

# Clinical Practice Guidelines for Psychosocial Interventions in Severe Mental Illness

CLINICAL PRACTICE GUIDELINES IN THE SPANISH NHS  
MINISTRY OF HEALTH AND SOCIAL POLICY





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This CPG is an aid for decision making in health care. It is not mandatory, and it is not a substitute for the clinical judgment of healthcare personnel

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# Presentation

Healthcare practice is increasingly more complex due to a multitude of factors, one of the most relevant of which is undoubtedly the exponential increase in scientific information available to us.

Science is something that is permanently changing and thus requires permanent updates. This means that clinicians have to constantly refresh their knowledge, objectives and interventions to be able to cover people's needs. This means that professionals have to face up to the situation of taking clinical decisions each day. These decisions are becoming more and more complicated due to the constant changes and the needs and expectations generated in society.

In 2003, the Interterritorial Council of the Spanish National Health Service (SNHS) created the GuiaSalud Project whose ultimate purpose is to improve clinical decision-making based on scientific evidence, through training activities and by setting up a register of clinical practice guidelines (CPG). Since then, the GuiaSalud Project, financed by the Ministry of Health and Consumer Affairs, has evaluated dozens of CPGs, according to explicit criteria determined by its scientific committee. It has registered those guidelines and it has disseminated them over the Internet.

At the beginning of 2006, the General Directorate of the Quality Agency of the National Health System prepared the Quality Plan for the National Health System, which is deployed according to twelve strategies. The purpose of this Plan is to increase the cohesion of the National Health System and help guarantee the highest quality healthcare for everyone, regardless of their place of residence.

As part of the Plan, the preparation of several CPGs was commissioned to various expert agencies and groups on prevalent pathologies related to health strategies.

This project was renewed in 2007 and the guideline on Psychosocial Interventions in Severe Mental Illnesses is the result of this assignment. This guideline follows the common guideline development methodology set for the NHS, which was prepared among the expert groups in CPGs in our country, combining their efforts and coordination.

Severe Mental Illness (SMI) encompasses different psychiatric diagnoses that persist in time to a certain extent and present serious difficulties in personal and social functioning as a result of the illness, reducing the quality of life of the person affected. This situation means that it is necessary to work on different areas of the person, incorporating other psychotherapeutic and psychosocial interventions, and not just the pharmacological intervention. This generates a considerable consumption of social health resources, causing an important economic impact.

This clinical practice guideline addresses all these aspects in adults who suffer from this disorder and it is the result of the work of a multidisciplinary team of professionals from the social, health and labour areas, who have dedicated many hours to the preparation of the recommendations.

The aim of this guideline is to answer many of the questions that arise from the day-to-day care of people who suffer Severe Mental Illnesses, given in the form of systematically prepared recommendations with the best available scientific evidence, the experience of the professionals from the guideline development group, and bearing in mind the needs of the users and families of people who suffer SMI.

We hope that this guideline will help people suffering from SMI and their families control the symptoms and overcome the illness, promoting people with SMI and their families recover and lead significant, decent and satisfactory lives. This is the goal that encourages us.

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Director General of the Quality Agency of the NHS

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**Spanish Association of Neuropsychiatry**

**National Association of Mental Health Nursing**

**Spanish Society of Psychiatry**

**Aragonese Association of Psychosocial Rehabilitation**

**Aragonese and Rioja Society of Psychiatry**

Members of these societies have participated as authors, expert collaborators or external reviewers of the CPG.

**Declaration of Interest:** All the members of the guideline development group as well as the people who have participated in the expert collaboration and in the external review, have made the declarations of interests that are presented in Appendix 7.



# Questions to answer

## a) PSYCHOLOGICAL INTERVENTIONS

- Is cognitive behavioural therapy-based psychological intervention effective in the treatment of people with SMI?
- Are the psychodynamic psychotherapy and the psychoanalytic approaches effective in the treatment of people with SMI?
- Is interpersonal therapy effective in the treatment of people with SMI?
- Is supportive therapy effective in the treatment of people with SMI?

### Family interventions

- Do family interventions in their different formats, present benefits compared with non-intervention or other types of psychosocial intervention, in people with SMI?
- At what time, during the course of the illness, is it best to start family intervention for people with SMI and their families?
- What is the most appropriate time framework for the family intervention programmes and/or sessions for people with SMI and their families?

### Psychoeducational interventions

- Are psychoeducational interventions effective in people with SMI?
- What are the key components in psychoeducational interventions in people with SMI?
- What is the most adequate level of psychoeducational intervention: individual, group or family?

### Cognitive rehabilitation

- Are cognitive rehabilitation interventions efficient in people with SMI and cognitive impairment?
- Which is the most adequate format of these interventions for people with SMI and cognitive impairment?

### Other psychotherapies

- Are morita therapy, drama therapy, distraction therapy or hypnosis effective in people with SMI?

## b) SOCIAL INTERVENTIONS

- Do social insertion programmes –daily living skills programmes, residential programmes in the community, or programmes aimed at leisure and spare time - improve the evolution of the illness and the quality of life of people with SMI?
- Which employment-related intervention format improves labour market insertion of people with SMI?
- Do therapeutic interventions, such as art therapy and music therapy, improve the evolution of the illness and the quality of life of people with SMI?

**c) SERVICE LEVEL INTERVENTIONS**

- Which service supply system –day centres and/or psychosocial rehabilitation centres, community Mental Health centres, Assertive Community Treatment, Intensive Case Management (ICM), non-acute day hospitals or Case management (CM)- is more effective in people with SMI?

**d) INTERVENTIONS WITH SPECIFIC SUB-POPULATIONS**

- What type of treatment has proven to be most effective in people with SMI and substance abuse: integral or parallel treatment?
- Which intervention is more efficient in people with SMI and “homeless”?
- Which psychosocial treatment is more effective in people with SMI and a low IQ?

# Summary of recommendations

<b>5. PSYCHOSOCIAL TYPE REHABILITATION INTERVENTIONS</b>	
<b>5.1. PSYCHOLOGICAL INTERVENTIONS</b>	
<b>5.1.1. Cognitive behavioural therapy</b>	
C	In people with SMI, cognitive behavioural treatment can be used combined with standard treatment to reduce positive symptomatology, mainly hallucinations.
C	People with SMI and persistent positive symptomatology can be offered a specific cognitive behaviour-orientated psychological intervention for this pathology, lasting for a prolonged period of time (more than one year), in order to improve the persistent symptomatology.
C	Incorporate cognitive therapy into strategies aimed at preventing relapses of depressive symptomatology in people with SMI and diagnosis of bipolar disorder.
B	When the main objective of the intervention in people with SMI is to improve their social functioning, it is advisable to incorporate social skills training.
	There is not sufficient evidence to make recommendations in the problem-solving area for people with SMI and diagnosis of schizophrenia and related disorders.
<b>5.1.2. Psychodynamic psychotherapy and psychoanalytic approach</b>	
	Sufficient evidence has not been found to make recommendations related to psychodynamic psychotherapy or the psychoanalytic approach in the treatment of people with SMI.
<b>5.1.3. Interpersonal therapy</b>	
C	The strategies aimed at preventing relapses in people with SMI and a diagnosis of bipolar disorder should evaluate the incorporation of interpersonal and social rhythm therapy (IPSRT) into the treatment.
<b>5.1.4. Supportive therapy</b>	
	Sufficient evidence has not been found to make recommendations related to supportive therapy or counselling in the treatment of people with SMI.
<b>5.1.5. Family interventions</b>	
B	For people with SMI and diagnosis of schizophrenia and related disorders and their families, family intervention should be offered as an integral part of the treatment.
B	In family interventions that are carried out with people with SMI and diagnosis of schizophrenia and related disorders, the intervention should be done in a single-family format.
B	The recommended duration in family interventions aimed at people with SMI and diagnosis of schizophrenia and related disorders must be at least 6 months and/or 10 or more sessions.

A	Psychosocial intervention programmes must be offered that include family intervention with a psychoeducational component and coping and social skills training techniques, added to the standard treatment for people with SMI and diagnosis of non-affective psychosis.
B	Family members and caregivers of people with SMI and a diagnosis of bipolar disorder must be offered group psychoeducational programmes that include information and coping strategies that permit discussions within a friendly emotional climate.
<b>5.1.6. Psychoeducational interventions</b>	
A	Quality information must be provided about the diagnosis and the treatment, giving support and handling strategies to people with SMI and diagnosis of schizophrenia and related disorders, to the family members and to the people with whom they live.
A	Psychoeducational programmes that are offered to people with SMI and diagnosis of schizophrenia and related disorders must incorporate the family.
B	Group psychoeducational programmes aimed at people with SMI and diagnosis of bipolar disorder must incorporate specific psychological techniques, carrying them out in a relatively stable period of their disorder and always as a supplement to the psychopharmacological treatment.
√	The psychoeducational programmes for people with SMI must be integrated as an additional intervention in an individualised treatment plan, whose duration will be proportional to the objectives proposed, considering a minimum of 9 months' intensive programme and the need for undefined refresher sessions.
<b>5.1.7. Cognitive rehabilitation</b>	
B	People with SMI and diagnosis of schizophrenia and related disorders that have cognitive impairment must be offered cognitive rehabilitation programmes.
B	Cognitive rehabilitation programmes aimed at people with SMI and cognitive impairment must be integrated into more extensive psychosocial rehabilitation programmes.
C	From the cognitive rehabilitation interventions or programmes aimed at people with SMI, it is advisable to choose those that include or are accompanied by “compensatory” interventions, in other words, changes in strategy, and training in coping skills or techniques.
<b>5.1.8. Other psychotherapies</b>	
	Sufficient evidence has not been found to make recommendations related to morita therapy, drama therapy, distraction therapy and hypnosis in the treatment of people with SMI.

<b>5.2. SOCIAL INTERVENTIONS</b>	
<b>5.2.1. Daily living skills programmes</b>	
√	Daily living skills training programmes could be offered to people with SMI in order to improve their personal independence and their quality of life.
<b>5.2.2. Residential programmes in the community</b>	
D	For people with SMI who require support to remain in their accommodation D it is advisable that the community residential offers include more extensive psychosocial programmes
<b>5.2.3. Programmes aimed at leisure and spare time</b>	
D	People with SMI and deficiencies perceived in their social relations should follow community leisure and spare time programmes.
√	During the monitoring of the individualised therapeutic programme, it is advisable to systematically assess the need to use spare time programmes and offer them to people with SMI who require them.
<b>5.2.4. Programmes aimed at employment</b>	
A	Sheltered employment programmes are necessary for people with SMI who express their desire to return to work or get a first job. Programmes based on placement models are recommended, with a short preliminary training period, immediate placement, and with frequent individual support.
C	Sheltered employment programmes aimed at searching for normalised employment must not be the only programmes related to labour activity that are offered to people with SMI.
D	It would be recommendable for the psychosocial rehabilitation centres that look after people with SMI and diagnosis of schizophrenia and related disorders, to include employment integration programmes.
B	When employment insertion programmes are offered to people with SMI, the preferences on the type of job to be carried out must be assessed and taken into account.
B	For people with SMI and diagnosis of schizophrenia and related disorders, who have a history of previous job failure, it would be advisable to incorporate cognitive rehabilitation as a part of the employment programmes they are going to participate in.
√	The mental health teams, in coordination with the institutions and other social agents involved, must advise about all types of employment resources, aimed at gainful occupation and production, and adapted to the local employment opportunities. Likewise, they must be orientated towards interventions that put into motion different devices adapted to the needs and to the ability level of the people with SMI, to increase stable and productive occupation expectations.
<b>5.2.5. Other therapeutic interventions</b>	
C	Music therapy and art therapy could be offered to people with SMI and schizophrenia and related disorders as a therapeutic complement to other types of interventions.

<b>5.3. SERVICE LEVEL INTERVENTIONS</b>	
B	When people with SMI need to be readmitted several times into acute units, and/or there is a past history of difficulties to engage with the services with the subsequent risk of relapse or social crisis (as for example becoming a “homeless” person) it is advisable to provide assertive community treatment teams.
√	The continuity of the treatment must be favoured via the integration and coordination of the use of the different resources by the people with SMI, maintaining continuity of care and interventions, and the psychotherapeutic relations established.
√	Care must be maintained from the perspective of the CMHC as a configuration of the most commonly implemented services in our context,, based on teamwork, on service integration and not losing the perspective of being able to integrate other ways of configuring the services that might be developed.
√	When the needs of the people with SMI cannot be covered from the CMHC, continuity of assistance must be given from units that provide day care, and whose activity is organised around the principles of psychosocial rehabilitation, whatever the name of the resource are (Day Centres, Psychosocial Rehabilitation Centres, etc.).
√	A certain level of care can be offered to people with SMI whose needs cannot be satisfied by resources that provide day-care in rehabilitation orientated residential resources whatever the name of the resource are (hospital rehabilitation units, medium stay units, therapeutic communities, etc.)
<b>5.4. INTERVENTIONS WITH SPECIFIC SUB-POPULATIONS</b>	
<b>5.4.1. SMI with dual diagnosis</b>	
B	People with SMI with dual diagnosis must follow psychosocial intervention programmes and drug-dependent treatment programmes, both integral and parallel.
B	The treatment programmes offered to people with SMI with dual diagnosis must have a multi-component nature, be intensive and prolonged.
C	For people with SMI and dual diagnosis and in a homeless situation, the treatment programmes should incorporate sheltered housing as a service.
√	When the care for people with SMI and dual diagnosis is provided in parallel, it is necessary to guarantee continuity of care and coordination among the different health and social levels.
<b>5.4.2. Homeless SMI</b>	
A	For homeless people with SMI who require psychiatric care and psychosocial intervention, it is advisable for both to be supplied together via integral programmes where residential programme/housing is offered.
C	When there is no active substance abuse, it would be advisable to provide grouped accommodation to homeless people with SMI included in integral intervention programmes.
C	When it is not possible to use accommodation and support programmes in the integral psychosocial intervention of homeless people with SMI, the intervention of assertive community treatment team should be offered.

### 5.4.3. SMI and low IQ/mental retardation

B	For people with SMI and a low IQ, and when there is a presence of persistent productive symptoms, it is recommendable to indicate cognitive behavioural therapy adapted to that condition.
√	To improve the diagnosis of psychiatric disorders included within the concept of SMI in people with a low IQ, adapted criteria and specific and validated instruments must be used.



# 1. Introduction

Mental disorders are a problem of extreme importance, due to their high prevalence (there are estimations that suggest that between 15 and 25% of the general population suffer from them) and due to the impact of suffering and disintegration in the people, their families and their closest environment<sup>1</sup>. It can be said that in Spain, excluding the disorders caused by the improper use of substances, at least 9% of the population suffer from a mental disorder at the present time, and a little over 15% will suffer from it throughout their lives. An increase in these figures is predicted in the future<sup>2</sup>.

Improving mental health care in Spain is one of the strategic objectives of the Ministry of Health and Consumer Affairs, the Quality Agency of the Ministry, and with the coordination of the Autonomous Communities, scientific societies and associations of people and families have developed the *Strategy in Mental Health of the National Health System (2006)* report, whose aim is to provide an answer to the population's health needs in mental health-related matters. One of the suggestions it includes is "the standardisation of the following care processes: common mental disorder of adults, Severe Mental Illness in adults, Severe Mental Illness in the elderly, Severe Mental Illness of the personality, common mental disorder in childhood and adolescence, severe child-youth mental illness and generalised development disorder"<sup>3</sup>.

