline and at 1-year follow-up were excellent. With regard to FSSQ domains, the FSSQ confidant scores showed good internal consistency at baseline and excellent at 1-year follow-up. The FSSQ affective scores showed appropriate internal consistency values both at baseline and at 1-year follow-up. In the study validation of the FSSQ [6], the internal consistency value of the FSSQ affective score was 0.64 , which is very similar to that observed in the present study (i.e., 0.66 at baseline and 0.69 at 1-year follow-up). The internal consistency values for FSSQ confidant score were 0.83 at baseline and 0.86 at 1-year follow-up, which are similar to those observed in Bellón Saameño [5]. Even so, the factors of the FSSQ were formed by different items across studies so comparison should be made with precaution. The internal consistency values observed in this study for the total FSSQ score are also in agreement with the body of evidence regarding the psychometric properties of the FSSQ. De la Revilla Ahumada [13] and Bellón Saameño [5] showed internal consistency values for the total FSSQ score of 0.81 and 0.90 , respectively.

We expected to find that perceived social support had a positive relationship with functioning [12] and quality of life [34, 44], while the severity of symptoms [10, 36] and disability [9] would have a negative one. Those were the directional relationships observed. It is relevant to highlight that the correlation coefficients of perceived social support with those variables ranged between small and large, with disability and quality of life showing the largest coefficients. This might suggest that disability and quality of life are more closely related to perceived social support than psychiatric symptoms and global functioning. It should be also emphasised that psychiatric symptoms and functioning were assessed by clinicians, while perceived social support

and quality of life were self-rated. Again, it seems that the results may reflect differences between the perceptions made by patients with schizophrenia and other informants [37, 39, 43]. Therefore, the highest correlations might have been observed for those measures provided by the same informant as is shown in other studies [4].

Our results regarding differences in FSSQ scores between groups of patients with schizophrenia established according to socio-demographic variables are, in general terms, consistent with the results of the validation study of the FSSQ [6]. In this study, most of the socio-demographic variables included (i.e., gender, marital status, employment status, age, education and socio-economic status) did not show significant associations with FSSQ domains except for race, which was associated with confidant support, and living situation, which was associated with both FSSQ domains. We did not include race in our study since 100 % of the sample was Caucasian and the lack of association between employment and FSSQ domains could be explained by sample differences between our study and the study conducted by Broadhead [6]. While in our study the sample included outpatients with diagnosis of schizophrenia, the study conducted by Broadhead [6] included patients attending a family medical practice. Even so, McFarlane [28] showed that four out of five social support measures were not associated with employment status. McFarlane [28] also observed a similar trend for education, which is also consistent with our results.

There were significant differences between groups of patients with schizophrenia according to clinical and psychosocial variables. Patients who had higher levels of somatic complaints and patients who were disabled showed poorer levels of perceived social support in almost all FSSQ scores. Bellón Saameño [5] also showed similar associations between perceived social support and psychosomatic symptoms and Cechnicki [9] between the former and disability. As for psychiatric symptoms, a body of evidence supports negative associations between perceived social support and psychiatric symptoms in general terms [10, 36]. This has only been observed to a certain extent in our study since depressed and anxious patients did not show lower levels of social support and only patients with somatic complaints scored lower in the overall measure of perceived social support. Group differences may not be wholly accurate since they were made according to cut-offs of single instrument items rather than through diagnostic interviews, which may explain our results. Broadhead [6] described lower levels of social support for patients with higher levels of health service use, but no association can be seen in the present study. Specifically, patients who used primary care services and social care services did not show lower levels of social support. This might be related to the fact that all patients received services from community

treatment programmes, which have been shown to decrease use of services in patients with severe mental illness [45].

At 1-year follow-up, as a consequence of the role of AMHC in the provision of care to patients with schizophrenia, we expected an increase in levels of social support, global functioning and quality of life and a decrease in levels of psychiatric symptoms and disability. There were only improvements in psychiatric symptoms and global functioning along with a rise of the frequency of visits to community psychiatric nurses. There was a decrease but non-significant in disability levels. We did not observe improvements regarding social support and quality of life as perceived by patients. The lack of changes in FSSQ scores at 1-year follow-up might be one of the reasons for the mainly small significant associations between changes in FSSQ scores from baseline to 1-year follow-up and changes in the rest of the test scores, and AMHC visits between baseline and 1-year follow-up. It is important to consider a range restriction phenomena in our results since the score variability was quite small. The above results might somehow reflect the need for more specific psychosocial interventions aimed at improving social support and quality of life [40].

The FSSQ has been considered for the assessment of patients with schizophrenia although it has yet to be validated. The present findings provide evidence regarding the psychometric properties of the FSSQ in patients with schizophrenia which supports its use in this patient population. It shows that the FSSQ scores are reliable and valid, and that the instrument could be used for the assessment of perceived social support in patients with schizophrenia for research or clinical practice purposes. Further studies should involve psychometric properties in other samples, such as other mental disorders, as well as other populations.

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Conflict of interest The authors declare no conflict of interest.

Appendix

The Working Group on Severe Mental Disorder is composed of the following members from Adult Mental Health Care Centres in Barcelona: M^a Antonia Argany, Francesca Asensio, Marta Berruezo, Carlos Blecua, Ignasi Bros, Ana Isabel Cerrillo, Ana del Cuerpo, Amparo Escudero, Judit Farré, Clara Fort, Marisa García, M^a Carmen González, Eva Leno, Lluís Mauri, Isabel Mitjà, Mónica Montoro,

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Annex 5

Study 5:

Mas-Expósito L, Amador-Campos JA, Gómez-Benito J and Lalucat-Jo L. Considering variables for the assignment of patients with schizophrenia to a case management programme. *Community Mental Health Journal*. 2012.

Considering variables for the assignment of patients with schizophrenia to a case management programme

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Introduction

Case Management (CM) has been described as the coordination, integration and allocation of individualised care within limited resources through the assignment of a key worker from a community mental health team (Thorncroft, 1991). It is widely considered to be a major component of the services provided to patients with severe mental illness (SMI) (Rubin, 1992).

Nowadays, it has been highlighted the importance of establishing the elements and the intensity of CM on the basis of patients' needs (Working Group of the Clinical Practice Guideline for Schizophrenia and Incipient Psychotic Disorder, 2011). For instance, the Flexible Assertive Community Treatment model (van Veldhuizen, 2007) has been developed in the Netherlands as an adaptation of CM. It is a rehabilitation-oriented clinical CM model that can operate individually or by means of a team approach depending on patient's needs.

Patients with schizophrenia differ in their level of needs as suggested by the existence of different profiles of those patients (Lora, Consentino, Rossini, & Lanzara, 2001; Lykouras, Oulis, Daskalopoulou, Psarros, & Christodoulou, 2001). Lykouras et al. (2001) found five profiles of patients with schizophrenia with regard to psychiatric symptoms, while Lora et al. (2001) found four profiles of patients with schizophrenia, considering disability, psychiatric symptoms, psychosocial measures and use of mental health services. The existence of different profiles of patients with schizophrenia show the need to tailor interventions according to those profiles especially for those persons with greater care needs (Lora et al., 2001), which is associated with the previous idea of considering CM practices according to patients' needs (Working Group of the Clinical Practice Guideline for Schizophrenia and Incipient Psychotic Disorder, 2011).

Taking into account all the above mentioned, it is important to improve the knowledge of the characteristics/needs of persons with schizophrenia receiving community-based interventions such as CM. This study deals with this issue by: 1) characterizing two groups of patients with schizophrenia receiving either CM or a standard treatment programme (STP) in Catalonia (Spain); and 2) identifying the socio-demographic, use of services, clinical and psychosocial characteristics of patients with schizophrenia associated with the provision of CM in the aforementioned setting. Our final aim is to help improve the knowledge of the needs of patients receiving CM in Catalonia, which might help to tailor services to those needs and, consequently, design and adapt CM services in such a setting. This is of relevance because there is country culture influence on CM practices (Burns, Fioritti, Holloway, Malm, & Rössler, 2001).

A CM programme model

During the Spanish political transition to democracy which began in 1975, a new model of mental health care was developed in Catalonia, one of Spain's autonomous regions. This new model involved a state mental health network within the national health system and structured into health-care sectors of approximately 100,000 inhabitants. This network is community-based and relies on community resources such as Adult Mental Health Centres (AMHCs), community rehabilitation centres and hospitals.