The Spanish terms "trastorno mental grave (TMG)" or "trastorno mental severo (TMS)" are broadly implemented in our context and come from the Anglo-Saxon *Severe Mental Illness* which is being replaced by the term *Severe and Persistent Mental Illness*, which refers to a theoretic construct that groups together a series of clinical conditions with high prevalence and considerable repercussion in healthcare practice, and which would coincide with the term of chronicity, with more positive connotations<sup>1</sup>. In addition, the *Strategy in Mental Health of the National Health System (2006)*<sup>3</sup> report points out the need to differentiate it from "Trastorno mental Común" (*Common mental disorder*) and includes interventions aimed at integrating the care given to people with SMI among its best practices.

All the definitions of SMI<sup>2</sup> make reference –apart from referring to the clinical diagnosis and to the duration of the illness- to the social, family and job functioning of the person affected. The greatest level of consensus was reached with respect to the definition formulated by the United States National Institute of Mental Health (NIMH) in 1987, which defines this group as "a group of heterogeneous people who suffer from severe psychiatric disorders together with long-term mental disturbances, which entail a variable degree of disability and social dysfunction, and who must be cared for by means of different social and health resources of the psychiatric and social healthcare network"<sup>4</sup>.

Despite the fact that the main treatment for people with SMI has been pharmacological interventions since they were introduced in the fifties of the last century, the partial and limited control of the symptomatology, the short and long-term side effects, and the poor treatment adherence of quite a considerable percentage of people affected, pose the need to use a broader approach, where pharmacological treatment is complemented with other psychotherapeutic and psychosocial interventions, which must be efficiently coordinated and applied to help them recover from acute episodes and from the functional deficit during the episodes and between them.

Caring for people with SMI requires the integration of different levels of care and different types of intervention that form an inseparable whole and that are integrated into new objectives:

independence, quality of life, personal well-being, social participation around the concept of personal recovery. Caring for mental illnesses no longer just means relieving symptoms but it also means having to cope with the different resulting needs. All in all, caring for these people requires integrating psychopharmacological interventions and psychosocial interventions into a mental health network comprised of interdisciplinary teams.

This text is the full version of the *Clinical Practice Guide on Psychosocial Interventions in Several Mental Illness* (<http://www.guiasalud.es>).

## 2. Scope and objectives

As mentioned in the introduction, a therapeutic approach to SMI is complex and must include different types of interventions, which require an interdisciplinary team.

The last few years have brought about numerous therapeutic novelties in the pharmacological field (new atypical or second-generation antipsychotics, new mood stabilisers, etc.), which have contributed to an improvement in the evolution of people with SMI, but which require other interventions to improve aspects related to functioning in different behavioural, social, occupational and family integration areas.

The evidence on the effectiveness of psychopharmacological treatment is specific for each disorder included in the SMI concept, which are unique and can not be extrapolated to other disorders. There are different clinical practice guidelines for people with schizophrenia and for people with bipolar disorders that have been prepared by different institutions where this type of intervention is included.

The new therapeutic and rehabilitation approaches commit to the paradigm of recovery and well-being and concepts such as “integral and integrated care” have been introduced, whose aim is to cover the entire deficit and the social disadvantages produced by the impact of mental illness on the person that suffers from it. This represents a shift towards the participation of other agents, apart from health-care personnel, and other interventions apart from the pharmacological intervention.

The objective of this CPG is to assess the existing and available evidence, and formulate the appropriate recommendations on the effectiveness of the different psychosocial (therapeutic and rehabilitating) interventions on people who suffer from SMI. This CPG sums up the available evidence for key questions related to psychosocial interventions and intend to facilitate health professionals, the people affected and their families the shared decision making process. These recommendations are not mandatory nor do they replace the clinical opinion of health or social professionals.

This CPG is aimed at people who suffer Severe Mental Illness and satisfy the three classification dimensions chosen in this guideline (diagnosis, chronicity and disability). The following cases are excluded from the target population group of this CPG:

- People with mental disorders in childhood and adolescence (under 18s).
- People over the age of 65 , as they are subject to receiving treatment in different services other than the Mental Health Service.
- People affected by mental disorders that are secondary to medical illnesses.
- People who have organic psychoses.
- People whose disorder is included in psychotic categories but has a transitory or episodic nature.
- People whose main diagnosis is substance abuse, moderate-serious intellectual impairment, general development disorders, who reach adult age or organic mental disorder.
- People with personality disorders. This does not mean that personality disorders that present a psychotic symptomatology are excluded, but that this diagnosis per se does not mean that it is included.

This guideline is aimed at mental health teams, rehabilitation, residential and community services, as well as outpatients that attend people with SMI. It could also be useful for certain primary and specialised healthcare areas, as well as social services, employment services, prisons, education and voluntary sector (associations, NGO, etc.) that are or come into contact with the care or services provided to people with SMI. Likewise, it may help people who are responsible for planning and guaranteeing health and social services, as well as users and families.

This guideline does not include any pharmacological intervention in the treatment of Severe Mental Illness.

## 3. Methodology

The methodology used to prepare this CPG is contained in the manual, *Preparation of Clinical Practice Guidelines in the National Health System. Methodology Manual* from the Ministry of Health and Consumer Affairs and the Aragon Health Sciences Institute<sup>5</sup>. The scientific levels of evidence and modified degrees of recommendation of the Scottish Intercollegiate Guidelines Network, SIGN<sup>6</sup> (appendix 1) were used to classify the effectiveness of the interventions selected.

The first steps taken to prepare this guideline was to constitute a guideline development group that was made up of professionals from the fields of psychiatry, nursing, psychology, social work and labour insertion from different fields (hospital and community), as well as from foundations, public health and employment system from the mental health field.

### 3.1. Formulation of questions

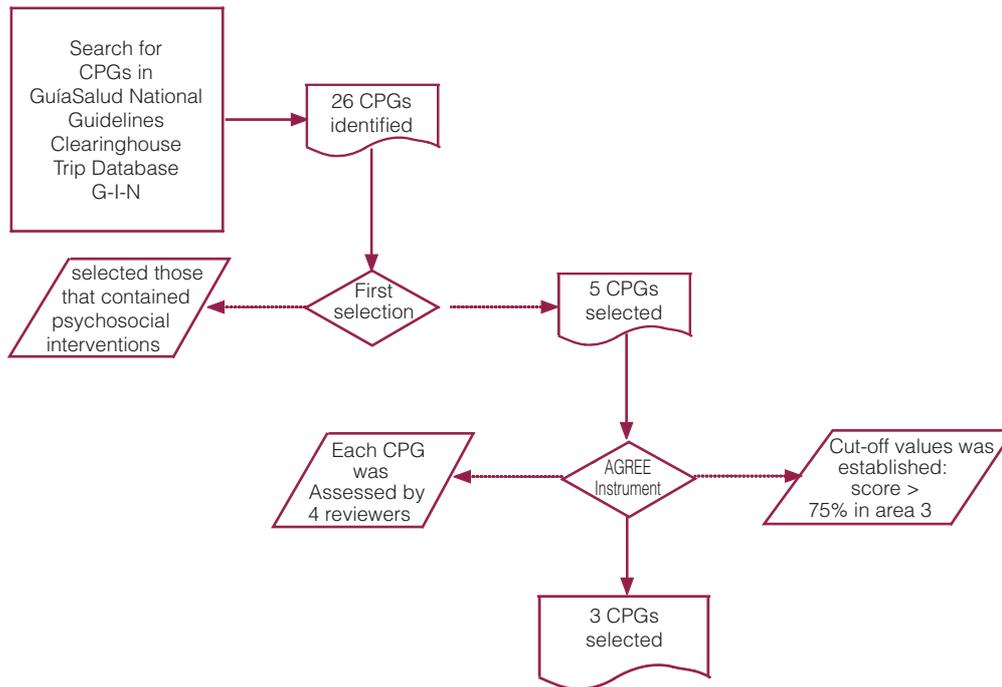
The following format was used for the clinical question formulation phase: Patient / Intervention / Comparison / Outcome. The process started with a methodology workshop to prepare the questions. All the members of the development group participated, creating a first draft with the questions and the question category subgroups. In parallel, groups of people suffering from mental illnesses and family members of people suffering these illnesses also participated. Two group interviews were arranged, one with people with mental illnesses and another with family members separately, where they were informed of the scope and objectives of the CPG and they were asked to give their opinions about the areas that the questions should address (appendix 2). Based on the suggestions of family members and people affected, and those of the CPG development group, 20 questions were developed which are answered in this CPG.

### 3.2. Search strategy

The search strategy started by identifying the most relevant CPGs (local, national and international) in different databases and information sources, prepared by other groups that could be relevant for this CPG: *National Guideline Clearinghouse*, Tripdatabase, GuíaSalud, NICE, and G.I.N (see figure 1).

26 CPGs were identified on some of the diagnoses that were included within the criterion of SMI. Of these 26 guidelines, those where the population, topics, interventions, development date or methodology did not comply with the objectives and scope of this CPG were rejected. Finally, 5 guidelines were selected.

**Figure 1. Search Strategy**



Each one of the 5 CPGs selected was assessed by 4 independent reviewers. The cut-off values to accept the guidelines was set at 60%, except for the methodology section, area 3: rigour and preparation, where the cut-off had to be over 75%. Finally, only 3 CPG passed the established cut-off value: The CPGs on Schizophrenia, Bipolar Disorder and Compulsive Obsessive Disorder developed by the National Institute for Health and Clinical Excellence of the United Kingdom (NICE)<sup>7,8,9</sup>, and it was decided to use them as a secondary source of evidence that would help answer some specific aspects.

Once the part corresponding to the identification and analysis of published CPGs had ended, in order to make the bibliographic search for relevant evidence that might respond to the questions of the CPG formulated previously, it was established that the following general databases would be consulted: Medline, Cochrane Library, Embase and PsycINFO. Furthermore, different websites, entities and associations were consulted, such as the Centre for Reviews and Dissemination (CRD), NICE, American Psychiatric Association (APA), and ClinicalTrials.gov. Mesh term and free language were used for the search strategy in order to improve the sensitivity and specificity of the search. The search was restricted to systematic reviews of randomised control trials and original studies of randomised and non-randomised control trials and to English, French, Portuguese and Spanish languages. A hand search was also carried out to review the references of the identified, included or excluded studies. A hand search was carried out in scientific magazines to obtain information on some aspects of the CPG.

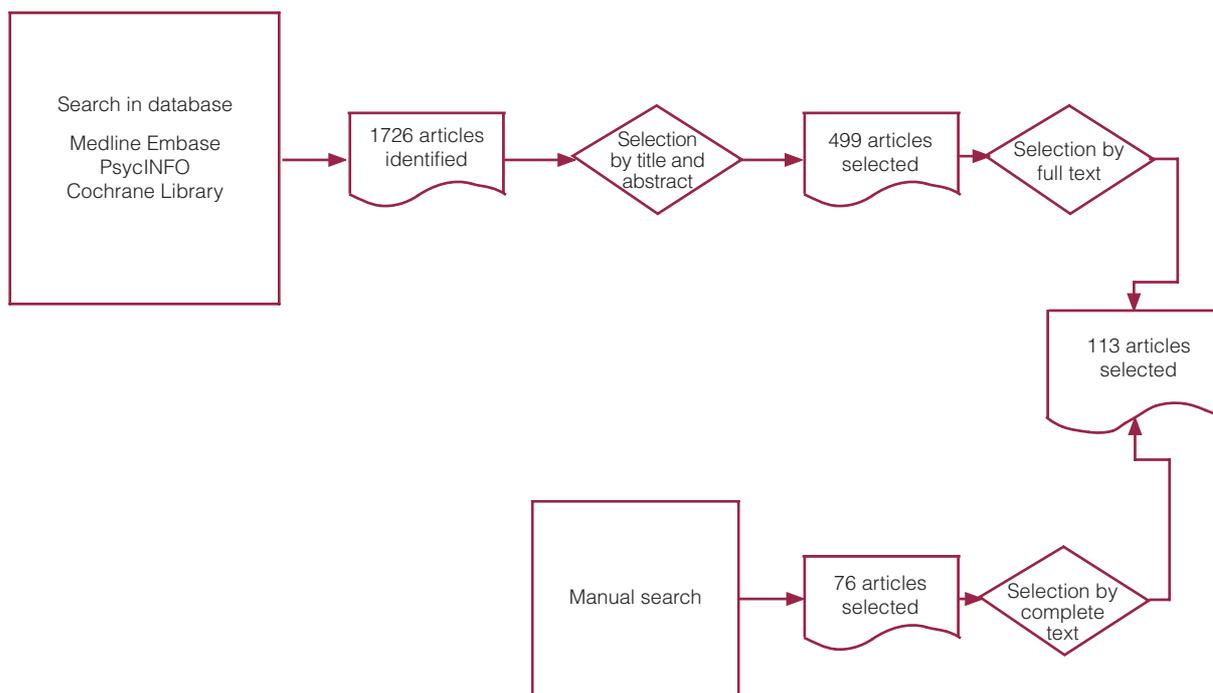
Due to the lack of quality evidence relating to some specific aspects of the questions, an extended search for original observational studies and case series was carried out, and grey literature (conferences, unpublished reports, etc.) at national and international level, was consulted.

Before finishing the CPG, a final search was carried out for recently published articles (until December 2008) that might help answer some of the questions of the CPG. It was then critically

appraised them to assess the quality of the article and determine if it could be included in the evidence used to formulate the recommendations. No articles published after that date was included as a source of evidence for the CPG (See figure 2).

Prior to the publication of this guideline, a preliminary draft was brought out with the update of the Schizophrenia CPG prepared by the NICE<sup>10</sup>. This document was reviewed by this guideline development group to analyse the possible contributions and/or changes that had arisen in this new update and that might modify the recommendations of the previous schizophrenia guideline<sup>8</sup> published by the NICE, too.

**Figure 2. Article selection**



### 3.3. Evidence assessment and synthesis

Once the bibliographic search had finalised, a first screening of the articles found was carried out. Articles were rejected which, according to the title or abstract, could not respond to the questions. With the remaining articles, those whose title and abstract appeared to be useful, a second screening was carried out and a first reading was done to see if they could answer some of the questions of the CPG.

Afterwards, the quality of those articles that had passed the two screenings was assessed, using the OSTEBA (OST FLCritica) critical appraisal tool.

To classify the evidence of the effectiveness of the interventions selected, the modified hierarchic classification system of the Scottish Intercollegiate Guidelines Network, SIGN<sup>6</sup> (appendix 1) was used, and the data obtained from the selected articles were dumped onto a grid for assessment and subsequent development of the guideline recommendations (appendix 3).

The highest evidence level found was selected for each intervention questions. When there was a systematic review (SR) or meta-analysis in relation to the question, these were used as a source of evidence and the less solid and worst quality studies were rejected. When SR or meta-analyses could not be found, observational studies or case series were used.