AMHCs offer specialised care for people suffering from mental health problems and are staffed by multidisciplinary teams that include psychiatrists, psychologists, nurses and social workers. AMHCs care for patients with SMIs through a STP, the key components of which are a general clinical and psychosocial assessment and medical interventions and follow-ups.

In 1997, the Catalan Health Department set up a new programme for the care of patients with SMI at risk of dropping out, clinical relapse and recurrent hospitalisation. This new

programme is based on the principles of clinical CM (Kanter, 1989), is non-intensive (Dieterich, Irving, Park, & Marshall, 2010) and includes as main elements (Ruggeri & Tansella, 2008): 1) assignment of a case manager (i.e. a community mental health nurse) to look at and organise the care of patient; 2) thorough assessment of needs at a medical and psychosocial level; 3) individualised therapy plans based on the patient's needs; and 4) regular checks and updating of therapy plans. The STP and the CM programme are alike in that they both include a psychiatrist as clinician in charge, and medical interventions and follow-ups (4-6 visits per year). However, the CM programme not only contains the elements described above, but also includes specific psychosocial interventions (i.e. psychoeducation, family therapy, assistance in daily living and crisis intervention) and nursing follow-ups (12 visits per year). All interventions provided by the STP or the CM programme adhere to the Clinical Practice Guidelines for Schizophrenia issued by the Spanish Ministry of Health and Consumer Affairs (Working Group for the Clinical Practice Guidelines for Schizophrenia and Incipient Psychotic Disorder, 2009).

Improving knowledge about both community treatment programmes is particularly important since this concerns the treatment of most long-term patients with schizophrenia in the Catalan Health System. Our study addresses this issue by characterizing the profiles of patients with schizophrenia according to treatment programme. Our aim is to test the working hypothesis that CM patients exhibit greater social and care needs and clinical and psychosocial disadvantages than STP patients. The issue is also addressed through more in-depth analysis of the socio-demographic, use of services, clinical and psychosocial characteristics of patients with schizophrenia associated with the provision of CM services in Catalonia (Spain). To our knowledge, no such studies have been conducted to date and, moreover, studies on CM in Spain

with large sample sizes have been few and far between and restricted to cost-effectiveness (Gutiérrez-Recacha, Chisholm, Haro Abad, Salvador-Carulla, & Ayuso-Mateos, 2006) and hospitalisation variables (Alonso Suárez, Bravo-Ortiz, Fernández-Liria, & González-Juárez, 2011). This study may help to enhance understanding of patient needs, tailor interventions to those needs and, consequently, design and adapt the CM programme.

Methods

This study has been conducted as part of a one-year, longitudinal, quasi-experimental study that aims to compare the effectiveness of the CM programme and the STP. The patients, instruments, procedures and data analysis are described below.

Patients

The sample was a group of 241 patients with schizophrenia from 10 AMHC in Barcelona (Catalonia, Spain) recruited between December 2006 and January 2008. Patients for the CM programme were consecutively selected among those in the STP who met the following inclusion criteria: 1) diagnosis of schizophrenia according to the International Classification of Diseases-10 or ICD-10 (World Health Organisation, 1995); 2) Global Assessment of Functioning or GAF \leq 50 (Endicott, 1976); 3) duration of illness greater than 2 years; and 4) clinical stability at time of assessment. It is worth highlighting that the three first inclusion criteria are based on the National Institute of Mental Health (NIMH, 1978) criteria for SMI operationalized by Ruggeri, Leese, Thornicroft, Bisoffi, and Tansella (2000). Clinical stability was defined as the patient condition that allows to treat her or him in an outpatient setting as that in our study. Patients were excluded if they had dementia, organic brain injury or mental retardation. Patients in the STP were selected from the AMHC databases by intentional non-probabilistic sampling among all patients in the STP who could be matched with

patients in the CM programme according to the following criteria: gender; diagnosis; age (+/- 5 years); dysfunction (GAF score, +/- 10 points); and duration of illness (+/- 5 years). Socio-demographic characteristics of patients according to each treatment programme are described in Table 1.

INSERT TABLE 1 ABOUT HERE

Instruments

The following instruments were used in the study for the assessment of patients:

The Schizophrenia Cost Evaluation Questionnaire (Haro, Salvador-Carulla, Cabases, Madoz, & Vázquez-Barquero, 1998) based on the Client Socio-Demographic and Services Receipt Inventory (Beecham, 1994). This instrument assesses use of healthcare and social services and its indirect costs.

The GAF (Endicott, 1976). This is a reliable and valid measure of global psychological functioning in patients with SMI that was included in the Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (American Psychiatric Association, 1994).

The Positive and Negative Syndrome Scale or PANSS (Kay, Fiszbein, & Opler, 1987). This instrument is used for assessing symptom severity in patients with schizophrenia and it has been translated into and validated in Spanish (Peralta & Cuesta, 1994). Internal consistency values of its subscales range between medium and high and its convergent validity with other measures of psychiatric symptoms were high and range from 0.70 to 0.81 (Peralta & Cuesta, 1994).

The Disability Assessment Schedule, short form or DAS-s (Janca et al., 1996). This is a seven-item scale developed by the World Health Organisation and is a valid and reliable measure of global functioning in patients with mental disorders included in the ICD-10 (World Health Organisation, 1995). It has been validated in patients with schizophrenia (Mas-Expósito, Amador-Campos, Gómez-Benito, & Lalucat-Jo, 2011a).

The World Health Organisation Quality of Life Scale Brief Version or WHOQOL-BREF (World Health Organisation, 1993). This is a short version of the World Health Organisation Quality of Life Scale or WHOQOL-100, which is considered an international cross-culturally analogous quality of life evaluation tool (World Health Organisation, 1998). Internal consistency values ranged from 0.66 to 0.84; and correlations with the WHOQOL-100 subscales ranged from 0.89 to 0.95 (World Health Organisation, 1998). Skevington, Lotfy, and O'Connell (2004) confirmed and extended information about its properties and showed good-to-excellent psychometric properties. There is a Spanish version (Lucas, 1998) that shows good psychometric properties in patients with schizophrenia (Mas-Expósito, Amador-Campos, Gómez-Benito, & Lalucat-Jo, 2011b).

The Functional Social Support Questionnaire or FSSQ (Broadhead, Gelbach, Degruy, & Kaplan, 1988). This is an eight-item questionnaire that measures the strength of the patients' social network. It has also been translated into and validated in Spanish (Bellón Saameño, Delgado Sánchez, de Dios Luna del Castillo, & Lardelli Claret, 1996) and the reliability indexes are of 0.80 and of 0.92 for hetero-report and self-report, respectively. Concurrent validity with other health measures ranged in absolute values from 0.13 to 0.81 (Bellón Saameño et al., 1996).

Camberwell Assessment of Needs or CAN (Phelan, Slade, & Thornicroft, 1999). It is an assessment tool to measure the psychosocial needs of people suffering from mental illness. Inter-rater and test-retest correlations of the total number of needs recognised by staff were 0.99 and 0.78, respectively. The percentage of agreement on individual items ranged from 81.6-100% (inter-rater) and 58.1-100% (test-retest) (Phelan et al., 1999). It is translated into and validated in Spanish (Jiménez-Estévez, Moreno-Kustner, & Torres-González, 1997). In a Spanish sample of patients with schizophrenia, the inter-

rater correlations were high for either clinicians (0.99) or patients (0.98); test-retest correlations were high for clinicians (0.79) and patients (0.77) (Rosales, Torres, Del Castillo, Jiménez, & Martínez, 2002).

Procedures

The procedures and assessments were described to each patient and informed consent was obtained. The AMHC multidisciplinary teams performed the patient assessments. For both the CM group and the STP group, the diagnosis was established by the psychiatrists by means of a non-structured interview following the ICD-10 (World Health Organisation, 1995) research diagnosis criteria and considered self-reports and caregiver reports. The psychiatrist also carried out the assessment of psychiatric symptoms, while the remaining assessments were performed by the other members of the AMHC multidisciplinary team under the psychiatrist's supervision or by an assigned community psychiatric nurse from the AMHC multidisciplinary team in the STP. The psychiatrist was responsible for setting up the assessment agenda, supervising its development and sending the score sheets to the psychologist in charge of the design and analysis of the study database.

To ensure the quality of assessment data, all psychiatrists participated in a schizophrenia diagnostic agreement workshop comprising two case vignettes. All researchers were trained in the administration of the instruments in a 4-hour session run by a psychologist with experience in psychological assessment of psychiatric patients. Systematic reviews of data coding and registration were taken and patient information was contrasted with data from the AMHC responsible for each patient.

Data analysis

To test differences between groups, Chi-square analysis for categorical variables and independent samples Student's *t* test for continuous variables were used and the effect

size was calculated (Field, 2005). Block-entry logistic regression was used to determine the patients' characteristics associated with the provision of CM services. Programme allocation (i.e. CM or STP) was introduced as the dependent variable. Variables with significant between-group differences, except for program inclusion criteria, were included in the logistic regression model and their contribution to the model was assessed. The variables introduced were: educational level, social services visits, community psychiatric nursing visits, positive psychiatric symptoms (PANSS positive), total psychiatric symptoms (PANSS total), disability (DAS-s), physical health (WHOQOL-BREF physical health) and psychosocial needs from the clinicians' point of view (CAN total needs). Since educational level was a categorical variable with more than two categories, it was necessary to recode it into the following dummy variables: no education, primary education, secondary education and higher education. P values < 0.05 were considered significant. Data was analysed using the Statistical Package for the Social Sciences (SPSS) v.18.

Ethic Aspects

The study was approved by the Ethics Committee of the Fundació Unió Catalana d'Hospitals and was conducted in accordance with the ethical standards of the 1964 Declaration of Helsinki. The authors declare that they have no conflict of interest and they certify their responsibility for the manuscript.

Results

Table 1 shows the results for socio-demographic variables. There were statistically significant between-group differences, with small effect sizes, in educational level. Patients in the CM program had lower educational level than patients in the STP. No other statistically significant differences were found in socio-demographic variables.

Table 2 shows the results for variables regarding health-service use during the previous year. There were statistically significant between-group differences in the use of emergency services, community psychiatric nursing services and social services with medium effect sizes. Patients in the CM program made higher use of the above-mentioned services than patients in the STP. No other statistically significant differences were observed.

INSERT TABLE 2 ABOUT HERE

Table 3 shows the results for clinical and psychosocial variables. There were statistically significant between-group differences in positive (PANSS positive) and total psychiatric symptoms (PANSS total), disability (DAS-s), quality of life related to physical health (WHOQOL-BREF physical health), overall quality of life (WHOQOL-BREF general) and psychosocial needs from the clinicians' point of view (CAN total needs). The effect size was small for all variables. CM patients had higher levels of positive and total psychiatric symptoms, disability and needs; whilst they showed lower quality of life related to physical health and overall quality of life than patients in the STP. There were no other statistically significant differences between groups. However, there was a tendency to significance in negative psychiatric symptoms (PANSS negative) and general psychiatric symptoms (PANSS general).

There were statistically significant between-group differences in clinical functioning (GAF clinical) and social functioning (GAF social). CM patients showed lower clinical ($M=43.82$, $SD=8.73$) and social functioning ($M=40.95$, $SD=8.57$) than patients in the STP (clinical functioning: $M=50.02$, $SD=10.06$; social functioning: $M=47.62$, $SD=10.27$). The effect size was medium (GAF clinical: $r=0.31$; GAF social: $r=0.34$). Those differences may be related to the assignment of patients to the intervention

programmes. The STP group patients were matched to CM patients considering a range of GAF scores of +/- 10 points.

INSERT TABLE 3 ABOUT HERE

Table 4 shows the patients' variables significantly associated with the provision of CM services. Community psychiatric nursing visits, social services visits, educational level (i.e. higher vs. secondary), quality of life related to physical health (WHOQOL-BREF physical health), psychosocial needs from the clinicians' point of view (CAN total needs) and positive psychiatric symptoms (PANSS positive) were significantly associated with the provision of CM services. The following variables were not significantly associated with the provision of CM services: emergency visits (B=0.222, B.SE=0.192, Wald statistic=1.347, d.f.=1, p=0.246); total psychiatric symptoms (PANSS total; B=-0.003, B.SE=0.013, Wald statistic=0.059, d.f.=1, p=0.808); disability (DAS-s; B=-0.031, B.SE=0.047, Wald statistic=0.451, d.f.=1, p=0.502); and overall quality of life (WHOQOL-BREF general; B=0.020, B.SE=0.021, Wald statistic=0.913, d.f.=1, p=0.339).

INSERT TABLE 4 ABOUT HERE

Discussion

The aim of this work was two-fold: 1) characterize the two group of patients with schizophrenia according to treatment programme (i.e. CM programme and STP); and 2) identify the patients' characteristics associated with the provision of CM practices in Catalonia (Spain). This may help have further knowledge of patients' needs and thus design and adapt the CM programme for patients with long-term schizophrenia running in the aforementioned setting.

Patients included in the CM programme and the STP showed distinctive profiles as shown by differences between both groups. Patients in the CM programme had lower

educational level and used emergency services, community psychiatric nursing services and social services more frequently. Also, these patients had higher levels of positive psychiatric symptoms, total psychiatric symptoms, psychosocial needs and disability, while they had poorer levels of quality of life related to physical health and overall quality of life. As expected, patients in CM services were found to have greater social and care needs, and higher clinical and psychosocial disadvantages than patients in the STP. With regard to our second objective, the patients' characteristics significantly associated with the provision of CM practices in Catalonia were use of community psychiatric nursing services, use of social services, educational level, quality of life related to physical health, psychosocial needs and positive psychiatric symptoms.

Our results are consistent with the available literature about the existence of different profiles of patients with schizophrenia (Lykouras et al., 2001; Lora et al., 2001) and the need to tailor interventions according to those profiles especially for those persons with greater needs (Lora et al., 2001). Patients receiving more intensive and comprehensive services (i.e. CM services) appear to have higher social, care, clinical and psychosocial needs. Also, our results provide a better understanding of the needs of patients with schizophrenia receiving CM services in that setting, which may help to tailor CM practices into patients' needs. Taking into account patients' needs, the CM programme may consider other interventions besides those described in the introduction. Cognitive behaviour therapy may be considered to decrease positive psychiatric symptoms (Wykes, Steel, Everitt, & Tarrier, 2008); while strategies that target patients' social cognition may help to promote community functioning (Harvey & Penn, 2010) and strategies aimed at improving patients' physical health (Acil, Dogan, & Dogan, 2008; Sáiz Ruiz, Bobes García, Vallejo Ruiloba, Giner Ubago, & García-Portilla González, 2008; Saravane et al., 2009) may decrease physical morbidity and mortality (Sáiz Ruiz

et al., 2008). Physical activities to cope with cardio-metabolic risk factors (Vancampfort, Sweers, Probst, Mitchell, Knapen, & De Hert, 2011) or physical health in general terms (Van Citters et al., 2010) may be introduced into the CM programme by mental health nurses, who have the knowledge and expertise in this type of intervention and are the patients' key workers. We suggest a reconfiguration of the CM programme taking into account patients' needs. If so, a study about its efficacy/effectiveness should be conducted by comparing outcomes in a group of patients with schizophrenia receiving the reconfigured CM programme with outcomes in a group of patients with schizophrenia receiving the original CM programme.

In addition, our findings highlight other variables, besides those stated by NIMH (1987), which may be considered in the definition of SMI in the Catalan Health Service. It is worth noting that there is no consensus on the definition of SMI (Parabiaghi, Bonetto, Ruggeri, Lasalvia, & Leese, 2006; Slade, Powell, & Strathdee, 1997) as seen in the inclusion criteria program of studies on the efficacy of CM for persons with SMI (Bond, McGrew, & Fekete, 1995; Burns, Catty, Dash, Roberts, Lockwood, & Marshall, 2007; Dieterich et al., 2010; Gorey, Leslie, Morris, Carruthers, John, & Chacko, 1998; Herdelin & Scott, 1999; Marshall, Gray, Lockwood, & Green, 2000; Marshall & Lockwood, 2000; Ziguras & Stuart, 2000). Therefore, some authors (Ruggeri et al., 2000; Parabiaghi et al., 2006) have operationalized it considering the NIMH definition (1987) and mental disorders and psychotic disorders in general terms. Our study goes beyond the NIMH (1987) definition and is exclusively based on patients with schizophrenia. This study may help to provide a context for improving the definition of SMI at a regional level but, in view of the fact that the outcomes used are common to clinical practice and research, our results may also be easily replicated at other levels.