The evidence level of the information obtained from other sources, such as the aforementioned CPGs, was maintained, so long as the original source that the evidence came from was clearly specified. In those cases where this was not clear, that information was used, but the evidence level was lowered to a lower level, and subsequently, the degree of recommendation.

### 3.4. Forming guideline recommendations

Following the critical appraisal of the available evidence, the recommendations were formulated. A discussion group was made up with the entire CPG development group, using a well-reasoned opinion, and bearing in mind the quality of the evidence found and the clinical experience of the CPG development group, the recommendations were gradually developed with their relative classification.

Several recommendations were prepared for each answer, indicating the level of evidence and degree of recommendation. When the recommendations were controversial or there was no evidence, it was solved by consensus of the development group. In those questions with respect to which there was no clear evidence about a particular topic, the group proposed research recommendations.

### 3.5. Collaboration and external review

The guidelines established in the *Methodology Manual for the Preparation of Clinical Practice Guidelines in the (Spanish) National Health System*<sup>5</sup> include the participation of expert collaborators and external reviewers. The expert collaborators participated in the review of the questions and the recommendations of the CPGs and the external reviewers contributed to the review of the draft. Before sending the draft CPGs to the external reviewers, the clinical leaders of the CPG also carried out a review of the text. The guideline development group meticulously took into consideration all the comments and contributions made during the consultation period with the CPG collaborators and reviewers and introduced any changes they deemed appropriate derived from their comments. The recommendations made in this CPG do not necessarily have to coincide or be in agreement with the contributions of the reviewers and collaborators. The final responsibility for the recommendations lies in the CPG development group.

The informative document for people with SMI and their families, prepared by the CPG development group, was anonymously reviewed by people who suffer from SMI and their family members, introducing appropriate changes as a result of their comments.

The following scientific associations collaborated in the preparation of this CPG: Aragonese Mental Health Association-Spanish Neuropsychiatry Association, National Mental Health Nursing Association, Spanish Psychiatry Society, Aragonese Psychosocial Rehabilitation Association,

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FL Crítica Versión 1.0.7 OSTEBA. Health Technologies Assessment Service Department of Health Basque Government [http://www.euskadi.net/r33-2288/es/contenidos/informacion/metodos\\_formacion/es\\_1207/metfor.html](http://www.euskadi.net/r33-2288/es/contenidos/informacion/metodos_formacion/es_1207/metfor.html)

Aragon and La Rioja Psychiatry Society, represented by members of the development group, of the expert collaborators and external reviewers. The invaluable contribution of the Aragonese Pro Mental Health Association (ASAPME) and the Federation of Aragonese Pro Mental Health Associations (FEAFES-ARAGON) must also be mentioned.

An update of the CPG is planned every three years, and if new scientific evidence that modifies any of the recommendations it contains appears, the update will be made earlier. The updates will be carried out on the electronic version of the CPG, available on the GuiaSalud website (<http://www.guiasalud.es>).



## 4. Characteristics of the CPG

### 4.1. Definition of Severe Mental Illness

There are different ways of defining Severe Mental Illness. The most commonly agreed definition in bibliography,<sup>2,11</sup> has been used in this GPC, which considers three dimensions: clinical diagnosis, duration of the disorder (chronicity) and the level of social, family and labour disability of the person affected.

#### Diagnostic criteria

It includes psychotic disorders (excluding organic disorders). All the diagnostic categories included in SMI are considered as psychotic in the broad sense. This bears in mind not only the presence of positive and negative symptoms, but also a seriously altered pattern of relationships, inadequate behaviour for the context or serious inappropriate affectivity, which imply a distorted perception of reality. People who satisfy the diagnostic criteria of at least one of the following diagnostic categories, taken from the International Classification of Diseases ICDS-10 (WHO, 1992)<sup>12</sup> will be included.

- Schizophrenic disorders (F20.x)
- Schizotypal disorders (F21)
- Persistent delirious disorders (F22)
- Induced delirious disorders (F24)
- Schizoaffective disorders(F25)
- Other non-organic psychotic disorders (F28 and F29)
- Bipolar disorder (F31.x)
- Serious depressive episode with psychotic symptoms (F32.3)
- Recurrent serious depressive disorders (F33)
- Compulsive obsessive disorder (F42)

#### Duration of the disease

The criterion used to established SMI, was a 2-year or more evolution of the disorder, or progressive and marked impairment in functioning over the previous 6 months (abandonment of social roles and chronification risk), although the symptoms remit.

The disorder duration criterion attempts to distinguish that group of people who have prolonged duration disorders and rules out those cases that may present severe symptoms or diagnoses, but still have a short evolution time and therefore the prognosis is still not very clear. The NIMH4 criteria define the following criteria as an alternative:

- Having received more intensive psychiatric treatment than at outpatient level more than once throughout their lives.

- Having received continuous residential support other than hospitalisation for sufficient time so as to have significantly interrupted their life situations.

From the viewpoint of the duration of the illness, the CPG development group will consider any of the criteria mentioned as valid, assuming that the duration dimension of the illness is the dimension that presents the most weaknesses of the three and that many of the interventions included within this guideline are applicable to patients in initial stages of their disorders and that in a strict sense would not enter the concept of SMI. This CPG will pay attention to the consistency of this criterion in future reviews.

## Presence of disability

Defined by the moderate to severe affectation of personal, labour, social and family functioning, and measured through different scales, such as the Global Activity Assessment Scale (GAAS) with scores <50; and the WHO disability assessment scale (DAS-I) with scores >3 in all the items.

According to the definition of the NIMH<sup>4</sup>, this disability produces functional limitation in important activities of life and includes at least two of the following criteria either continuously or intermittently:

- Unemployment, or sheltered or supported employment, clearly limited skills or poor labour history.
- Need for public economic support to stay out of hospital and may require support to get this aid.
- Difficulties to establish or maintain personal social support systems. Need for help in daily living skills, such as hygiene, food preparation or management of finances.
- Inappropriate social behaviour that determines the intervention of the Mental Health System or the Judicial System.

In more recent formulations, this disability can be defined by the moderate to severe affection of labour, social and family functioning, and measured through the (GAAS), using as a cut-off value the score corresponding to light affections ( $\leq 70$ ) in the less restrictive cases or moderate (<50), which indicates considerable severity of the symptoms with serious affection in social functioning and competence.

The people that this CPG is aimed at are people who suffer from Severe Mental Illnesses and satisfy the three classification dimensions described above.

## 4.2. Definition of psychosocial rehabilitation concept

The concept of psychosocial rehabilitation falls within a space where there level of confusion and imprecision is considerable due to “*factors such as the polysemous nature of many of the terms that we use, the complexity of theoretic positions and practices and their differing level of development in general, and especially in our country*”<sup>14</sup>. Psychosocial rehabilitation, also called psychiatric rehabilitation consists in “*a series of psychosocial and social intervention strategies that complement the pharmacological interventions and management of the symptoms, and whose aim is to improve personal and social functioning, quality of life, and support to the community integration of people affected by severe and chronic mental illnesses*”<sup>11</sup>

The main focus of rehabilitation is the functioning of people in their normal environments, improving their personal and social skills, giving support for them to undertake the different roles of social and community life and, in short, to improve the quality of life of the persons affected and of their families, as well as support for their social participation in the community in the most active, normalised and independent way possible in each case. In other words, the aim of psychosocial rehabilitation is to help people with severe and persistent mental illnesses develop intellectual, social and emotional skills that they need to live, learn and work in the community with the least possible professional support<sup>15</sup>.

In this CPG, the importance of the psychosocial rehabilitation concepts is based on defining its field as a series of psychosocial interventions aimed at improving the autonomy and functioning of people in their environment and support to their normalised social integration and participation, and their role in the framework of a community service system that cares for this population. Thus, the term refers to a spectrum of psychosocial and social intervention programmes for people who continuously suffer from Severe Mental Illnesses.

Psychosocial rehabilitation, therefore, is an instrument made available to help people recover and its integration into the whole Mental Health Community Service System is necessary.

### 4.3. The concept of recovery

The SMI recovery concept has become a dominating concept in the health care system, but it lacks a consistent definition<sup>16</sup>. This refers more to the process of overcoming the illnesses than the mere control of symptoms, and going beyond the actual illness, it pursues a significant and satisfactory life. Recovery has been conceptualised as a process, as a result and as both at the same time. It involves the development of a new meaning and purpose in one's life as one surpasses the catastrophic effects of mental illness, and it does not just refer to the alleviation of symptoms, but also to social and personal competence in areas that the person defines as important<sup>17</sup>.

The recovery concept has been defined as *“the process where people are capable of living, working, learning and participating fully in their community”*<sup>18</sup>. Anthony *et al*<sup>19</sup> indicate that practices aimed at recovery recognise that people with mental illness have the same wishes and needs for work, accommodation, relationships and leisure as any other person who does not suffer from a mental illness.

Mental illness represents important changes that break with life expectations both on a personal level and in the environment, especially the family environment. The recovery concept shows the need to renew these life expectations, overcoming these changes through the different techniques that the services must provide. Any intervention based on the recovery model, increases its efficiency as it is aimed at recovering the person's meaning in life. It is, therefore, an integral conception of the interventions, which bears in mind people's lives, interests and motivation, and not just the efficiency of partial interventions.

Reintegration into society is a result that can be reached through the use of therapeutic mental health services, such as community psychiatry and rehabilitation, among others, as well as a political and community initiative, to promote solidarity and openness with respect to individuals who suffer from several mental illnesses. Recovery is neither a service nor a unitary result of the services; it is a personal status<sup>20</sup>. This term must be referred to in this CPG because it is an objective of psychosocial interventions, although it is difficult to find an operative universal definition of the term that is agreed by consensus.

## 4.4. Research into psychosocial interventions

The preparation of quality randomised control trials to be able to determine the possible effectiveness of the different interventions and psychosocial formats is complicated. This may be due in part to the type and complexity of the actual interventions referred to and to the ethical implications entailed. When a research study is proposed in this specific area, these limitations should be taken into account, considering the execution of good quality observational studies, which, although they fall below the RCTs in the evidence pyramid, can provide evidence about the effectiveness of some interventions, bearing in mind the limitations of these designs.

The use of qualitative research techniques, which are widely used in the field of social sciences and to a lesser extent, in health sciences, should also be considered, as they cover the compilation, analysis and interpretation of data that are difficult to reduce to numbers. This type of techniques permit studying contexts and interventions, which, due to their nature, are difficult to prove with quantitative techniques as is the case of some psychosocial interventions addressed in this CPG.

## 5. Psychosocial type rehabilitation interventions

As indicated by Gisbert *et al*<sup>11</sup> the aim of psychosocial rehabilitation interventions as part of the integral care of people with SMI is to overcome or compensate for the psychosocial and social integration difficulties that these people undergo, giving them support in their daily lives in the community in the most independent and decent manner, as well as in undertaking and handling the different roles and demands represented by living, working and mixing in different community environments.

This type of intervention focuses on the functioning of persons, improving their personal and social skills and providing support to the different roles undertaken in their social and community lives. All in all, they aim to improve the quality of life of people affected and their families, supporting their social participation in the community in the most active, normalised and independent possible way.

They are organised through an individualised process that combines, on the one hand, training and development of the skills and competences that each person requires to effectively function in the community and on the other hand, actions on the environment. It includes several aspects that vary from psychoeducation and advice to families to the development of social supports aimed at offering the necessary aid to compensate or strength the level of psychosocial functioning of chronic mental patients<sup>21</sup>.

Psychosocial interventions in rehabilitation have gained in operativity and efficiency with the incorporation of different extrapolated strategies, adapted from the field of psychology, social learning, behaviour modification, social intervention and human resources, including, among others: training and development of personal and social skills, psychoeducational and psychosocial intervention strategies with families and users, development of social networks, social support, etc. This series of psychosocial intervention strategies have proved to be efficient in improving the psychosocial functioning of people with SMI and in their adaptation and maintenance in the community<sup>11</sup>.

### 5.1. Psychological interventions

#### 5.1.1. Cognitive-behavioural therapy

Cognitive-behavioural therapy (CBT) is a psychological intervention that is based on the hypothesis that cognitive activity determines behaviour. Many differences can be found when approaching the cognitive aspects, as some of them focus on structures, beliefs or basic cases as the main causal entities of emotions and behaviour<sup>22,23</sup>, whilst others focus on processes such as problem-solving, cognitive distortions or thought content: self-instructions, automatic thoughts, etc.<sup>23,25</sup> In addition, there are important differences in the intervention strategies.

Despite these differences, the following characteristics, which they all have in common, can be pointed out:

- Behavioural change has been mediated by cognitive activities. In other words, the systematic alteration and identification of disadaptive cognitive aspects will produce the desired behavioural changes.
- The acceptance of reciprocal determinism between thought, environment and behaviour.
- The therapy is designed to help people identify, test reality and correct dysfunctional conceptions or beliefs. Patients are helped to recognise the connections between cognitions, affection and behaviour, together with their consequences, to make them aware of the role of images and negative thoughts on maintaining the problem.
- The techniques applied in this approach include cognitive restructuring, problem-solving, self-instructional training, etc. In general, environmental manipulations are used in cognitive-behavioural modification, as in other approaches, but here these manipulations represent information feedback tests or experiments that provide an opportunity for people to question, reassess and acquire self-control over disadaptive behaviour, feelings and cognitions, at the same time as they practice trained skills.
- The therapeutic relationship is collaborative and the active role of the client is emphasised<sup>26</sup>.

### ***Social Skills Training***

Social skills are understood as the specific response capacities required for effective social performance<sup>27</sup>. Social skills, therefore, are a series of behaviours carried out by an individual in an interpersonal context that express feelings, attitudes, desires, opinions or rights of that individual in a way that adapts to the situation, respecting that behaviour in others, and which generally solve the problems of the situation at the same time as they reduce the probability of future problems to a minimum<sup>28</sup>.

Social skills training consists in behavioural learning techniques that permit people with schizophrenia and other incapacitating mental disorders to acquire an interpersonal handling of the illnesses and independent living skills to improve their functioning in the community<sup>29</sup>. The module postulates that social competence is based on a set of three skills: social perceptions or reception skills, social cognition or processing skills and behavioural response or expression skills<sup>30</sup>. Following these premises, social skills training has been included in CBT because it is in this paradigm where work is mainly done on social skills of people with schizophrenia.

To be able to acquire this series of attitudes and behaviours, there are social skills training programmes that integrate structured psychosocial interventions, either in groups or individually, or both, created to improve social behaviour and reduce the stress and difficulty in handling social situations. The components of the social skills training procedure are derived from the basic principles of learning that include operational conditioning, experimental analysis of behaviour, the theory of social learning, social psychology and social cognition<sup>29</sup>.

There are four key components:

- Meticulous behavioural assessment of a list of interpersonal social skills.
- Emphasis on both verbal and non-verbal communication.
- Training focused on the individual's perception and on the processing of relevant social situations, as well as the individual's ability to offer adequate social reinforcements.
- Work done at home, as well as the interventions that are carried out in the clinic<sup>8</sup>.

From another point of view, social skills training can be based on three models: the basic model based on corrective learning, social problem-solving and cognitive rehabilitation<sup>27</sup>. There are very few definitions in literature of any of these three approaches, with respect to their effects on the generalisation of behaviours and the improvement in social functioning<sup>31</sup>.

The grounds for using social skills training in schizophrenia are based on multiple empiric and conceptual sources. Social skills and social competence can be considered as protective factors within the stress-vulnerability diathesis model for schizophrenia. Reinforcing the skills and social competence of people with schizophrenia -together with other evidence-based interventions- reduces and compensates the harmful effects of the cognitive deficit, neurobiological vulnerability, stressful events and social maladjustment<sup>29</sup>.

#### **Question to be answered**

- Is cognitive behavioural therapy-based psychological intervention effective in the treatment of people with SMI?

The studies found analyse the effectiveness of CBT either aimed at people with SMI and a diagnosis of schizophrenia and related disorders or at people with SMI and a diagnosis of bipolar disorders. No studies have been found that discriminate psychosocial interventions for severe compulsive obsessive disorder or Severe Mental Illnesses as only population.

#### ***Cognitive-behavioural therapy (CBT) for people with SMI and a diagnosis of schizophrenia and related disorders***

Jones *et al*<sup>32</sup> perform a SR comprised of 19 RCTs; quasi-randomised studies were excluded. No trial was able to use a double-blind experiment, due to the difficulties inherent to the concealment process in psychosocial interventions. Out of all the RCTs, 7 studies tried to reduce any resulting bias by using assessors who were unaware of the designation. The duration of the trials varied between 8 weeks<sup>33</sup> and 5 years<sup>34</sup>, but the average duration was approximately 20 months.

The 19 trials focused their study on people with psychosis, such as schizophrenia, delirium disorder or schizoaffective disorder, and they all used operative criteria for the diagnoses (DSM III-R, DSM-IV or ICD-10). It was reported that many people suffered other comorbid mental disorders such as depression or anxiety disorder. In only one trial, the duration of the illness was less than 5 years<sup>35</sup>. Some authors intentionally selected people with medication-resistant symptoms<sup>36,37</sup>. The ages of the participants varied between 18 and 65 years old.

The following interventions are assessed in this review:

- Cognitive-behavioural therapy: this has been used to make reference to different interventions, so the reviewers prepared the following specific criteria to be able to define a cognitive-behavioural intervention as such:
  - The intervention must represent the establishment of relationships between thoughts, feelings and actions of the person with respect to the symptom in question.
  - It must also represent the correction of false perceptions, irrational beliefs and reasoning biases of the person in connection with the symptom in question.
  - It must involve at least one of the following conditions: Control by the person of his or her thoughts, feelings and behaviours related to the symptom in question, and the proposal of alternatives to cope with it.

- Standard treatment: the treatment that a person normally received, if he or she were not included in the research trial. The “standard care” category also includes “control groups on waiting list”, where participants receive pharmacological treatment or other interventions.
- Specific medication: when the control group receives a specific drug compared with CBT.
- No intervention: control groups without treatment.
- Additional pharmacological interventions: when the standard treatment has been complemented with additional medication.
- Other psychosocial interventions: when the standard treatment has been complemented with additional social or psychological interventions, such as non-directive therapy, supportive therapy and other conversation therapies.

From all of the RCTs included in the review of Jones *et al*<sup>32</sup>, those obtained to answer this section come from just 9 RCTs<sup>33-35,37-42</sup>. The development team of this CPG decided to exclude the other RCTs from the review by Jones *et al* because it considered that they did not afford data that could be of interest to this topic.

The NICE CPG on Schizophrenia<sup>8</sup>, which contains a SR by Pilling *et al*<sup>43</sup> was also included, from whose 8 RCTs, NICE includes 7 (the RCT by Carpenter *et al*<sup>44</sup> was excluded because the definition that they had proposed did not coincide with theirs) and a further 6 RCTs were added. A total of 13 RCTs (n = 1297) were included.

All the participants in the study also received antipsychotics and the cognitive-behavioural treatment was offered mainly to the people with a longer illness evolution time or who were more resistant to the treatment. The control group receives standard care, recreational activities or advice.

The CBT studies included in this review used trained therapists, with regular supervision and using therapy manuals, with the exception of Turkington *et al*<sup>45</sup>, who had a 10-day training programme for a group of nurses specialised in psychiatry.

Finally, a meta-analysis by Zimmerman *et al*<sup>46</sup> was selected, which includes 14 studies (n = 1484), published between 1990 and 2004. From all the studies, 11 provided follow-up data. A total of 54 people took part in the early follow-up analyses (3-12 months) (256 with CBT compared with 284 receiving another treatment and a total of 353 people took part in the late follow-up analyses (more than 12 months) (127 of them with CBT compared with 226 receiving another treatment). The inclusion criteria used in the meta-analysis were that the comparisons were CBT vs. control group (waiting list, usual treatment or another therapeutic treatment); the people satisfied DSM-III R or DSM-IV criteria for schizophrenia, schizoaffective disorder or delirium disorder; that the studies were completed between 1990 and 2004, and that the results had statistical information.

The development group of this CPG decided to exclude the data referring to acute symptomatology from this review and extract those defined for chronic cases.

### ***Social skills training in people with SMI and a diagnosis of schizophrenia and related disorders***

The contributions of the NICE CPG on Schizophrenia<sup>8</sup>, which includes the Pilling *et al*<sup>47</sup> review, were taken into account in this sub-section, with the addition of one RCT<sup>33</sup>. All the controls were

defined as “standard care” or “discussion groups”. The studies included varied with respect to the duration of the treatment (from 4 weeks to 2 years), follow-up (from 6 months to 2 years), place of treatment (outpatients, hospitalised, day or mixed), and sex of the participants (mixed or all the participants were males). All the studies come from the Anglo-Saxon field.

The Kurtz and Mueser<sup>48</sup> review was also taken into account, which assesses the effects of social skills on people with schizophrenia or schizoaffective disorders and they are compared with other active therapies or standard intervention. Social skills training, to be considered an intervention, must include behavioural techniques such as instructions on skills, role play, training, and positive or negative feedback.

23 randomised studies (n = 1599) are included in this review and the effects magnitudes are differentiated for different proximal (such as the execution of trained skills), intermediate (such as social functioning) or distal (such as relapses) measurements.

There seems to be a divergence among the studies chosen regarding the force of the recommendation or the effect magnitude. This leads to divergences as occurs in the case of the data provided by the NICE Schizophrenia CPG<sup>8</sup>, which does not detect any evidence to support this intervention that is advised in the PORT criteria<sup>49</sup>. Kurtz and Mueser<sup>48</sup> argue that the Pilling *et al*<sup>47</sup> study, which the NICE Schizophrenia CPG<sup>8</sup> is based upon, is more restrictive and mixes distal measurements with proximal measurements, thus making it more difficult to find significant effects. Furthermore, the Kurtz and Mueser<sup>48</sup> review is later than the NICE Schizophrenia CPG<sup>8</sup> and includes more studies.

Measuring isolated symptoms is not sufficient to reflect significant results. To assess long-term results, it is essential to have information on the social situation of the people; namely, assess how they live, how they function in society and how they undertake their different roles, placing importance on distant (distal) and costly results compared with nearer (proximal) psychopathological results<sup>50</sup>.

The development group of this CPG chose to include both studies as it considered that they are congruent and complementary in many aspects due to the varied measurement approach they offer. The impact of this intervention is determined on the one hand by the low effect on distal measurements detected and by the population it addresses. The impact may be low if the intention is for it to be an intervention aimed at preventing relapses because the target population may present other types of problems, and the impact may be higher if the intention is to improve the psychosocial functioning.

### ***Problem-solving therapy in people with SMI and a diagnosis of schizophrenia and related disorders***

The problem-solving therapy is considered as a brief and focused form of psychotherapy. It involves holding a few practical sessions where the therapist organises a process with the patients to identify their more immediate problems and they design agreed tasks and ways of solving them. Problem-solving therapy has a cognitive and behavioural component, it tries to establish a link initially between the symptoms and the practical difficulties to be developed in several stages (explanation about the therapy and its fundamentals, identification and breakdown of the problem, establishing accessible objectives, generating solutions, assessing them, implementing them and assessing the result of the solution implemented).

The main objectives of the therapy are to make the people have a better understanding about the relationship between their symptoms and their problems, increasing their capacity to define

current problems and identify the resources available to address the problem, teaching them a specific procedure to solve the problem in an organised fashion, increasing their confidence and self-control in a problematic situation and preparing them for future problems.

Xia *et al* carry out a systematic review on the effectiveness of problem-solving therapy and compare it with other equivalent therapies or with normal care for people with schizophrenia. Three RCTs (n = 61) are identified, of which, in two, although said to be randomised, no randomisation or blinding methods are indicated.

### ***Motivational interview***

Cleary *et al*<sup>52</sup> perform a systematic review (including 25 RCTs) within cognitive-behavioural therapy (search period until April 2006), in order to assess the effect of psychosocial interventions on the reduction of substance consumption in people with SMI (schizophrenia, bipolar disorder or depression). Five of the RCTs<sup>53-57</sup> included provide information with respect to efficiency of the motivational interview in connection with the improvement of the mental aspect or consumption reduction.

The studies selected, to be able to respond to this subsection of the question, have a good level of generalisation to the population of the CPG, as the participants are, in their majority, people with schizophrenia and/or schizoaffective, diagnosed with DSM and ICD criteria and in adult population.

The population size is significant and the effect magnitude is moderate in the majority of the studies, so the impact that this type of intervention may have on the Spanish National Health System may be significant if the subtype of patients the intervention is aimed at and its characteristics (duration, number of sessions, etc.) is well defined.

### ***Cognitive-behavioural therapy (CBT) for people with SMI and a diagnosis of bipolar disorder (BD).***

For this population group, the data obtained by the Beynon *et al*<sup>58</sup> SR are used, including 20 RCTs or quasi-randomised studies, with at least 3 months' follow-up, of which only 5 assessed CBT. The patients were type I BD, combined type I and II patients; none presented just type II patients. The data that were extracted from this review are those provided by the Cochran<sup>59</sup> RCT.

The NICE Bipolar Disorder CPG7 has also been taken into account, which included 5 studies (one of them not published)<sup>60-63</sup>. The majority of these studies chose euthymic patients who were well-maintained with medication, and a proportion of patients in acute phase were included in the Scott *et al*<sup>63</sup> study, as well as some patients without medication. The data provided by this author were obtained by excluding those patients who were in the acute phase.

### ***Cognitive-behavioural therapy for people who suffer SMI and a diagnosis of schizophrenia and related disorders.***

Cognitive-behavioural therapy (BCT) + standard treatment (ST) vs standard treatment (ST)

#### ***Relapses/readmissions***

CBT administered with standard treatment, compared with standard treatment alone did not significantly reduce the rates of relapse or hospital re-admission in the mid-term (1 RCT; n = 61; RR 0.1; 95% CI: between 0.01 and 1.7)<sup>38</sup> nor in the long term (4 ; n = 357; RR = 0.8; 95% CI: between 0.5 and 1.5)<sup>32</sup>

RCT (1-)  
SR (1-)

### *General global state*

In the short run, a difference was observed in favour of CBT in agreement with the measurements carried out with the Global Assessment Scale (GAS) when compared with standard treatment. (2 RCT; n =100; WMD = 7.58; 95% CI: between 2.93 and 12.22; p = 0.001)<sup>32</sup>; in mid-term (1 RCT; n = 67; WMD = 12.6; 95% CI between 5.8 and 1.43; p = 0.0003)<sup>39</sup>; in the long term this effect was no longer significant (2 RCT; n = 83; WMD = 4.51; 95% CI: between -0.3 and 9.32; p = 0.07)<sup>32</sup>.

SR (1-)  
RCT (1-)  
SR (1-)

### *Mental state*

In the “no clinically significant improvement” measurement, the combined data showed a significant difference in favour of CBT administered with standard treatment, compared with standard treatment alone, when this result was measured between weeks 13 and 26 ( 2 RCT; n = 123; RR = 0.7; 95% CI between 0.6 and 0.9; NNT = 4; 95% CI between 3 and 9) The difference was no longer significant after one year (5 RCT; n = 342; RR = 0.91; 95% CI between 0.74 and 1.1)<sup>32</sup>

SR (1-)

Scores for general symptoms: No significant differences were observed in the short or medium term when CBT administered with standard treatment was compared with standard treatment alone (short term; 2 RCT; n = 126; WMD = 0.05; 95% CI: between -2.9 and 3; p = 1)<sup>32</sup>; (medium term, 1 RCT; n = 52; WMD= -1.7; 95% CI: between -5.4 and -0.2; proof of the global effect = -0.90; p = 0.4)<sup>40</sup>. However, after 18 months a statistically significant improvement was observed in the people assigned to CBT (1 RCT; n = 47; WMD = -4.7; 95% CI: between -9.2 and -0.2; p = 0,04)<sup>40</sup>

SR (1-)

RCT (1-)

Specific symptoms: When groups with specific symptoms were assessed, in the case of hallucinations a significant effect was observed in the long term in favour of CBT combined with standard treatment ( 1 RCT; n= 62; RR = 0.53; 95% CI: between 0.3 and 0.9)<sup>34</sup>

RCT (1-)

No effect of CBT was observed in the conviction of delusional beliefs during the same period of time (1 RCT, n = 62; RR = 0.8; 95% CI; between 0.4 and 1.3)<sup>34</sup>

Two trials described significant effects in favour of cognitive-behavioural therapy when the subscales of the PANSS were considered. A significant effect was observed for the positive symptoms (2 RCT; n = 167, WMD = -1, 95% CI: between -1.9 and -0.04; proof of the global effect = -2.04; p = 0.04), the negative symptoms (2 RCT; n = 167; WMD = -2.3; 95% CI: between -3.8 and -0.8; proof of the global effect = -3.05; p = 0.002), the global symptoms (2 RCT; n = 167; WMD = -2.59; 95% CI: between -4.91 and -0.3; proof of the global effect = -2.20 and p = 0.03)<sup>32</sup>

SR (1-)

### *Quality of life*

No significant effects were observed in the quality of life according to the *Quality of Life Scale* (1 RCT, n = 40, WMD = 9.7; 95% CI: between -3.2 and 2.2; proof of the global effect = 1.47; p = 0.14)<sup>33</sup>

RCT (1-)

### *Social functioning*

RCT (1-) One study informed of the results obtained from using the 7 subscales of the *Social Functioning Questionnaire*. No significant effects were observed for the withdrawal (n = 133; WMD = 0.54; 95% CI: between -0.4 and 1.5), interpersonal behaviour (n = 133; WMD = 0.5; 95% CI: between -0.1 and 1.2), independence (performance) (n = 133; WMD = 1.9; 95% CI: between -0.2 and 4), independence (competence) (n = 133; WMD = -0.3; 95% CI: between -1.5 and 1), recreation (n = 133; WMD = 1.17; 95% CI: between -0.7 and 3), or employment (n = 133; WMD = 0.9; 95% CI: between -0.2 and 2) However, a significant effect was observed in favour of CBT for prosocial behaviour (n = 133; WMD = 4.9, 95% CI: between 2 and 7.7)<sup>41</sup>

Cognitive-behavioural therapy (BCT) + standard treatment (ST) vs supportive psychotherapy + standard treatment (ST).