One of the limitations of our study is that we did not use a structured interview to establish patient psychiatric diagnosis. Although this might affect the reliability of diagnoses, they were conducted by experienced research psychiatrists and following the research criteria diagnosis established by the ICD-10 (World Health Organisation, 1995) as well as considered self-reports and caregiver reports. Another limitation is the fact that patients' assessments were not conducted by independent assessors, which might have biased the results. Even so, the consistency of our results with the literature gives some confidence that assessor bias did not affect outcomes. In addition, it is worth noting that patients in the STP were matched to patients in the CM group considering a range of GAF scores of +/- 10 points. The results show lower GAF scores in the CM group than in the STP group, which may be related to the aforementioned matching process. Since GAF scores are determined by social functioning but also psychiatric symptoms it was not unexpected that PANSS positive and total scores were higher in the CM group than in the STP group. Even so, only PANSS positive scores were significantly associated with the provision of CM services. The PANSS may be more specific than the GAF when assessing psychiatric symptoms since it takes into account the type of symptoms as well as its severity.

Further research may consider a shorter GAF range when matching programmes groups and include more specific and objective measures regarding physical health. Physical health was measured indirectly through an instrument that measures health-related quality of life and is rated by patients. Case managers in the study were community psychiatric nurses with high knowledge and high expertise on the field. Even so, the nature and level of expertise of case managers varies widely between settings. Additional studies may take into account case managers' variables and see how they may affect outcomes. It has been shown that there is a relationship between case

managers' expectations and employment in patients with schizophrenia (O'Connell & Stein, 2011).

In sum, the characterization of patients with schizophrenia according to treatment programme and the knowledge of patients' characteristics associated with the provision CM practices in the Catalan Health Service (Spain) may be important in identifying patients' needs and, consequently, designing and adapting the CM programme.

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Table 1. Socio-demographic variables according to treatment programme

Socio-demographic variables	CM (n=119)		STP (n=122)		Intergroup differences		
	f (%)	f (%)	f (%)	f (%)	χ^2	df	p r
Male	80 (67.2)	83 (68.0)	.018	1	.894		
Marital status			3.254	2	.196		
Single	90 (75.6)	91 (74.6)					
Married or long-term partner	12 (10.1)	20 (16.4)					
Separated, divorced or widowed	17 (14.3)	11 (9.0)					
Educational level			9.890	3	.020	.203	CM ↓
No education	14 (11.8)	11 (9.0)					
Primary education	37 (31.1)	51 (41.8)					
Secondary education	56 (47.1)	37 (30.3)					
Higher education	12 (10.1)	23 (18.9)					
ICD-10 code schizophrenia diagnosis			2.983	3	.394		
F20.0	81 (68.1)	89 (73)					
F20.3	11 (9.2)	15 (12.3)					
F20.5	14 (11.8)	8 (6.6)					
Other codes	13 (10.8)	10 (8.2)					
Living arrangement			3.566	5	.613		
Alone	24 (20.2)	18 (14.8)					
With son/daughter or son/daughter and partner	8 (6.7)	10 (8.2)					
With partner	9 (7.6)	14 (11.5)					
With parents	59 (49.6)	65 (50.8)					
With other relatives	8 (6.7)	11 (9.0)					
With other persons or in an institution	11 (9.2)	7 (5.7)					
Accommodation type			5.637	2	.060		
Family property	74 (62.2)	92 (75.4)					
Rented	32 (26.9)	24 (19.7)					
Hostel, supported sheltered accommodation, therapeutic community, homeless or other	13 (10.9)	6 (4.9)					

Employment status	8.086	6	.232
Employed or self-employed	5 (4.2)	16 (13.1)	
Student, volunteer or supported employment	7 (5.9)	10 (8.2)	
Unemployed or on sick leave	7 (5.9)	9 (7.4)	
House work	8 (6.7)	7 (5.7)	
Retired	12 (10.1)	8 (6.6)	
Never worked	10 (8.4)	7 (5.7)	
Incapacitated	70 (58.8)	65 (53.3)	

Employment attitude	8.439	5	.134
Patient feels cannot work	58 (48.7)	51 (41.8)	
Patient feels cannot do his/her usual work	8 (6.7)	6 (4.9)	
Patient does not want to work	8 (6.7)	6 (4.9)	
Patient wants to work but cannot find a job	18 (15.1)	12 (9.8)	
Patients works	9 (7.6)	9 (7.6)	
Other	18 (15.1)	21 (17.2)	

	Mean (SD)	Mean (SD)	t	p
Age	41.66 (11.67)	41.77 (11.58)	-.077	.939
Illness duration	2.65 (.65)	2.61 (.68)	.489	.635

CM: Case Management; STP: Standard Treatment Programme

f: frequency; %: percentage; df: degrees of freedom; r: effect size; SD: standard deviation; †: higher frequencies in the CM programme group; ‡: lower frequencies in the CM programme group

Table 2. Service-use variables during the previous year according to treatment programme

Service type	CM (n=119)		STP (n=122)		Intergroup differences		
	Mean (SD)		Mean (SD)		t	p	r
General hospital services							
Acute psychiatric unit (days)	5.67 (13.14)		4.18 (13.76)		.860	.390	
Acute psychiatric unit (admissions)	.50 (1.94)		.18 (.45)		1.727	.087	
Crisis unit (days)	.17 (1.83)		.01 (.09)		.962	.337	
Crisis unit (admissions)	.01 (.09)		.01 (.09)		.018	.986	
Sub-acute unit (days)	3.65 (17.98)		4.36 (29.02)		-.229	.819	
Sub-acute unit (admissions)	.05 (.22)		2.25 (24.44)		-.980	.328	
Psychiatric high-dependency/medium-long stay unit (days)	0		0		-	-	
Psychiatric high-dependency/medium-long stay units (admissions)	0		0		-	-	
General hospital unit (days)	.07 (0.47)		0		1.579	.117	
General hospital unit (admissions)	.03 (0.22)		0		1.645	.103	
Outpatient psychiatric hospital services							
External hospital visits	.82 (4.35)		.11 (.76)		1.731	.086	
Crisis unit visits	.07 (.48)		.03 (.36)		.628	.531	
Emergency service visits	.66 (1.98)		.16 (.57)		2.656	.009	.228 CM ↑
Day Hospital visits	3.48 (19.55)		3.32 (29.83)		.044	.965	
Community services							
Community psychiatry visits	6.18 (3.67)		5.47 (4.88)		1.273	.204	
Community psychology visits	.98 (3.19)		1.08 (4.64)		-.192	.848	
Community psychiatric nursing visits	7.58 (7.62)		3.96 (5.87)		4.127	<.001	.221 CM ↑
Community social work visits	2.43 (3.39)		1.74 (3.05)		1.666	.097	
Community day centre services visits	44.61 (112.92)		29.98 (94.57)		1.092	.276	
	f (%)		f (%)		χ²	df	p
Community services							
Specialised rehabilitation services	21 (17.6)		12 (9.8)		3.110	1	.093
Protected vocational workshops	8 (6.7)		8 (6.6)		.003	1	.959
Educational or vocational or leisure services	20 (16.8)		23 (18.9)		.172	1	.678
Social services	19 (16.0)		3 (2.5)		13.249	1	<.001
Primary care centre	46 (38.7)		52 (42.6)		.393	1	.531

Emergency phone calls	14 (11.8)	8 (6.6)	1.969	1	.161
Primary care services					
General practitioner	78 (65.5)	78 (63.9)	.069	1	.973
Primary care nursing	30 (25.2)	38 (31.1)	1.049	1	.306

CM: Case Management; STP: Standard Treatment Programme
SD: standard deviation; r: effect size; f: frequency; %: percentage; df: degrees of freedom; †: higher scores or frequencies in the CM programme group

Table 3. Clinical and psychosocial variables according to treatment programme

Assessment Scales	CM (n=119)	STP (n=122)	Intergroup differences		
	Mean (SD)	Mean (SD)	t	p	r
PANSS ¹ positive	17.90 (6.65)	15.80 (6.10)	2.561	.011	.163 CM ↑
PANSS negative	25.01 (6.87)	23.34 (7.16)	1.840	.067	
PANSS general	44.04 (12.66)	40.89 (12.62)	1.934	.054	
PANSS total	86.95 (22.47)	80.03 (22.43)	2.391	.018	.152 CM ↑
DAS-s ²	9.93 (4.42)	8.37 (4.40)	2.752	.006	.175 CM ↑
WHOQOL-BREF ³ physical health	12.84 (2.41)	13.61 (2.36)	-2.522	.012	.161 CM ↓
WHOQOL-BREF psychological health	11.86 (2.97)	12.47 (2.59)	-1.695	.091	
WHOQOL-BREF social relationships	10.24 (3.44)	10.93 (2.99)	-1.658	.099	
WHOQOL-BREF environment	13.06 (2.36)	13.37 (2.05)	-1.065	.288	
WHOQOL-BREF general	79.73 (14.39)	83.66 (12.53)	-2.260	.025	.145 CM ↓
FSSQ ⁴ social support	36.17 (9.86)	37.47 (8.64)	-1.089	.277	
FSSQ confidant support	16.42 (5.14)	16.99 (4.67)	-.902	.368	
FSSQ affective support	10.72 (3.12)	11.12 (3.14)	-.972	.332	
CAN ⁵ total needs	8.80 (4.01)	7.08 (3.44)	3.446	.001	.225 CM ↑