### *Relapses*

RCT (1-)  
SR (1-) The studies found no significant differences in the relapse ratios between CBT and supportive psychotherapy, in the medium term (1 RCT; n = 59; RR = 0.6; 95% CI: between 0.2 and 2; proof of the global effect = -0.75; p = 0.5), or long term (2 RCT; n = 83; WMD = 1.1; 95% CI: between 0.5 and 2.4; proof of the global effect = -0.12; p = 0.9)<sup>32</sup>

RCT (1-) One RCT informed of data based on the GAF scale and found no significant effects, either (1 RCT; n = 30, WMD = -0.5; 95% CI: between -7.6 and 6.6; proof of the global effect = -0.14; p = 0.9)<sup>42</sup>

### *Mental state*

RCT (1-)  
SR (1-) CBT did not significantly improve the clinically significant improvement ratios in the mid term (1 RCT; n = 59; RR = 0.8; 95% CI: between 0.6 and 1.1; proof of the global effect = -1.60, p = 0.11)<sup>38</sup> or in the long term (2 RCT; n = 100; RR = 0.9; 95% CI: between 0.8 and 1.1; proof of the global effect = -0.62; p = 0.5)<sup>32</sup>

RCT (1-) Scores for general symptoms: In a continuous measurement of the mental state (measured with the BPRS scale) no significant differences were found between CBT and supportive psychotherapy in the short term (1 RCT; n = 20; WMD = 8.5; 95% CI: between -3 and 20; proof of the global effect = 1.42; p = 0.16)<sup>35</sup>

RCT (1-) However, significant differences were observed in the medium term in favour of CBT (1 RCT; n = 37; WMD = -7.6; 95% CI: between -14 and -0.9; p = 0.03)<sup>37</sup>

RCT (1-) In the total score of the *Positive and negative syndrome scale* (PANSS), in one study no significant short-term effects were found (1 RCT; n = 149; WMD = 1.8; 95% CI: between -4.0 and 7.6; proof of the global effect = 0.60, p = 0.5)<sup>64</sup> or in the long term (1 RCT n = 40; WMD = -6.5, 95% CI: between -18.9 and 5.9; proof of the global effect = -1.02; p = 0.3)<sup>42</sup>

Specific symptoms: when CBT was compared with other psychological treatments, no positive effect was observed in the improvement of delirium (1 RCT, n = 40; WMD = 1.4; 95% CI: between -2.3 and 5.1; proof of the global effect = 0.74; p = 0.5), but it was found with respect to hallucinations (1 RCT; n = 40; WMD = 1.24; 95% CI: between 2.1 and 4.6; proof of the global effect = -0.12; p = 0.9)<sup>42</sup>

## Cognitive-behavioural therapy (BCT) vs standard treatment (ST)

### *Relapses*

There is not sufficient evidence to determine if CBT improves relapses when compared with standard care (routine care, *Case Management* and medication) during treatment (n = 121; RR = 0.88, 95% CI: between 0.46 and 1.66), when compared with standard care 12 months after treatment (n = 61; RR = 1.51; 95% CI: between 0.79 and 2.87) and 1-2 years after treatment (n = 154; RR = 0.83, 95% CI: between 0.6 and 1.13)<sup>8</sup> SR (1+)

Longer-lasting CBT programmes (more than 3 months) reduce relapses, compared with other interventions (n = 177; RR = 0.72, 95% CI: between 0.52 and 0.99; NNT = 7; 95% CI: between 4 and 100)<sup>8</sup>

### *Symptoms*

There is certain evidence that indicates that CBT, when compared with ST, reduces symptoms at the end of the treatment (there is no significant improvement taken as the reduction of 40% in the total score of the BPRS scale or as the reduction of 50% in the positive symptoms of the BPRS scale (n = 121; RR = 0.78; 95% CI: between 0.66 and 0.92; NNT = 5; 95% CI: between 4 and 13)<sup>8</sup> SR (1-)

CBT improves the mental state when compared with standard treatment at the end of the treatment (final scores of the PANSS/BPRS/CPRS scales: n = 580; SMI = -0.21; 95% CI: between -0.38 and -0.04)<sup>8</sup> SR (1+)

There is not sufficient evidence that indicates that CBT reduces symptoms when compared with other psychological interventions at the end of the treatment (there is no significant improvement when measured as the reduction of 50% in positive symptoms of the BPRS scale: n = 121; RR = 0.76; 95% CI: between 0.62 and 0.93; NNT = 5; 95% CI between 3 and 15), nor at 9-12 months after treatment (there is no important improvement, taken as the reduction of 20% in the total score of the BPRS scale or 20% in the reduction of the score of the positive symptoms of the BPRS scale: n = 149; RR = 0.79; 95% CI: between 0.63 and 1.00)<sup>8</sup> SR (1-)

### *Persistent Symptomatology*

It is not possible to determine if CBT reduces symptoms after 9 months' follow-up (there is no important improvement when measured as a 20% reduction in BPRS: n = 60; RR = 0.53; 95% CI: between 0.35 and 0.81; NNT = 3, 95% CI between: 2 and 6)<sup>8</sup> SR (1-)

SR (1+) There is strong evidence that indicates that CBT improves the mental state in post-treatment assessment (BRPR, CPRS scales: n = 182; SMI = -0.56; 95% CI: between -0.85 and -0.26)<sup>8</sup>

*Social functioning*

SR (1-) There is limited evidence of improvement when CBT is compared with non-standard care at the end of treatment (Role functioning scale: n = 15; WMD = -4.85; 95% CI: between -7.31 and -2.39)<sup>8</sup>

Cognitive-behavioural therapy (CBT) vs other treatments

SR (1-) In the systematic review of Zimmermann *et al*<sup>46</sup>, that compares CBT with other treatments in the improvement of the positive symptoms, the results indicate that CBT reduces positive symptoms when compared with other treatments, and that the benefit was greater for patients with acute episodes than for chronic patients. CBT vs. non specific treatment: chronic (5 studies; n = 246; RR = 0.32; 95% CI: between 0.06 and 0.57); and CBT vs. usual treatment (medication): chronic (6 studies; n = 569; RR = 0.26; 95% CI: between 0.09 and 0.43).

***Social Skills Training (SST)***

Social skills training vs standard treatment (ST) or other treatments

*Relapses/readmissions*

SR (1-) There is no clear evidence to show that social skills training vs. standard treatment reduces relapses or readmissions (n = 64; RR = 1.14; CI 95%: between 0.52 and 2.49 or when compared with other treatments (n = 80; RR = 0.94; 95% CI: between 0.63 and 1.40)<sup>47</sup>

*Improvement of the quality of life*

RCT (1-) It is impossible to determine that social skills training, when compared with standard treatment, improves people's quality of life ((n = 40; WMD = -9.67, CI 95%: between -22.56 and 3.22)<sup>33</sup> or when compared with other treatments (n = 80; WMD = -0.09; CI 95%: between -0.42 and 0.24)<sup>47</sup>

*Social functioning*

RCT (1-) There is no evidence to show that social skills training, when compared with standard treatment, improves social functioning (*Behavioural Assessment Task Scale*: n = 40; WMD = -2.61, 95% CI: between -4.56 and 0.66)<sup>33</sup>

*Mental state*

RCT (1-) There are no differences between social skills training or standard treatments with respect to the improvement of the mental state (BPRS: n = 40; WMD = -7.18; 95% CI: between -13.62 and -0.74); (SANS: n = 40; WMD = -8.03, 95% CI: between -15.27 and -0.79)<sup>33</sup>

In the systematic review by Kurtz and Mueser<sup>48</sup> which compares social skills training with other active therapies or ST, it indicates that the ES (Effect Size) obtained in the different measurements (from proximal or execution of trained skills, to distal, which entails the improvement and absence of relapses) were as follows: SR (1+)

There is no difference in the execution of trained skills (7 studies, n = 330): ES: 1.20, (95% CI: 0.96 to 1.43). There is some significance in favour of social skills training in the other measurements: social skills and daily living (7 studies, n = 481): ES: 0.52, (95% CI: Between 0.34 and 0.71); Social functioning (7 studies, n = 371): ES: 0.52, (95% CI: between 0.31 and 0.73); negative symptoms (6 studies, n = 363): ES: 0.40, (95% CI: between 0.19 and 0.61); Other symptoms 10 studies, n = 604): ES: 0.15, (95% CI: between -0.01 and 0.31); Relapses (9 studies, n = 485): ES: 0.23, (95% CI: between 0.04 and 0.41)

### ***Problem-solving in people with SMI and a diagnosis of schizophrenia and related disorders***

#### **Problem-solving vs. standard treatment (ST)**

Xia *et al*<sup>51</sup> indicate that there are no differences between problem-solving and ST with respect to (1 RCT, n = 12) the problem-solving capacity (RR = 0.20; 95% CI: between 0.03 and 1.2), aggressive behaviour (RR = 0.09; 95% CI: between 0.01 and 1.35), interaction with staff (RR = 0.09; 95% CI: between 0.01 and 1.35), interaction with companions (RR = 0.54; 95% CI: between 0.22 and 1.11) SR (1+)

#### **Problem-solving vs. coping skills**

No differences were detected either between problem-solving and coping skills in the following parameters:

- Number of admissions (1 RCT; n = 14, RR = 3.00; 95% CI between 0.14 and 63.15). SR (1+)
- 50% reduction of score in the BPRS scale after treatment (1 RCT; n = 27, RR = 0.42; 95% CI: between 0.14 and 1.21) or after 6 months (1 RCT; n = 23, RR = 0.87; 95% CI: between 0.31 and 2.44)
- Early abandonment of study (1 RCT; n = 16, RR = 1.00; 95% CI between 0.07 and 13.37)<sup>51</sup>

### ***Motivational interview in cognitive-behavioural therapy (CBT)***

#### ***Cognitive-behavioural therapy + motivational interview vs. standard treatment***

When the motivational interview is included in CBT and it is compared with standard treatment, no differences were found in the consumption of substances between either of the interventions in people with SMI who consume different types of drugs after 3 months (n=119, WMD=0.37; 95% CI: between -0.01 and 0.8) or 6 months after the intervention (n=119, WMD=0.19; 95% CI: between -0.2 and 0.6)<sup>57</sup> RCT (1-)

No improvement was found either in the mental state between the two groups (measured with the PANSS scale; (n=32, WMD= -6.59; 95% CI: between -16.0 and 2.09)<sup>56</sup> RCT (1-)

### *Motivational interview vs. standard treatment*

- RCT (1-) However, when the motivational interview alone is compared with standard treatment in SMI people, it appears to be efficient in obtaining alcohol abstinence 6 months after the intervention (n = 28; RR = 0.36; 95% CI: between 0.2 and 0.8; NNT = 2)<sup>53</sup>
- RCT (1-) With respect to the improvement of the mental state, no differences were found between the motivational interview alone and standard treatment (1 RCT; n = 30; WMD = -4.2; 95% CI: between -18.7 and -10.3)<sup>54</sup>
- RCT (1-) The motivational interview appears to be more efficient than standard treatment in the achievement of a greater percentage of follow-ups after the intervention (n = 93; 58% vs. 84%; RR = 0.69; 95% CI: between 0.5 and 0.9; NNT = 4)<sup>55</sup>

### ***Cognitive-behavioural therapy (CBT) for people with SMI and a diagnosis of bipolar disorder (BD).***

#### Cognitive-behavioural therapy (BCT) vs. standard treatment (ST)

##### *Relapses*

- RCT (1+) In one RCT where there is a 30-month follow-up, no significant differences were found to prevent maniac relapses (n = 103; OR = 0.48; 95% CI: between 0.21 and 1.13), but for depressive relapses, significant differences were found (OR = 0.32; 95% CI: between 0.13 and 0.74)<sup>61</sup>

##### *Readmissions*

- RCT (1-) No statistically significant differences have been found in the reduction of readmissions between either of the two interventions (n = 28; OR = 0.30; 95% CI: between 0.05 and 1.91)<sup>59</sup>

#### Cognitive-behavioural therapy (BCT) + standard treatment (ST) vs. standard treatment (ST)

##### *Social functioning*

- RCT (1+) Two studies by the same author found that there is no evidence that determines which intervention is more effective at 6 months' follow-up (n = 103; WMD = -0.13; 95% CI: between -0.37 and 0.1)<sup>60,61</sup>. Nor at 18 months (n = 68; WMD = -0.3; 95% CI between -0.5 and -0.1), nor at 24 months (n = 71; WMD = -0.2; 95% CI: between -0.46 and 0.06)<sup>61</sup>

##### *Readmissions*

- RCT (1+) There is certain evidence in favour of CBT in connection with readmissions (n = 103; RR = 0.42; 95% CI: between 0.23 and 0.8) 12 months after having begun the treatment<sup>61</sup>

##### *Relapses*

- RCT (1+) There is moderate evidence in favour of CBT compared with standard treatment with respect to the presence of relapses 6 months after the start of treatment (n = 155; RR = 0.61; 95% CI between 0.41 and 0.91)<sup>61</sup>, 12 months after the start of the study (n = 180; RR = 0.62; 95% CI: between 0.39 and 0.98)<sup>60,61</sup>, and after 30 months (n = 103; RR = 0.79; 95% CI: between 0.63 and 0.99)<sup>61</sup>

## Summary of evidence

	<b>People with SMI and a diagnosis of schizophrenia and related disorders</b>
1-	CBT + ST vs. ST does not reduce the rates of relapses or readmissions in the medium <sup>38</sup> or long term <sup>32</sup> .
1-	An improvement in the global state of people with SMI and a diagnosis of schizophrenia and related disorders is observed when they receive CBT in the short <sup>32</sup> and medium term <sup>39</sup> . However, this effect is no longer significant in the long term <sup>32</sup> .
1-	The application of CBT together with standard treatment is more effective in the improvement of the clinical state than when only standard treatment is applied. However, this difference was no longer significant after one year's treatment <sup>32</sup> .
1-	There are no differences between CBT + ST vs. ST in general symptoms in short <sup>32</sup> medium term <sup>40</sup> . However, there is an improvement after 18 months in favour of the CBT group <sup>40</sup> .
1-	In the case of hallucinations, CBT + ST vs. ST favours specific symptoms in the long term <sup>34</sup> .
1-	No effect was observed between CBT + ST vs. ST respect to the conviction of delusional beliefs <sup>34</sup> .
1-	There is a positive effect in favour of CBT + ST vs. ST in connection with positive and negative symptoms and global symptoms <sup>32</sup> .
1-	No significant differences have been found between CBT + ST vs. ST with respect to the improvement of quality of life <sup>33</sup> .
1-	There are no differences between CBT + ST vs. ST in the social functioning of people who suffer SMI and a diagnosis of schizophrenia and related disorders with respect to isolation, interpersonal behaviour, independence in performance and competence. However, there is a positive effect in favour of CBT for prosocial behaviours <sup>41</sup> .
1-	No differences have been observed between CBT + ST vs. Supportive psychotherapy + ST with respect to medium <sup>42</sup> or long <sup>32</sup> term relapse ratios.
1-	There are no differences between CBT + ST vs. Supportive psychotherapy + ST respect to clinical improvements in medium <sup>38</sup> or long term <sup>32</sup> . However, with respect to general symptoms, there are no significant differences in favour of CBT in the short term <sup>35</sup> , but there are in the medium term <sup>37</sup> .
1-	There are no differences between CBT + ST vs. supportive psychotherapy + ST in connection with the improvement of negative and positive symptoms in the short <sup>64</sup> or long <sup>42</sup> term.
1-	When CBT is compared with other psychological interventions, no improvement is observed in the specific symptoms with respect to delirium, but there is with respect to hallucinations <sup>42</sup> .
1+	There is not sufficient evidence to indicate that CBT when compared with ST reduces relapses during treatment, or 12 months or 2 years after finishing treatment.
1+	CBT programmes lasting for more than 3 months reduce relapses <sup>8</sup> .
1-	CBT, when compared with ST, reduces the symptoms at the end of the treatment <sup>8</sup> .
1+	BT, when compared with ST, improves the mental state at the end of the treatment <sup>8</sup> .

1-	There is no evidence of improvement in symptoms when CBT is compared with other psychological interventions at the end of the treatment and 9 to 12 months after it has ended <sup>8</sup> .
1-	There is no evidence that indicates that CBT reduces persistent symptoms after 9 months' follow-up, when compared with ST <sup>8</sup> .
1+	CBT, when compared with ST, improves the mental state (persistent symptomatology) after treatment <sup>8</sup> .
1-	There is limited evidence that indicates that CBT produces an improvement in social functioning of people with SMI and diagnosis of schizophrenia or related disorders <sup>8</sup> .
1-	When CBT is compared with other treatment, greater benefit is found in the reduction of positive symptoms in patients with acute episodes than in chronic patients <sup>46</sup> .
	<b>Social skills training in people with SMI and a diagnosis of schizophrenia and related disorders</b>
1-	There is no clear evidence that indicates that, when social skills training is compared with ST or with other treatments, it reduces relapses or readmissions <sup>47</sup> .
1-	It is impossible to determine that social skills training, when compared with ST, improves the quality of life <sup>33</sup> or when compared with other treatments <sup>47</sup> .
1-	There is no evidence that indicates that social skills training, when compared with ST, improves social functioning <sup>33</sup> .
1-	There are no differences between social skills training vs. ST with respect to the improvement of the mental state <sup>33</sup> .
1+	Training in social skills produces an improvement in the daily living skills, social functioning, negative symptoms and relapses, when compared with other active therapies <sup>48</sup> .
	<b>Problem-solving in people with SMI and a diagnosis of schizophrenia and related disorders</b>
1+	No differences were detected between problem-solving and standard treatment with respect to the ability to solve problems, aggressive behaviour, interaction with professional staff and with companions <sup>51</sup> .
1+	No differences were detected either between problem-solving and coping skills in connection with the number of admissions and reduction of the score in the BPRS scale after treatment <sup>51</sup> .
	<b>Motivational interview in CBT</b>
1-	When the motivational interview is included in CBT and compared with standard treatment, no differences were found between either of the two interventions in the consumption of substances in people who consume drugs 3 months or 6 months after the intervention <sup>57</sup> . No improvement in the mental state in either of the two groups was also found. <sup>56</sup>
1-	However, when the motivational interview alone is compared with standard treatment in people with SMI, the motivational interview appears to be efficient in alcohol abstinence 6 months after the intervention <sup>53</sup> and there is greater follow-up after the intervention <sup>55</sup> .
1-	There are differences between the motivational interview alone and standard treatment in the improvement of mental state <sup>54</sup> .

<b>People with SMI and a diagnosis of bipolar disorder</b>	
1+	There are no differences between CBT and ST regarding prevention of maniac relapses, but there are differences when avoiding depressive relapses in favour of CBT (30 months follow-up period) <sup>61</sup> .
1-	There are no differences between CBT and ST in the reduction of hospital readmissions <sup>59</sup> .
1+	When comparing CBT + ST with ST alone, no differences have been found that determine which intervention is more effective in connection with social functioning at 6 <sup>60,61</sup> , 18 or 24 <sup>61</sup> months' follow-up.
1+	When CBT + ST are compared only with ST, it improves the readmissions and relapses at 6 <sup>61</sup> , 12 <sup>60,61</sup> and 30 <sup>61</sup> months after starting the treatment.

### Recommendations

C	In people with SMI, cognitive behavioural treatment can be used combined with standard treatment to reduce positive symptomatology, mainly hallucinations.
C	People with SMI and persistent positive symptomatology can be offered a specific cognitive behavioural-orientated psychological intervention for this pathology, lasting for a prolonged period of time (more than one year), in order to improve the persistent symptomatology.
C	Incorporate cognitive therapy into the strategies aimed at preventing relapses of depressive symptomatology in people with SMI and diagnosis of bipolar disorder.
B	When the main objective of the intervention in people with SMI is to improve their social functioning, it is advisable to incorporate social skills training.
	There is not sufficient evidence to make recommendations in the problem-solving area for people with SMI and a diagnosis of schizophrenia and related disorders.

## 5.1.2. Psychodynamic psychotherapies and psychoanalytical approach

In individual therapy, psychoanalytical principles are applied that have evolved from basic theoretic-technical principles of psychoanalytical treatment, so normally, the treatment is called psychodynamic psychotherapy or psychoanalytical counselling. The central part of these treatments is the analysis of the transfer that arises in the relationship between the patient and the therapist, the observation of the countertransference reactions and the processes related to this phenomenon. The studies must be orientated towards the patients' needs, and the starting point must be the patient's needs and not the investigator's needs<sup>65</sup>

In the article by Bachmann *et al*<sup>66</sup> on psychological treatment for psychosis, it indicates that psychodynamic and psychoanalytical approaches have common fields even though they are different. There are three main models in psychodynamic approach: the concept of conflict-defence, the concept of ego impairment and the concept of self-object representations.

Currently there is agreement in the following aspects:

1. Psychotherapy is possible in psychosis.
2. The classical psychoanalytical framing is contraindicated.
3. Greater emphasis must be placed on the present than on the past.

4. Interpretation must be used with precaution.
5. The objectives of this type of interventions include: the experience of the self-object as two separate and independent entities that are, at the same time, related to each other; the stabilisation of the limits of the self and identity; the integration of psychotic experience.
6. The frequency of the sessions must not exceed three sessions a week, and must last for at least two years.
7. Therapists need a high level of tolerance to frustration and independence of the narcissistic reward.

#### Question to be answered

- Are psychodynamic psychotherapy and the psychoanalytic approaches effective in the treatment of people with SMI?

The benefit of psychodynamic or psychoanalytical interventions to treat schizophrenia has been and is still being discussed in depth due to the fact that the existing scientific evidence is very scarce and of low quality.

In the United States, in an attempt to improve the quality of health interventions and promote the adoption of treatments that have scientifically proven their effectiveness, some years ago the Department of Health and Human Services, through the Agency for Health Care Policy and Research (AHCPR), known as the Agency for Healthcare Research and Quality (AHRQ) started up the programme.

Patient Outcomes Research Team (PORT). The PORT schizophrenia programme compiles scientific literature on the efficiency of treatments and examines the practices and implications of their variability in health quality. The PORT recommendation on psychodynamic intervention, in people with schizophrenia and based on very low quality and non-conclusive studies, is that psychodynamic intervention should not be applied to people with schizophrenia, due to the lack of evidence and to the high cost of the intervention<sup>49</sup>.

There is a SR by Malmberg & Fenton<sup>67</sup> (3 RCTs, n = 492)<sup>68-70</sup> which compares the effects of individual psychodynamic psychotherapy or psychoanalysis with standard treatment (which may include just medication, reality-adapted psychotherapy or group psychotherapy) and with no intervention in people with schizophrenia or SMI. Considerable variations have been found in this review during the treatment, in the follow-up and in the phase of the disease when the intervention is applied (first episode and subsequent ones), in the results and the intervention comparator, with biases in the randomisation and blinding in the studies. This study does not provide any result on the effectiveness or not of this intervention.

Leichsenring *et al*<sup>71</sup> publish a metaanalysis that assesses the effectiveness of long-term psychodynamic psychotherapy. 11 RCTs and 12 observational studies are included in this study, and the mental disorders included are eating disorders, personality disorders, depression and anxiety and heterogeneous disorders. No data are provided on psychosis or bipolar disorder which is the study population in this guideline.

#### Summary of evidence

Sufficient evidence has not been found to make recommendations related to psychodynamic psychotherapy or the psychoanalytic approach in the treatment of people with SMI.

### 5.1.3. Interpersonal therapy

The lifestyle or social rhythms of stabilised people with bipolar disorder (BD) are different to those of people who do not suffer from the disease<sup>7</sup>. The Interpersonal and Social Rhythm Therapy (IPSRT) is an adaptation of interpersonal psychotherapy that is based on the fact that stability and regularity of the social routine and interpersonal relations act as a protection factor in mood disorders. The treatment focuses on the relationship between the mood symptoms, the quality of social roles and relations, and the importance of maintaining daily routines on a regular basis, as well as identifying and managing potential events that trigger the circadian or biological rhythm<sup>72</sup>. In short, the IPSRT aims to stabilise the social rhythms and sleep patterns of people with BD, as well as teach how to manage internal and external stress in order to avoid relapses<sup>73</sup>.

#### Question to be answered

- Is interpersonal therapy effective in the treatment of people with SMI?

Frank *et al*<sup>72</sup> perform a cross-over RCT (n = 175) in two phases, where participants are randomised into four treatment strategies:

- T1 Acute phase and IPSRT maintenance phase (IPSRT/IPSRT)
- T2 Acute phase and ICM maintenance phase (ICM/ICM)
- T3 IPSRT acute phase followed by ICM maintenance (IPSRT/ICM)
- T4 ICM acute phase followed by IPSRT maintenance (ICM/IPSRT).

In the first acute phase, patients are randomised to one of the two interventions. Once the patients are stabilised, they enter the second phase where they are once again randomised to IPSRT or ICM (intensive clinical management). The elements that include it are: education about the disease, symptoms, medication, sleep patterns, adverse events effects and how to manage them. The sessions last between 20 and 25 minutes. The patients are intervened weekly until they are stabilised. Visits in the preventive phase take place every two weeks for 12 weeks and then every month until the end of the 2 years' maintenance phase.

#### ***Interpersonal therapy for people with SMI and a diagnosis of bipolar disorder (BD).***

Frank *et al*<sup>72</sup>, when comparing between (T1 + T3) vs. (T2 + T4) indicate that the patients assigned to the IPSRT group in the acute phase of the treatment spend more time without affective episodes (P = 0.01). RCT (1+)

However, when Scott, Colom and Vieta<sup>73</sup> re-analyse the results of the study by Frank *et al*<sup>72</sup> where they compare ICM vs. IPSRT, they indicate that there are no statistically significant differences in the relapse ratios, in those who received the same treatment in both phases (acute and maintenance), [T1 (41%) and T2 (28%)] They also state that, according to Frank *et al*, the participants that were re-assigned to the treatment alternative in the second phase (IPSRT followed by ICM, or ICM followed by IPSRT), had higher relapse ratios and symptoms when they were monitored after two years. This suggests that the stable and constant model of the therapy may be more important than the treatment that was used in this population (no data are provided).

Experts' opinion (4)

## Summary of evidence

1+	The IPSRT applied to people with a diagnosis of bipolar disorder in acute phase, maintains these patients without affective episodes for a longer period of time <sup>72</sup> .
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## Recommendations

C	The strategies aimed at preventing relapses in people with SMI and a diagnosis of bipolar disorder should evaluate the incorporation of interpersonal and social rhythm therapy (IPSRT) into the treatment.
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### 5.1.4. Supportive therapy

There are different types of psychotherapies that can be used to treat people with schizophrenia and that are based on different theoretic and technical models. Despite these differences, they all share a series of factors, such as the fact that the interventions last for a certain length of time and have a certain format, and that a therapeutic relationship must be established with the patient.

According to the NICE CPG on Schizophrenia<sup>8</sup>, “supportive therapy” is defined as the psychological intervention where “the intervention is facilitative, non-directive and relationship-focused, with the content of sessions largely determined by the service user. For supportive therapy to be considered, this type of intervention does not have to fulfil the criteria for any other type of psychological interventions (CBT, psychoanalysis, etc.).

Supportive therapy can include any intervention carried out by one single person, with the main goal of maintaining the present functioning or helping the patients with their pre-existing skills, and it can be aimed at individuals or groups of people. The key support elements are to maintain an existing situation or offer help in connection with pre-existing skills<sup>74</sup>.

Supportive therapy is not a costly technique, and when used correctly and there are professionals available, it can be useful temporarily and if there is a lack of other more effective treatment methods.

#### Question to be answered

- Is supportive therapy effective in the treatment of people with SMI?

The SR by Buckley *et al*<sup>74</sup> (21 ECA; n =1683), assesses the effectiveness of supportive therapy in people with schizophrenia compared with standard care (treatment received in the normal environment, including the patients’ preferences, and is conditioned by them, the professionals’ criterion, and the availability of resources) or other treatments (CBT, psychoeducation, family intervention, social rehabilitation programme, etc.). The majority of the studies of this review are designed to examine specific supportive therapies, such as cognitive-behavioural therapy, and supportive therapy is used as a comparison group. Normally the trials last from 5 weeks up to 3 years. The results measurements that are presented are short-term (up to 12 weeks), medium-term (13 to 26 weeks), or long-term (more than 26 weeks).

In the experimental group, all the patients receive supportive therapy as well as standard care (including antipsychotic medication). The majority of the studies include 2 sessions per week,

weekly or fortnightly sessions. The SR bears in mind that there may be differences in the practice of the supportive therapy, depending on the country, with respect to the frequency and duration of the sessions.

In the NICE CPG<sup>8</sup> on Schizophrenia, the supportive therapy or counselling is compared with standard treatment. 14 RCTs were included (n = 1143) (from 1973 to 2002). The studies included duration and frequency of the sessions (10 – 90 minutes; 1 to 4 times per week). The duration of the treatment varied between 3 weeks and 3 years. It included a schizophrenia diagnosis, from first episodes to chronic cases. The treatments were normally applied in hospitals, outpatients, at home and in the community. The great majority of the studies included in this section of the CPG have selected RCTs where they use or contemplate supportive therapy (control group) and compare it with other forms of psychological intervention (experimental group). Supportive therapy and counselling only appear in 4 studies as an experimental group (3 of these studies compare it with cognitive-behavioural therapy; the other with standard treatment). This means that the studies were not selected based on the applicability of this intervention, but based on the intervention of the experimental group.

### ***Supportive therapy for people who suffer from SMI and a diagnosis of schizophrenia and related disorders***

#### **Supportive therapy vs. standard care**

There are no significant differences in the hospitalisation ratios between people who received supportive therapy or counselling and those who received standard care (n = 48; RR = 1.00; 95% CI: between 0.07 and 15.08)<sup>74</sup>. SR (1-)

The NICE Schizophrenia CPG indicates that there is not sufficient evidence to determine that supportive therapy or counselling improves the relapse ratios at the end of the treatment (n = 54; RR = 0.86, 95% CI: between -10.13 and 1.29) or after a follow-up period when the treatment has ended (the follow-up period is not indicated) (n = 54; RR = 1.08; 95% CI: 0.51 and 2.29)<sup>8</sup>. SR (1-)

There is not sufficient evidence to determine that supportive therapy or counselling improves the mental state at the end of the treatment (PANSS: n = 123; WMD = -2.90; 95% CI: between -10.01 and 4.2) or after a follow-up period once the treatment has ended (the follow-up period is not indicated) (PANSS: n = 131; WMD = -4.42; 95% CI: between -10.13 and 1.29)<sup>8</sup>.