CM: Case Management; STP: Standard Treatment Programme

1. PANSS: Positive and Negative Syndrome Scale; 2. DAS-s: Disability Assessment Schedule Short Form; 3. WHOQOL-BREF: World Health Organisation Quality of Life Scale Brief Version; 4. FSSQ: Functional Social Support Questionnaire; 5. CAN: Camberwell Assessment of Needs

SD: standard deviation; r: effect size; ↑: higher scores in the CM programme group; ↓: lower scores in the CM programme group

Table 4. Variables that better classify patient assignment to case management

Included	B (SE)	p	95% CI for Exp (B)		
			Lower	Exp B	Upper
Constant	0.725(1.622)	0.665		2.065	
Educational level					
Higher vs. no education	0.564(0.664)	0.396	0.478	1.757	6.458
Higher vs. primary	0.360(0.485)	0.458	0.554	1.434	3.708
Higher vs. secondary	1.318(0.483)	0.006	1.449	3.735	9.628
Positive psychiatric symptoms (PANSS positive)	0.081(0.045)	0.074	0.992	1.085	1.185
Physical health					
(WHOQOL-BREF, physical health)	-0.238(0.113)	0.035	0.632	0.789	0.984
Needs from the clinicians' point of view (CAN needs)	0.107(0.055)	0.050	1.000	1.113	1.238
Community nursing visits	0.096(0.027)	0.000	1.045	1.1045	1.160
Social services visits	-2.316(0.741)	0.002	0.023	0.099	0.421

Note: $R^2 = .211$ (Hosmer & Lemeshow).

CI: Confidence Interval; Exp B: Exponentiation of the Beta coefficient; B: Beta coefficient; SE: Standard Error

WHOQOL-BREF: World Health Organisation Quality of Life Scale Brief Version; CAN: Camberwell Assessment of Needs

Annex 6

Study 6:

Mas-Expósito L, Amador-Campos JA, Gómez-Benito J and Lalucat-Jo L. Clinical case management for patients with schizophrenia with high care needs. *International Journal of Clinical and Health Psychology*. 2012.

Clinical case management for patients with schizophrenia with high care needs

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Clinical case management for patients with schizophrenia and high care needs

Abstract

The aim of this quasi-experimental study is to establish the effectiveness of a clinical case management (CM) programme compared to a standard treatment programme (STP) in schizophrenic patients. Patients for the CM programme were consecutively selected among patients in the STP with schizophrenia who had poorer functioning. Seventy-five patients were admitted to the CM programme and were matched to 75 patients in the STP regarding age, diagnosis, gender, duration of illness and psychiatric symptoms. Patients were evaluated at baseline and at one year follow-up. At baseline, the patients in the CM programme showed poorer clinical and psychosocial functioning and more care needs than patients in the STP. After the follow-up, both treatment programmes were effective in maintaining contact with services and the CM group improved, achieving a similar level to that of the STP group at baseline, regarding most outcomes. This study shows the effectiveness of two community treatment programmes that may be offered consecutively since they seem to match different levels of clinical, psychosocial functioning and care needs of patients with schizophrenia.

Key words. Case management. Severe mental disorder. Schizophrenia. Quasi-experiment

Gestión de clínica casos para pacientes con esquizofrenia y muchas necesidades asistenciales

Resumen

El objetivo de este estudio cuasi-experimental es establecer la efectividad de un programa de gestión clínica de casos (GCC) en comparación con un programa de tratamiento estándar (PTE) en pacientes esquizofrénicos. Los pacientes del programa de

GC fueron seleccionados consecutivamente entre los pacientes del PTE con peor funcionamiento. Setenta y cinco pacientes fueron admitidos en el programa de GCC y fueron emparejados con 75 pacientes del PTE en relación a edad, diagnóstico, sexo, duración del trastorno y síntomas. Los pacientes se evaluaron en el momento basal y al año de seguimiento. En el momento basal, el grupo de GCC mostró peor funcionamiento clínico y psicosocial y mayores necesidades asistenciales. Al año, ambos programas fueron efectivos en mantener los contactos con los servicios y el grupo de GCC mejoró, alcanzando un nivel similar al del grupo de PTE en el momento basal, en la mayoría de resultados. Este estudio muestra la efectividad de dos programas de tratamiento comunitario, que podrían ofrecerse de forma consecutiva, ya que responden a niveles diferentes de funcionamiento clínico, psicosocial y de necesidades asistenciales de pacientes con esquizofrenia.

Palabras clave. Gestión de casos. Trastorno mental grave. Esquizofrenia. Cuasi-experimento

Clinical case management for patients with schizophrenia with high care needs

Case Management (CM) is one of the main components of the services for severe mental disorders (SMDs). Although CM was initially defined as a way of coordinating resources for a patient, nowadays, case manager activities are broader and usually include the direct provision of services (Mueser, Bond, Drake, and Resnick, 1998).

CM is successful in community-based models (Marshall, Gray, Lockwood, and Green, 2000; Mueser *et al.*, 1998; Van Os, 2009; Ziguras and Stuart, 2000). Its effects have been positively associated with patients' needs (Burns, 2008) and the need to develop CM approximations according to those needs has been stressed (Alonso Suárez, Bravo-Ortiz, Fernández-Liria, and González-Juárez, 2011).

In Spain, where mental health care is community-based, CM has proven to be cost-effective in decreasing the burden of schizophrenia (Gutiérrez-Recacha, Chisholm, Haro Abad, Salvador-Carulla, and Ayuso-Mateos, 2006) and use of services (Alonso Suárez *et al.*, 2011), and protocols tailoring CM to patients' needs are being developed (Alonso Suárez *et al.*, 2011).

In Catalonia, a Spanish autonomous community, a new model of mental health care was developed during the transition to democracy. It led to a public mental health network integrated into the national health system, organised into health care sectors and based on Adult Mental Health Centres (AMHCs) and hospitals and community rehabilitation centres.

AMHCs consist of multidisciplinary teams (psychiatrists, psychologists, nurses and social workers) that offer outpatient and specialist care for mental disorders through programmes and interventions included in their care services. Since their establishment, AMHCs offer care to patients with SMDs through a Standard Treatment Program (STP)

that includes: 1) general clinical and psychosocial assessments; and 2) medical interventions and follow-ups.

In 1997, the Health Department of Catalonia developed a specific type of CM programme for patients with SMDs that requires a higher level of care and other resources in addition to those in the STP. Its elements are those described by Ruggeri and Tansella (2008) and it meets the criteria of a clinical CM model by offering direct provision of care, and of a non-intensive CM programme since the caseload size is over 20 patients (Dieterich, Irving, Park, and Marshall, 2010). Table 1 shows a comparison of the STP and the CM programme. All interventions in both programmes follow the Clinical Practice Guideline for Schizophrenia (Working group of the clinical practice guideline for schizophrenia and incipient psychotic disorder, 2009).

Insert here Table 1

Studies on the effects of CM in Spain are scarce, have been conducted without control groups and are restricted to specific outcomes (Alonso Suárez *et al.*, 2011; Gutiérrez-Recacha *et al.*, 2006). Moreover, no studies on the effects of the Spanish protocols that tailor CM interventions to patients' needs have been conducted. This paper deals with these issues by establishing the effectiveness of a clinical CM programme versus a STP regarding clinical, psychosocial and service use variables.

Method

A quasi-experimental study, pre-post, two groups, one quasi-control, was used (Montero and León, 2007). This paper has been elaborated following the guidelines established by Ramos-Álvarez and Moreno-Fernández (2008), and Hartley (2012).