It is impossible to determine whether supportive therapy or counselling reduces the cases of death at the end of treatment and after a follow-up period once the treatment has ended (the follow-up period is not indicated) (n = 208; RR = 2.89; 95% CI: between 0.12 and 70.09)<sup>8</sup>.

#### **Supportive therapy vs. cognitive-behavioural therapy**

There appears to be evidence in favour of cognitive-behavioural therapy when compared with supportive therapy in the improvement of general functioning (2 RCT; n = 78; SMI = -0.50; 95% CI: between -1.0 and -0.04)<sup>74</sup>. SR (1-)

There is no difference in the number of hospitalisation between the two intervention groups (2 RCT; n = 88; RR = 1.59; 95% CI: between 0.79 and 3.22)<sup>74</sup>.

## Supportive therapy vs. any other psychological or psychosocial therapy

RCT (1-) There are insufficient data to determine if supportive therapy or counselling improves the relapse rates at the end of the treatment period (n = 361; RR = 1.33; 95% CI: between 0.80 and 2.21) or after a non-specified follow-up period (n = 154; RR = 1.21; 95% CI: between 0.89 and 1.66)<sup>8</sup>.

These results concur with those reviewed by Buckley *et al*<sup>74</sup>, which indicate that there are no differences between either of the two interventions with respect to relapses (5 RCT; n = 270; RR = 1.18; 95% CI: between 0.91 and 1.53).

There is evidence that indicates that supportive therapy or counselling leads to an improvement in the mental state at the end of the treatment (BPRS/PANSS/CPRS: n = 316; WMD = 0.02; 95% CI: between -0.20 and 0.24) or after a non-specified follow-up period (BPRS/PANSS/CPRS: n = 284; WMD = 0.20; 95% CI: between -0.03 and 0.44)<sup>8</sup>.

Supportive therapy or counselling does not produce a reduction of the positive symptoms of schizophrenia at the end of the treatment (BPRS positive symptoms: n = 59; RR = 1.27; 95% CI: between 0.95 and 1.70), or after a follow-up period (the period is not indicated in the review) once the treatment has ended (CPRS positive symptoms: n = 90; RR = 1.66; 95% CI: between 1.06 and 2.59)<sup>8</sup>.

It is impossible to determine that supportive therapy or counselling reduces the cases of death at the end of the treatment and after a follow-up period once the treatment has ended (the follow-up period is not indicated) (n = 281; RR = 2.86; 95% CI: between 0.12 and 69.40)<sup>8</sup>.

### Summary of evidence

1-	There is no evidence that the use of supportive therapy or counselling, when compared with standard treatment, improves the hospitalisation ratios <sup>74</sup> relapses, mental state and death <sup>8</sup> .
1-	When supportive therapy or counselling is compared with CBT, the results are positive in favour of CBT with respect to general functioning <sup>74</sup> .
1-	There are insufficient data to determine if supportive therapy or counselling when compared with any other psychological or psychosocial therapy, improves the rate of relapses and mental state, reduces positive symptoms or decreases the cases of death <sup>8</sup> .

### Recommendations

	Sufficient evidence has not been found to make recommendations related to supportive therapy or counselling in the treatment of people with SMI.
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### 5.1.5. Family interventions

There appears to be general consensus about the fact that SMI has a considerable effect on the family relations of people who suffer from it, and that family relations can also, in some way or another, affect the course of the disease.

Some studies show that people with schizophrenia that come from families with high levels of “expressed emotion”, in other words, that show high levels of over-protection, criticism and hostility, are more likely to suffer relapses than those people with the same type of pathology but with lower levels of “expressed emotion” within the family<sup>8</sup>.

Nowadays, there is a great variety of methods to help people with mental diseases and their families manage the disease in a more effective manner. These interventions are designed to improve the relationships between family members, reduce the levels of “expressed emotion” and, in some way, reduce the relapse ratios and improve the quality of life both of the patient and of the families.

Psychosocial interventions have been reviewed as well as the evidence that exists about their efficiency in people with SMI with respect to their isolated application compared with standard treatment or other interventions. However, studies have been found in the review where the experimental group receives two or more interventions. The question of how these interventions must be combined, not only together but also added to other types of interventions, is directly related to the need to integrate treatments and to the debate on the artificial delimitation between treatment and rehabilitation. No specific question has been contemplated in this CPG to define which combination of psychosocial interventions is more efficient. It is, however, considered advisable to indicate that there are studies that propose the application of interventions that combine family therapy and other therapies.

For some authors there is an international agreement about the need to offer a combination of three essential interventions in the treatment of patients with schizophrenia and related disorders: optimal doses of antipsychotic medication, education of users and their caregivers to cope more effectively with environmental stress, and Assertive Community Treatment that helps resolve social needs and crisis, including symptomatic exacerbation<sup>75</sup>. Despite the evidence that supports this, there are very few mental health plans that foresee these programmes in a routine manner. However, for other authors, it is the combination of family treatment, social skills training and pharmacological treatment that can be the appropriate treatment to avoid relapses<sup>76</sup>.

A combined psychosocial treatment project started up in 1994, which included family intervention and other psychosocial interventions (Optimal Treatment Project, OTP). It was multicentre (in 21 countries and with 35 venues) and its aim was to assess costs and benefits of applying evidence-based optimal psychosocial and biomedical strategies, to treat schizophrenia and other non-affective psychosis, through the implementation and assessment of optimal therapeutic interventions in ordinary mental health resources –not investigators- after the adequate training of multidisciplinary professionals teams and with a 5-year follow-up period<sup>77</sup>. Although the project proposed incorporating patients as soon as possible after the onset of the disease (in the first ten years), some venues incorporated patients with more than 10 years’ evolution, where the treatment was focused on improving their quality of life through social and occupational skills training, and on providing pharmacological and psychosocial strategies for persistent symptoms. The interventions included pharmacological strategies, psychoeducation of patients and caregivers, Assertive Community Treatment, social skills training, pharmacological and psychosocial handling of persistent and residual symptoms.

### Question to be answered

- Do family interventions in their different formats, present benefits compared with non-intervention, or other types of psychosocial intervention, in people with SMI?
- At what time, during the course of the illness, is it best to start family intervention for people with SMI and their families?
- What is the most appropriate time framework for the family intervention programmes and/or sessions for people with SMI and their families?

All the evidence found refers to SMI with schizophrenia and/or bipolar disorder. The NICE Schizophrenia CPG<sup>8</sup> includes one SR<sup>43</sup> and 2 RCTs<sup>78,79</sup> (total of 18 RCTs; n = 1458). This CPG assesses family intervention in different formats (individual, group or multi-family), as well as the duration and frequency of the interventions. The sessions that are held with the family and with specific support, based on systemic, cognitive-behavioural and/or psychoanalytical principles, are considered as family intervention. The interventions included must have a psychoeducational content, “crisis treatment” orientated work, and with a duration of 6 weeks at least.

In the systematic review by Pharoah *et al*<sup>80</sup>, which includes a total of 43 RCTs (n = 1765), the effectiveness of family intervention is assessed in people with schizophrenia and is compared with standard treatment (understood as normal psychiatric intervention levels that includes pharmacological treatment). In the studies included in this review, family therapies have an educational component with a view to improving the family atmosphere and reducing the relapse of schizophrenia<sup>81-86</sup>.

The results from studies such as the study by Pharoah *et al*<sup>80</sup> must be taken with precaution because they include a great variety of ages and people with a background of long-lasting disease and first episodes, so they are partially applicable to the target population of the CPG. Furthermore, it must be recalled that these studies come from different cultures and environments, which must be taken into account when preparing strategies and taking decisions.

Bressi *et al*<sup>87</sup> performed a RCT (n = 40) which compared the effectiveness of the systematic family therapy + standard treatment with standard treatment alone (which only consisted in pharmacological treatment), in people with schizophrenia, in connection with readmissions, relapse and treatment adherence, and with a two-year follow-up period. The family intervention consisted in a series of 12 sessions with family members, lasting for one and a half hours, once a month and over a one year period.

In our context, DA IGUAL in the study by Montero *et al*<sup>88</sup>, two family therapy techniques are compared, one intervention in group format (group of families) and another individual intervention of a cognitive-behavioural style. These interventions are applied to a sample of 87 people with a diagnosis of schizophrenia and their families for 12 months (weekly the first 6 months, then every two weeks for the following 3 months and finally during the last 3 months’ intervention, every month).

Falloon, together with the OPT Collaborative Group<sup>89</sup> publish the preliminary results (n = 603) of one multicentre RCT after two years’ follow-up of their project. The results reached are for groups of patients with a diagnosis of recent-onset non-affective psychosis, and with a majority of patients with more than 10 years’ evolution of the disease, results which could be more easily extrapolated to the criteria of our CPG.

In the RCT carried out by Hogarty *et al.* (they included 103 patients with a diagnosis of schizophrenia or schizoaffective disorder and who come from homes with high expressed emotion), were randomised to four treatment conditions: family psychoeducation (FP) and pharmacology treatment (FP+PT); social skills training and pharmacological treatment (SST+PT); family psychoeducation, social skills training and pharmacological treatment (FP+SST+PT), and pharmacological treatment (PT)<sup>76</sup>. The same author publishes the results of the same study two years after the treatment<sup>90</sup>.

In the Spanish study by Lemos *et al*<sup>91</sup> they submit to verification the effectiveness of psychosocial therapy programmes added to the pharmacological treatment in the prevention of relapses, the control of symptoms and the functional improvement of patients with schizophrenia after 4 years' follow-up. The 46 initial patients were assigned by order of arrival at the centre to the standard treatment control group (n = 15) and to the psychosocial intervention programme (n = 20), consisting in psychoeducation and integrated psychological therapy, IPT of Brenner and Roder<sup>92-93</sup> for patients, and psychoeducation and family therapy (improvement of communication, problem-solving and stress handling) for family members.

With respect to the people who suffer from SMI and a diagnosis of bipolar disorder, the NICE Bipolar Disorder CPG<sup>7</sup> which includes 3 RCT<sup>94-96</sup> (n = 246), from which the development group of this CPG rejected the study by Rea *et al*<sup>96</sup> because 40% of the sample corresponds to people with a first episode of the disease, from a sample of n = 53, and does not satisfy the inclusion criteria established in this CPG. The studies observe different family intervention formats and compare them with other interventions or with standard treatment. The sessions that are held with the family and with specific support based on systemic, cognitive-behavioural and/or psychoanalytical principles, are considered as family intervention. The interventions included must have psychoeducational content, and/or "crisis treatment" orientated work.

Justo *et al*<sup>97</sup>, in the SR that they perform, analyse the effectiveness of family intervention compared with non-intervention or other psychosocial interventions in people who suffer bipolar disorder. The search period lasts until 2006 and includes 7 RCTs (n = 393), which provided data to respond to this section from 6 RCT<sup>98-103</sup>. All the people were taking medication at the time of the study. The family psychosocial interventions include any type of psychological therapy or psychoeducational method (about the disease and the possible strategies to cope with it) to treat people and their families or carers (partners or family members of a bipolar person, or group of families of different bipolar people, with the attendance or not of the bipolar person) They also include couple therapies and therapies with groups of families, and they can be administered by psychiatrists, psychologists or other health professionals.

Reinares *et al*<sup>104</sup> performed a study (RCT, n = 113) with the aim of evaluating the efficiency of a group of psychoeducational intervention for families of people with a diagnosis of bipolar disorder in euthymic phase and with a 12 month follow-up period.

Up to two family members per patient of the 113 were randomised between a group of twelve 90-minute sessions where they were offered information and coping guidelines compared with the control group. The assignation, when they were randomised, was not concealed, but the evaluation was blind. The condition of SMI is not specified, but the description of the sample indicates clinical severity and prolonged course: 10 years' evolution, 82% type I, 66% had had psychotic symptoms, with an average of 7 episodes and 1.5 hospitalisations per patient.

The interventions with families and users can be applied to the National Health System. However, and for them to be effective, a considerable amount of time must be invested as well as training of the professional who are going to use them.

No study indicates or analyses possible adverse effects of these types of intervention.

## ***Family intervention for people with SMI and a diagnosis of schizophrenia and related disorders***

Family intervention vs. other interventions (standard treatment, psycho education, family support, supportive psychotherapy, etc.)

### *Relapses*

SR (1+) Family intervention, compared with other interventions, reduces relapses during treatment (n = 383; RR = 0.57, 95% CI: between 0.37 and 0.88)<sup>8</sup>, and 4 to 15 months after finishing the treatment (n = 305; RR = 0.67; 95% CI: between 0.52 and 0.88)<sup>8</sup>.

SR (1+) It reduces the relapses after 12 months' treatment, in people who had relapses during the 3 months prior to the intervention (n = 320; RR = 0.55; 95% CI: between 0.31 and 0.97; NNT = 5)<sup>8</sup>.

RCT (1-) Dyck *et al*<sup>79</sup> indicate that family intervention compared with standard intervention reduces persistent symptoms after 12 months' treatment (n = 63; RR = 0.57, 95% CI: 0.33 to 0.97; NNT = 5).

SR (1-) Family intervention of less than 5 sessions, or an unknown number of sessions, significantly reduces relapses (5 RCT; n = 600; RR = 0.41; 95% CI: between 0.31 and 0.53; NNT = 4) one year after intervention<sup>80</sup>.

The relapse ratios after 2 years were also less in the intervention group (n = 225; RR = 0.45; 95% CI: between 0.28 and 0.71; NNT = 5)<sup>80</sup>.

The results after 3 years (n = 326; RR = 0.31; 95% CI: between 0.20 and 0.49; NNT = 4) and after 10 years (n = 196; RR = 0.83, 95% CI: between 0.15 and 0.38; NNT = 2) indicate too that they significantly favoured family intervention compared with standard intervention<sup>80</sup>.

### *Readmissions*

SR (1-) Family intervention of more than 5 sessions proves to be more effective in reducing hospitalisations after 18 months follow-up (3 RCT; n= 228; RR = 0.46; 95% CI: between 0.3 and 0.69; NNT = 4)<sup>80</sup>.

SR (1+) Family intervention, compared with standard intervention, does not reduce the likelihood of readmission 2 years after having finished the treatment, (n = 330; RR = 0.01; 95% CI between 0.79 and 1.28)<sup>8</sup>.

### *Effect of family intervention on users and caregivers*

SR (1-) In patients whose family members received a family intervention of more than 5 sessions, when compared with standard treatment, an improvement is observed in pharmacological treatment adherence (7 RCT, n = 369; RR = 0.74; 95% CI between: 0.6 and 0.9; NNT = 7)<sup>80</sup>.

A family intervention of more than 5 sessions indicates a significant reduction in the burden perceived by family caregivers (n = 48; WMD = -7.01; 95% CI between -10.8 and -3.3)<sup>81</sup> and (n = 60; WMD = -0.4; 95% CI: between -0.7 and -0.1)<sup>82</sup>.