Participants

Patients were recruited from December 2006 to January 2008 from 10 AMHCs in Barcelona (Catalonia, Spain). All patients had: 1) diagnosis of schizophrenia

according to the International Classification of Diseases-10 or ICD-10 (World Health Organization [WHO], 1995), 2) illness duration greater than 2 years and 3) clinical stability. Patients were excluded if they had dementia, organic brain injury or mental retardation. Patients for the CM programme were consecutively selected among those in the STP visiting the AMHCs with a Global Assessment of Functioning or GAF score \leq 50 (Endicott, 1976). Patients in the STP were selected from the AMHC databases through an intentional non-probabilistic sampling among all patients in the STP that could be matched with the patients selected for the CM programme regarding: age (\pm 5 years), gender, illness length (\pm 5 years) and symptoms by the Positive and Negative Syndrome Scale (PANSS) (Kay, Friszbein, and Opler, 1987; total score, \pm 10 points).

Instruments

Patients were assessed at baseline and at one year follow-up with these instruments:

The Schizophrenia Cost Evaluation Questionnaire (Haro *et al.*, 1998). It records on the use of health care and social services.

The GAF (Endicott, 1976). This is a valid measure of psychological functioning in SMD included in the fourth edition of the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association [APA], 1994).

The PANSS (Kay *et al.*, 1987). It assesses symptom severity in schizophrenia. Its validation into Spanish shows good psychometric properties (Peralta and Cuesta, 1994).

The Disability Assessment Schedule short version or DAS-s (Janca *et al.*, 1996). It is a valid and reliable measure of functioning for mental disorders included in the

ICD-10 (WHO, 1995) validated in schizophrenia (Mas-Expósito, Amador-Campos, Gómez-Benito, and Lalucat-Jo, 2011a).

The Camberwell Assessment of Needs or CAN (Phelan, Slade, and Thornicroft, 1999). It measures the needs of people with mental illness and shows good psychometric properties in schizophrenia (Rosales, Torres, Del Castillo, Jiménez, and Martínez, 2002).

The World Health Organization Quality of Life Scale Brief Version (WHO, 1993) or WHOQOL-BREF. It is an international, cross-culturally analogous quality of life (QoL) instrument that shows good psychometric properties in schizophrenia (Mas-Expósito, Amador-Campos, Gómez-Benito, and Lalucat-Jo, 2011b).

The modified DUKE-UNC Functional Social Support Questionnaire or FSSQ (Broadhead, Gelbach, Degruy, and Kaplan, 1988). It measures the strength of social networks. The Spanish version shows good psychometric properties (Bellón-Saameño, Delgado-Sánchez, de Dios-Luna del Castillo, and Lardelli-Claret, 1996).

Procedure

The study was approved by the Ethics Committee of the Catalan Union of Hospitals and carried out in accordance with the ethical standards of the 1964 Declaration of Helsinki. The procedures were described to each patient who then provided informed consent.

Each AMHC provided both programmes. The AMHC teams performed patient assessments. For both programmes, the psychiatrists established the diagnosis, following the ICD-10 (WHO, 1995) research diagnosis criteria and considered self and caregiver reports, and assessed psychiatric symptoms. The rest of assessments were performed by the other members of the teams under the psychiatrist's supervision or by a community psychiatric nurse from the teams in the STP. The psychiatrist was

responsible for setting up and supervising the assessment agenda and sending the score sheets to the psychologist who designed and analysed the database.

To guarantee quality data, the psychiatrists participated in a schizophrenia diagnostic consensus workshop comprising two case studies. All researchers were trained in the instruments in a 4-hour session run by a psychologist. Systematic reviews of data coding and recording were made and patient information was compared with data from the AMHC responsible for each patient.

Statistical analysis

Clinical and psychosocial outcomes and use of health services were analysed using the Statistical Package for the Social Sciences v. 19.

Chi-square analysis and Student's *t*-tests for independent samples were used for categorical and continuous data, respectively. Mann–Whitney U tests were applied for continuous data to compare independent samples with fewer than 30 patients.

Results

The sample was composed of 150 patients (67.3% males; 75 in the CM programme and 75 in the STP). Seventy percent of patients in both programmes had illness duration longer than 10 years and 66.7% of them had diagnosis of paranoid schizophrenia. The mean age was 41.47 years (SD = 11.80) and the mean GAF score was 44.52 (SD = 8.32). There were significant differences between the study groups in the type of housing they lived in. A lower percentage of patients in the CM programme reported to live in family-owned housing (See Table 2).

Insert here Table 2

A total of 69 patients (92%) in the CM programme were successfully followed up. Four individuals (out of 6) had no contact with services, 1 refused to participate and

1 committed suicide. Regarding the STP, 69 patients (92%) were successfully followed up. Six patients had no contact with services. No significant differences between study groups were observed regarding treatment attrition ($\chi^2(1) = 0.000$; $p > 0.05$).

Table 3 shows the differences between the CM programme group and the STP group in clinical and psychosocial variables at baseline and at one year follow-up. At baseline, no significant differences were found between the CM programme and the STP groups in symptoms, disability, subjective QoL regarding psychological health, social relationships and environment, and perceived social support. However, there were differences between groups in patients' needs from the clinician's point of view, clinical and social functioning, subjective QoL regarding physical health and overall QoL (Table 3). Patients in the CM programme group showed more needs, lower clinical and social functioning, and lower subjective QoL regarding physical health and overall QoL compared to patients in the STP. At one year follow-up, there were intergroup differences in social functioning. Patients from the CM group showed poorer social functioning than patients in the STP.

Insert here Table 3

Table 4 shows the use of health services for the CM group and the STP group at baseline and at one year follow-up for categorical variables. At baseline, there were significant differences between the study groups in the proportion of patients that used acute units, overall inpatient hospital services, emergency services and social services. A greater proportion of patients from the CM group used those services. After one year follow-up, there were differences between groups in the proportion of patients who used overall outpatient psychiatric services, community social work services, social services and primary care nursing services. A greater proportion of patients from the CM group used outpatient psychiatric services, community social work services and social

services, while a greater proportion of patients from the STP used primary care nursing services.

Insert here Table 4

Table 5 shows the use of health services for the CM group and the STP group at baseline and at one year follow-up for continuous variables. At baseline, there were significant differences between the study groups in outpatient hospital visits, overall outpatient psychiatric hospital visits, community psychiatric visits and community psychiatric nursing visits. Patients in the CM group had more visits to all those services. After one year follow-up, there were differences between the groups in community psychiatric nursing visits. The CM programme group showed higher number of visits to community psychiatric nursing services.

Insert here Table 5

Discussion

This paper aimed to establish the effectiveness of a CM programme versus a STP regarding clinical, psychosocial and service use variables.

Both programmes were effective in maintaining contact with services. Only eight per cent of patients in each programme lost contact with services, which concurs with Marshall *et al.* (2000) with regard to the efficacy of CM. It also shows favourable effects regarding the STP.

The clinical CM programme was effective in clinical and psychosocial functioning. After the follow-up, the CM group showed a similar profile to that of the STP group regarding clinical functioning, QoL and needs. Our results contradict Marshall *et al.* (2000) but coincide with those in a meta-analysis on the effectiveness of clinical CM versus usual treatment in clinical functioning (Ziguras and Stuart, 2000)

and in other reviews (Mueser *et al.*, 1998). The inconsistencies between reviews may arise from the strictness of the methodology used by Marshall *et al.* (2000). Patients in the STP experienced improvements in clinical functioning as well. Regarding QoL, our results coincide with those from other studies (Lichtenberg, Levinson, Sharshevsky, Feldman, and Lachman, 2008) that found improvements in subjective QoL but with a non-validated scale. We used the WHOQOL-BREF (WHO, 1993) which has good psychometric properties in schizophrenia (Mas-Expósito *et al.*, 2011b). To our knowledge, this is the first study conducted in Spain dealing with this relevant outcome (Van Esch, Den Oudsten, and De Vries, 2011). Our results also suggest that CM was associated with decreasing health care needs. Studies are needed to see whether our findings are replicated. The CM group still showed a poorer level than that the STP group in social functioning at one year follow-up. This may not coincide with Ziguras and Stuart (2000) but a closer examination suggests improvements in social functioning in both treatment programme groups. At baseline, the CM group already showed poorer social functioning, which may explain the differences between groups at one year follow-up. A longer follow-up period might be required to determine CM effects (Lichtenberg *et al.*, 2008).

Our results seem to contradict CM studies in other settings where CM is associated with increasing hospitalisation (Marshall *et al.*, 2000; Ziguras and Stuart, 2000). Nevertheless, they concur with Spanish studies about the effectiveness of clinical CM (Alonso Suárez *et al.*, 2011) that show a drop in the number of hospitalised patients which is similar to that observed in our study. Alonso Suárez *et al.* (2011) also showed a significant decrease in the number of patients visiting emergency rooms. To our knowledge, ours is the second study conducted regarding this outcome. At follow-up, the CM group still used more social services, which may be associated to their poorer

social functioning at both assessment points and there were new differences regarding some health care services. A higher proportion of patients in the CM programme group used overall outpatient hospital services, while a higher proportion of patients in the STP group used primary care nursing services. One possible explanation might be that, after the follow-up, patients were ready to use less intensive services. At baseline, the CM group made more visits to outpatient hospital services, outpatient psychiatric hospital services, community psychiatric services and community psychiatric nursing services. At one year follow up, the CM programme group only showed more community psychiatric nursing visits. There was an increase of visits in the CM programme group not observed in the STP, which coincides with the meta-analyses of Ziguras and Stuart (2000) that shows that clinical CM increases contact with services. The increase of such visits in the CM group might have turned into a decrease of outpatient psychiatric hospital service visits. Hospital service use was quite low, which contradicts the hypothesis that CM is effective where hospital bed use is high (Burns *et al.*, 2007) but coincides with other Spanish studies (Alonso Suárez *et al.*, 2011).

Although the aforementioned strengths when comparing our study with other Spanish studies, our results are limited to a one year follow-up and we did not use a randomised controlled design (Montero and León, 2007). This study is a quasi-experiment that is considered to be an appropriate design in clinical and ordinary settings, such as that in this study.

In summary, patients from the clinical CM group achieved a similar profile to that of patients in the STP at one year follow-up regarding clinical and psychosocial outcomes and health care service use. These results highlight the effectiveness of a clinical CM programme in Spain that could be directed at patients with more health care needs. The clinical CM programme and the STP could be provided consecutively in the

care of schizophrenia, and responds to the importance of establishing CM considering patients' needs (Working group of the clinical practice guideline for schizophrenia and incipient psychotic disorder, 2009).

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Table 1.

Intervention Programme Characterisation

Programme	
ST	CM
Clinician in charge	Psychiatrist
Case manager	Community mental health nurse
Assessment	Global assessment including medical and psychosocial aspects Systematic assessment: <ul style="list-style-type: none"> - Medical assessment - Psychosocial assessment
Therapeutic plan	Development of an individualized therapeutic plan (ITP) <ul style="list-style-type: none"> - Regularly reviewed and updated - Modified if necessary
Treatment	Medical intervention : <ul style="list-style-type: none"> - pharmacological treatment set up

Specific psychosocial interventions:

- Psychoeducation
- Family Therapy
- Assistance in Daily Living
- Crisis interventions (assertive outreach)

Follow-up Medical follow-up: 4-6 visits per year

Medical follow-up: 4-6 visits per year

Nursing follow-up: 12 visits per year

ST: Standard Treatment; CM: Case Management

Table 2.

Socio-demographic variables according to treatment programme

	Programme		Intergroup differences		
	CM	ST	χ^2	df	p
Socio-demographic variables	f (%)	f (%)			
Male gender	51 (68.0)	50 (66.7)	0.030	1	0.862
Diagnosis of schizophrenia type			0.348	3	0.951
Paranoid	50 (66.7)	50 (66.7)			
Undifferentiated	7 (9.3)	8 (10.7)			
Residual	10 (13.3)	8 (10.7)			
Other	8 (10.7)	9 (12.0)			
Illness duration			0.286	2	0.867
< 5 years	8 (10.7)	7 (9.3)			
From 5 to 10 years	16 (21.3)	14 (18.7)			
> 10 years	51 (68.0)	54 (72.0)			
Marital status					
Single	59 (78.7)	56 (74.4)			
Married or common-law marriage	7 (9.3)	11 (14.7)			
Separated, divorced or widowed	9 (12.0)	8 (10.7)			

Educational level			4.678	3	0.197
Primary school not completed	9 (12.0)	7 (9.3)			
Primary school	26 (34.7)	35 (46.7)			
Secondary school	31 (41.3)	20 (26.7)			
College or university	9 (12.0)	13 (17.3)			
Living situation			5.864	5	0.320
Alone	16 (21.3)	12 (16.0)			
With son/daughter or son/daughter and partner	5 (6.7)	7 (9.3)			
With partner	5 (6.7)	9 (12.0)			
With parents	35 (46.7)	39 (52.0)			
With other relatives	6 (8.0)	6 (8.0)			
With other people or in an institution	8 (10.7)	2 (2.7)			
Type of housing			9.832	2	0.007
Family-owned	43 (57.3)	60 (80.0)			
Rented	21 (28.0)	12 (16.0)			
Hostel, supported sheltered house, therapeutic community, homeless or others	11 (14.7)	3 (4.0)			
Employment status			2.331	3	0.507
Employed/self-employed/ supported employment/student/volunteer	7 (9.3)	13 (17.3)			
House work/on sick leave/retired/unemployed	14 (18.7)	12 (16.0)			

Never worked before	7 (9.3)	5 (6.7)			
Incapacitated	47 (62.7)	45 (60.0)			
	Mean (SD)	Mean (SD)	t		
Age	41.23 (11.98)	41.72 (11.70)	-0.255	148	0.799

Note. n=75 for the case management and the standard treatment programmes

CM: Case Management; ST: Standard Treatment; f: frequency; %: percentage; df: degrees of freedom; SD: Standard Deviation

Table 3.

Clinical and psychosocial variables in the case management programme group and the standard treatment programme group at baseline and at one year follow-up

Measure	Time (months)	Programmes		Intergroup differences	
		CM	ST	t	p
		Mean (SD)	Mean (SD)		
CAN patients' needs	0	9.14 (7.43)	7.43 (3.32)	2.784	0.006
	12	7.89 (3.56)	7.01 (2.80)	1.527	0.129
PANSS positive	0	17.60 (4.54)	17.08 (4.97)	0.669	0.504
	12	16.03 (5.17)	15.26 (5.28)	0.864	0.389
PANSS negative	0	25.64 (5.46)	25.15 (5.79)	0.537	0.592
	12	23.43 (6.06)	22.64 (6.11)	0.769	0.443
PANSS general	0	44.35 (7.98)	43.64 (7.47)	0.560	0.576
	12	41.14 (10.10)	38.64 (9.35)	1.513	0.133
PANSS total	0	87.59 (12.48)	85.87 (12.28)	0.851	0.396
	12	80.61 (17.50)	76.54 (16.81)	1.394	0.165
GAF clinical	0	42.03 (7.15)	47.01 (8.71)	-3.834	0.000
	12	46.65 (11.20)	49.14 (10.46)	-1.351	0.179
GAF social	0	40.44 (8.63)	45.27 (9.10)	-3.335	0.001

	12	42.35 (9.43)	47.04 (10.77)	-2.725	0.007
DAS-s	0	10.20 (4.51)	9.03 (3.86)	1.712	0.089
	12	9.03 (4.46)	8.93 (4.36)	0.135	0.893
WHOQOL-BREF physical health	0	12.64 (2.25)	13.61 (2.29)	-2.614	0.010
	12	13.00 (2.64)	13.62 (2.20)	-1.499	0.136
WHOQOL-BREF psychological health	0	11.64 (2.80)	12.36 (2.57)	-1.621	0.107
	12	12.02 (2.82)	12.46 (2.56)	-0.969	0.334
WHOQOL-BREF social relationships	0	10.17 (3.20)	10.52 (2.90)	-0.713	0.477
	12	12.30 (3.18)	10.43 (2.95)	-0.259	0.796
WHOQOL-BREF environment	0	12.75 (2.28)	13.16 (2.04)	-1.156	0.250
	12	13.07 (2.27)	13.63 (2.43)	-1.412	0.160
WHOQOL-BREF general	0	78.12 (13.14)	82.72 (11.82)	-2.254	0.026
	12	80.51 (14.46)	83.72 (12.23)	-1.411	0.161
FSSQ total social support	0	36.23 (9.94)	37.31 (8.54)	-0.713	0.477
	12	37.22 (10.02)	36.64 (8.71)	0.363	0.717
FSSQ confidant support	0	16.40 (5.20)	16.97 (4.80)	-0.699	0.486
	12	16.72 (4.96)	16.51 (5.19)	0.252	0.802
FSSQ affective support	0	10.82 (3.20)	11.16 (3.08)	-0.652	0.516
	12	11.16 (3.18)	10.75 (3.11)	0.757	0.450

Note. n=75 at baseline and n=69 at one year follow-up for the case management and standard treatment programmes

CM: Case Management; ST: Standard Treatment; SD: Standard Deviation; CAN: Camberwell Assessment of Needs Questionnaire; PANSS: Positive and Negative Syndrome Scale; GAF: Global Assessment of Functioning; DAS-s: Disability Assessment Schedule Short Form; WHOQOL-BREF: World Health Organization Quality of Life Scale Brief Version; FSSQ: Modified DUKE-UNC Functional Social Support Questionnaire

Table 4.

Use of services (categorical variables) according to treatment programme

	Time (months)	CM		ST		χ^2	df	p
		f	%	f	%			
Inpatient hospital services								
Acute unit	0	20	26.7	10	13.3	4.167	1	0.041
	12	10	14.5	4	5.8	2.862	1	0.091
Sub-acute unit	0	5	6.7	3	4.0	0.528	1	0.467
	12	4	5.8	1	1.4	1.868	1	0.172
General hospital unit	0	2	2.7	0	0	2.027	1	0.155
	12	0	0	0	0	-	-	-
Overall use of inpatient hospital services	0	24	32.0	12	16.0	5.263	1	0.022
	12	11	15.9	6	8.7	1.677	1	0.195
Outpatient hospital services								
Day hospital	0	4	5.3	2	2.7	0.174*	1	0.677
	12	0	0	1	1.4	1.007*	1	1.000
Outpatient hospital services	0	5	6.7	5	6.7	0.000	1	1.000
	12	2	2.9	0	0	0.507**	1	0.154

Emergency services	0	17	22.7	8	10.7	3.888	1	0.049
	12	9	13.0	3	4.3	3.286	1	0.070
Crisis services	0	3	4.0	1	1.3	1.027**	1	0.620
	12	1	1.4	0	0	1.007	1	1.000
Overall use of outpatient hospital services	0	22	29.3	15	20.0	1.758	1	0.185
	12	12	17.4	3	4.3	6.059	1	0.014
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Community services								
Community psychological services	0	10	13.3	10	13.3	0.000	1	1.000
	12	6	8.7	6	8.7	0.000	1	1.000
Community social work services	0	42	56	33	44.0	2.160	1	0.142
	12	52	69.3	38	50.7	5.444	1	0.020
Community rehabilitation services	0	16	21.3	13	17.3	0.385	1	0.535
	12	19	27.5	12	17.4	2.039	1	0.153
Specialised rehabilitation services	0	14	18.7	8	10.7	1.918	1	0.166
	12	16	23.2	9	13.0	2.394	1	0.122
Protected vocational workshops	0	6	8.0	6	8.0	0.000	1	1.000
	12	3	4.3	6	8.7	1.070	1	0.301
Educational, vocational or leisure services	0	11	14.7	18	24.0	2.095	1	0.148
	12	10	14.5	15	21.7	1.221	1	0.269

Social services	0	16	21.3	1	1.3	14.927	1	0.000
	12	9	13.0	2	2.9	4.840	1	0.028
Emergency phone calls	0	9	12.0	6	8.0	0.667	1	0.414
	12	4	5.8	5	7.2	0.119	1	0.730
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Primary care services								
General practitioner	0	47	62.7	47	62.7	0.000	1	1.000
	12	49	71.0	52	75.4	0.332	1	0.564
Primary care nursing	0	19	25.3	25	33.3	1.158	1	0.282
	12	17	24.6	28	40.60	3.990	1	0.046
Home, family and social work	0	9	12.0	3	4.0	3.261	1	0.071
	12	7	10.1	5	7.2	0.356	1	0.546

Note. *Yate's test continuity correction; **Exact Fish Test

CM: Case Management; ST: Standard Treatment; f: frequency; %: percentage; df: degrees of freedom

Table 5. Service use variables in the case management programme group and the standard treatment programme group at baseline and at one year follow-up

Service	Time (months)	Programme				Intergroup differences	
		CM		ST		T/Z	p
		n	Mean (SD)	n	Mean (SD)		
Inpatient hospital services							
Acute psychiatric unit (days)	0	19	17.84 (11.41)	9	22.56 (9.28)	-1.480	0.139
	12	8	18.13 (8.54)	4	15.75 (10.81)	-0.681	0.496
Acute psychiatric unit (admissions)	0	19	1.00 (0.00)	9	1.00 (0.00)	-	-
	12	8	1.00 (0.00)	4	1.25 (0.50)	-1.414	0.157
Crisis unit (days)	0	0	0.00 (0.00)	0	0.00 (0.00)	-	-
	12	1	18.00 (0.00)	0	0.00 (0.00)	-	-
Crisis unit (admissions)	0	0	0.00 (0.00)	0	0.00 (0.00)	-	-
	12	1	1.00 (0.00)	0	0.00 (0.00)	-	-
Sub-acute unit (days)	0	5	62.40 (38.19)	3	88.00 (67.62)	-1.050	0.294
	12	3	67 (27.40)	2	29.50 (9.19)	-1.732	0.083
Sub-acute unit (admissions)	0	5	1.00 (0.00)	3	1.00 (0.00)	-	-
	12	3	1.00 (0.00)	2	1.00 (0.00)	-	-

Medium/long stay unit (days)	0	0	0.00 (0.00)	0	0.00 (0.00)	-	-
	12	0	0.00 (0.00)	1	6.00 (0.00)	-	-
Medium/long stay unit (admissions)	0	0	0.00 (0.00)	0	0.00 (0.00)	-	-
	12	0	0.00 (0.00)	0	0.00 (0.00)	-	-
General hospitalisation unit (days)	0	2	2.00 (1.41)	0	0	-	-
	12	0	0.00 (0.00)	0	0.00 (0.00)	-	-
General hospitalisation unit (admissions)	0	2	1.00 (0.00)	0	0	-	-
	12	0	0.00 (0.00)	0	0.00 (0.00)	-	-
Overall inpatient hospital (days)	0	25	29.68 (29.86)	10	21.30 (9.60)	-0.293	0.770
	12	11	46.18 (51.20)	6	21.33 (19.49)	-1.409	0.159
Overall inpatient hospital (admissions)	0	22	1.00 (0.00)	10	1.00 (0.00)	-	-
	12	11	1.45 (0.69)	4	1.00 (0.00)	-1.348	0.178
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Outpatient psychiatric hospital services							
Outpatient hospital visits	0	5	17.80 (13.18)	4	1.25 (0.50)	-2.491	0.013
	12	2	3.00 (2.83)	0	0	-	-
Crisis unit visits	0	3	1.00 (0.00)	1	4.00 (0)	-1.732	0.083
	12	1	1.00 (0.00)	0	0	-	-
Emergency service visits	0	15	1.53 (0.74)	8	1.38 (0.74)	-0.612	0.540
	12	9	2.11 (1.69)	3	16.67 (24.58)	-1.025	0.413

Day hospital	0	4	55.00 (54.08)	2	160.00 (224.86)	-0.651	0.628
	12	0	0.00 (0.00)	1	9.00 (0.00)	-	-
Outpatient psychiatric hospital visits	0	20	8.40 (11.24)	13	1.62 (0.96)	2.684	0.039
	12	12	2.17 (1.75)	3	19.67 (29.77)	-1.023	0.306
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Community services							
Community psychiatric visits	0	73	5.85 (2.94)	73	4.70 (2.54)	2.528	0.013
	12	68	6.18 (3.50)	69	5.22 (2.57)	1.830	0.069
Community psychology visits	0	9	4.22 (2.86)	10	5.90 (4.41)	-0.495	0.621
	12	6	6.50 (4.51)	6	4.67 (2.94)	-1.158	0.247
Community psychiatric nursing visits	0	75	7.81 (7.48)	74	4.42 (5.38)	3.183	0.002
	12	69	11.64 (8.35)	68	4.94 (5.97)	5.409	0.000
Community social work visits	0	42	4.55 (3.59)	33	4.79 (3.57)	-0.288	0.774
	12	45	3.82 (3.21)	32	4.09 (2.61)	-0.394	0.695
Community rehabilitation centre	0	16	183.63 (168.19)	13	252.62 (138.13)	-0.774	0.439
	12	19	132.32 (168.99)	12	242.92 (140.52)	-1.453	0.146

CM: Case Management; ST: Standard Treatment; SD: Standard Deviation