A family intervention of more than 5 sessions, compared with standard treatment, favours the reduction of expressed emotion levels within the family (3 RCT; n = 164; RR = 0.68; 95% CI: between 0.5 and 0.9; NNT = 4; 95% CI: between 3 and 10)<sup>80</sup>. SR (1-)

Patients who have received family intervention have a higher quality of life than those who did not receive it (n = 213; WMD = 19.18; 95% CI between 9.8 and 28.6) after two years' treatment<sup>80</sup>.

There is not sufficient evidence to determine if family interventions reduce the levels of negative symptoms (MSANS: n = 41; WMD = -1.20; 95% CI: between -2.78 and 0.38) 79 or if they improve social functioning (Social Functioning Scale: n = 69; WMD = -1.60; 95% CI: between -7.07 and 3.87)<sup>78</sup>. RCT (1-)

Sufficient evidence has not been found, either, that determines if family intervention reduces the suicide rate (7 RCT, n = 377; RR = 0.79; 95% CI between 0.35 and 1.78)<sup>80</sup>. SR (1-)

#### *Duration of the interventions*

When the programme is provided for a period of 6 months or more, or for more than 10 scheduled sessions, there is evidence that indicates that family intervention reduces relapses at 4 to 15 months' follow-up after treatment (n = 165; RR= 0.65; 95% CI: between 0.47 and 0.90)<sup>8</sup>. SR (1+)

### Family intervention formats

#### *Single-family intervention vs. multi-family intervention*

There are no differences between multi-family intervention and single-family interventions with respect to relapses at 13 to 24 months (n = 508; RR = 0.97, 95% CI: between 0.76 and 1.25)<sup>8</sup>. SR (1+)

No differences were found, either, between the two types of family interventions regarding experiencing greater pharmacological treatment adherence (n = 172; RR = 1.0; 95% CI: between 0.5 and 2.0)<sup>84</sup>. RCT (1-)

Leff *et al*<sup>85</sup> indicate that the people who received single-family intervention, compared with those who received multi-family intervention, were able to lead more independent lives (n = 23; RR = 2.18; 95% CI: between 1.1 and -4.4).

In the study by Montero *et al.*<sup>88</sup> they indicate that (although both techniques improved the patient's clinical situation), the families that received individual behavioural approach therapy had better results in social functioning, doses of antipsychotic medication and psychotic symptoms (p< 0.05), than the families that received group format (there were no differences in the relapse or readmission rates). RCT (1-)

### *Behavioural family intervention vs. family support intervention (> 5 sessions)*

RCT (1-) There are no differences between the two interventions related to hospital readmissions (n = 528; RR = 0.98; 95% CI: between 0.1 and 1.12)<sup>86</sup>.

### *Systemic family therapy vs. standard treatment*

RCT (1-) It is observed that patients who receive systemic family therapy improve during the treatment in readmission rates (p = 0.273); relapses (p = 0.030) and treatment adherence (p = 0.009). However, after 2 years there are no differences between the two groups<sup>87</sup>.

### *Inclusion of the patient in family interventions*

SR (1+) When the user is included in the family sessions, there is evidence that shows that family intervention reduces the levels of relapses once the treatment has finished (n = 269; RR = 0.68; 95% CI between 0.50 and 0.91)<sup>8</sup>.

### **Family interventions combined with other interventions**

RCT (1+) When comparing family interventions that incorporated another psychosocial intervention (OPT group) vs. standard treatment, the latter presented significant improvements in the clinical severity rates (41%), disability (39%) and stress perceived by carers (48%) 24 months after the intervention<sup>89</sup>.

35% of the patients from the OPT group satisfied the criteria of complete recovery after 24 months, compared with 10% of the patients from the standard treatment group. The observation of significant improvements in all the parameters when applying the standard treatment for 24 months reflects the high clinical standards that exist in the centres that participated in the project<sup>89</sup>.

In one out of every four cases with recent-onset schizophrenia or with a first episode of schizophrenia, as well as 40% of the chronic cases, no type of improvement was observed at the end of two years' OPT treatment<sup>89</sup>.

RCT (1++) Of the patients who received treatment (n=90) those from the group that received FP+SST+PT did not present any relapse in 12 months; those from the group of FP+PT (19%); those from the group of SST-PT (20%) and those from the control group 38% (p=0.007).

On performing the same analysis with the subgroup of patients who presented no difficulty in taking the medication (n=78), a smaller percentage of relapses was observed in the group FP+ PT (11%; p=0.012), a similar percentage of relapses in the group SST+PT (17%; SST p=0.084), a similar percentage in the control group PT (32%) and again a clear additive effect in the combined group without relapses in 12 months (0%)<sup>74</sup>.

After two years' treatment, and bearing in mind the study design, where a reduction in frequency in both interventions was foreseen in the second year, maintenance of the effect of family therapy (FT) is observed in the prevention of relapses (29%) and the effect of social skills training (SST) is not maintained (50%). This reduction in the effect is late-arriving (after 21 months) returning to similar rates in the control group (62%) and the additive effect of FT and SST is lost with 25% relapses ( $p=0.004$ ). Failure to comply with the medication was less frequent in the experimental groups than in the control group (21% and 40% respectively). Failure to comply with the medication was associated with the relapse (26 of the 28 non-complying people suffered a relapse)<sup>90</sup>. RCT (1-)

The group with psychosocial intervention experienced a significant clinical improvement in the intervention period and this was maintained after 4 years' follow-up ( $p<0.05$ ), compared with the control group where no substantial changes were observed. In the evaluation after 4 years' psychosocial intervention, the clinical state and social functioning were similar in both groups ( $p>0.05$ ); there were significant differences in the presence of clinical relapse criteria at some moments of the follow-up, which were satisfied by 29.4% of the patients from the experimental group and by 50% from the control group<sup>91</sup>.

### ***Family intervention for people with SMI and a diagnosis of bipolar disorder***

#### *Family intervention vs. individual intervention*

There are no differences between family and individual psychosocial interventions in people who suffer SMI and a diagnosis of bipolar disorder at the end of the treatment (12 months) with respect to relapses ( $n=53$ ; RR = 0.89, 95% CI: Between 0.51 and 1.54), readmissions ( $n = 53$ ; RR = 0.71; 95% CI: between 0.33 and 1.52) and at the end of the treatment (24 months) with respect to treatment adherence ( $n = 29$ ; SMI = 0.08; 95% CI: between -0.65 and 0.82)<sup>98</sup>. RCT (1-)

#### *Family interventions vs. crisis-orientated treatment (also administered to the family, but in a less intensive and complex manner)*

Family intervention represented a reduction of the relapses after 24 months ( $n = 101$ ; RR = 0.59; 95% CI: between 0.39 and 0.88; NNT = 3)<sup>99</sup>. RCT (1+)

There is an improvement with respect to treatment adherence during the follow-up in the family intervention group ( $n = 65$ ; WMD = -0.45; 95% CI: between -0.97 and 0.07<sup>99</sup>).

Family intervention favours a remission of the symptoms after 3 months ( $n = 101$ ; RR = 0.54; 95% CI: between 0.33 and 0.89) and after 15 months ( $n = 101$ ; RR = 0.59; 95% CI: between 0.39 and 0.88)<sup>94</sup>. It is not clear if the intervention began during the acute phase of the disease. RCT (1-)

*Group psychoeducation for relations of people with SMI and a diagnosis of bipolar disorder*

RCT (1+) Patients whose family members followed a group psychoeducational programme presented a significantly longer period of time until any recurrence, than those of the control group ( $p=0.044$ ). When the analysis described the type of relapse, only the time until hypomaniac or maniac relapse was significant ( $P=0.015$ ) but not for depressive relapses<sup>104</sup>.

Furthermore, 42% of the patients whose family members followed a group psychoeducational programme presented relapses compared with 66% in the control group after 12 months' follow-up ( $p=0.011$ ). In a detailed analysis, this difference was exclusively due to the lower percentage of hypomaniac and maniac relapses in the experimental group (37.5%  $p=0.017$ )<sup>104</sup>.

*Family intervention vs. multi-family intervention*

RCT (1-) In a study performed when the patient was in an acute phase, individual family intervention has not been found to be more effective than multi-family intervention with respect to the improvement in symptoms at the end of the treatment (28 months) ( $n = 92$ ; RR = 0.67; 95% CI: between 0.34 and 1.32)<sup>95</sup>.

*Family intervention vs. non-intervention*

RCT (1-) No differences are found in the clinical improvement between the two groups (at the end of treatment) ( $n = 26$ ; RR = 0.49; 95% CI: between 0.10 and 2.4), nor after 6 months' follow-up ( $n = 26$ ; RR = 0.73; 95% CI: between 0.05 and 10.49)<sup>101</sup>.

RCT (1-) People from the family intervention group presented an increase in anxiety levels, compared with the group that did not receive any intervention ( $n = 39$ ; WMD = 0.69; 95% CI between 0.05 and 1.34)<sup>102</sup>.

RCT (1-) No differences are found between the family psychoeducation intervention groups for carers caregivers and non-intervention in the relationships in the family environment (expressiveness, cohesion and conflict). Expressiveness ( $n = 45$ ; WMD = -0.03; 95% CI: between -0.65 and 0.59); cohesion ( $n = 45$ ; WMD = 0.10; 95% CI: between -0.52 and 0.72), and conflict ( $n = 45$ ; WMD = -0.33; 95% CI: between -0.95 and 0.29)<sup>103</sup>.

RCT (1-) Van Gent & Zwart<sup>102</sup> indicate that there are no differences between the marital psychoeducation family intervention groups for couples vs. no intervention ( $n = 45$ ; WMD = -0.33; 95% CI: between -0.95 and 0.29). There are no differences, either, between either of the two groups with respect to treatment adherence at the end of the study (12 months) ( $n = 36$ ; RR = 1.06, 95% CI: between 0.73 and 1.54).

RCT (1-) With respect to the recovery of the person at the end of the study (28 months), no differences have been found between multi-family group psychoeducation intervention and no intervention ( $n = 59$ ; RR = 1.49, 95% CI: between 0.76 and 2.95) or in people with mania ( $n = 45$ ; RR = 1.57, 95% CI: between 0.67 and 3.68)<sup>100</sup>.

### Family intervention vs. other psychosocial interventions

There are no differences in the recovery ratios between systemic family RCT (1-) therapy focused on problem-solving and multi-family psychoeducational group therapy at the end of the study (28 months) in all the people (n = 63; RR=1.72; 95% CI: between 0.91 and 3.25) or in people with mania (n = 47; RR = 1.57; IC between 0.67 and 3.68)<sup>100</sup>.

### Summary of evidence

	<b>People with SMI and a diagnosis of schizophrenia and related disorders</b>
1+	Family intervention in people with schizophrenia reduces relapses <sup>8</sup> .
1-	Family intervention reduces persistent symptoms after 12 months' treatment <sup>79</sup> .
1-	Family intervention of less than 5 sessions, or of unknown number, reduces relapses after one year's treatment, after 1, 3 and 10 years' follow-up <sup>80</sup> .
1-	Family intervention of more than 5 sessions reduces hospitalisations after 18 months' follow-up <sup>80</sup> .
1+	There are no differences between family intervention and standard intervention in the reduction of hospital readmissions 2 years after finishing the treatment <sup>8</sup> .
1-	There is better compliance with the pharmacological treatment when the family intervention is more than 5 sessions <sup>80</sup> .
1-	Family intervention of more than 5 sessions represents a significant reduction of the burden perceived by family carers. <sup>81,82</sup>
1-	Family intervention of more than 5 sessions reduces the expressed emotion levels within families <sup>80</sup> .
1-	Patients who have received family intervention have a higher quality of life <sup>83</sup> .
1-	There are no differences that determine that family intervention reduces negative symptom levels of people with schizophrenia <sup>79</sup> or improves social functioning <sup>78,79</sup> .
1-	The evidence found is not sufficient to determine if family intervention reduces suicide rates <sup>80</sup> .
1+	Family intervention of 6 months or more, or more than 10 scheduled sessions, reduces relapses at 4 to 15 months' follow-up after treatment.
1+	There are no differences between multi-family intervention and single-family intervention in connection with relapses at 13 to 24 months <sup>8</sup> .
1-	There are no differences between multi-family intervention and single-family intervention related to pharmacological treatment adherence <sup>84</sup> .
1-	People with schizophrenia who received single-family intervention compared with those who received multi-family intervention, can lead a more independent life <sup>85</sup> .
1-	Individual family therapy with a behavioural approach improves the results of social functioning, doses of antipsychotic medication and psychotic symptoms compared with group family therapy <sup>88</sup> .
1-	There is no difference between behavioural family intervention and family supportive intervention of more than 5 sessions with respect to hospital re-admissions <sup>86</sup> .

1-	The people who receive systemic family therapy obtain an improvement respect to readmissions, relapses and treatment adherence; however, this improvement is not maintained after 2 years' follow-up <sup>87</sup> .
1+	When the person affected by the disease is included in family interventions the relapse levels drop <sup>8</sup> .
	<b>Family interventions combined with other interventions</b>
1+	Combined psychosocial treatment produces improvements of 40% in the evaluation of the clinical severity, social functioning and stress perceived by the caregiver in the 24 month evaluation <sup>89</sup> .
1+	Combined psychosocial treatment achieves 25% more cases of complete recovery in a 24 month period <sup>89</sup> .
1+	In 25% of the cases of recent-onset schizophrenia (<10 years' evolution) and in 40% of the chronic cases (>10 years) the combined psychosocial treatment applied for 24 months does not achieve any type of improvement <sup>89</sup> .
1++	Psychoeducational type family therapy together with SST and pharmacological treatment in people with schizophrenia who come from homes with high expressed emotion did not present any relapse in 12 months <sup>76</sup> .
1++	Respect to the degree of treatment adherence, lower percentages of relapses are observed in the psychoeducational type family intervention group <sup>76</sup> .
1-	Two years after the treatment, maintenance of the effect of the family therapy is observed when preventing relapses but the SST effect is not maintained, observing similar percentages to those of the control group <sup>90</sup> .
1+	With respect to pharmacological treatment adherence, failure to comply with the medication was less frequent in the experimental groups than in the control group (21% and 40% respectively) <sup>90</sup> .
1-	Combined psychosocial intervention of patients and family members achieves greater clinical improvements than the control group, and this effect is maintained for 4 years <sup>91</sup> .
1-	After 4 years' follow-up, the clinical state and the social functioning of the people who followed a combined psychosocial intervention were similar to the control group, but they achieved 40% less relapses <sup>91</sup> .
	<b>People with SMI and a diagnosis of bipolar disorder</b>
1-	No differences have been found between family psychosocial intervention and individual intervention with respect to relapses, readmissions and treatment adherence at the end of the treatment (12 months) <sup>98</sup> .
1+	Family intervention reduces relapses, compared with crisis treatment, after 24 months <sup>99</sup> .
1+	There is an improvement with respect to treatment adherence in people who have received family intervention compared with those who received crisis intervention. <sup>99</sup>
1-	Family intervention favours the remission of symptoms after 3 and 15 months of the intervention, compared with crisis intervention. <sup>94</sup>
1+	Patients whose family members followed a group psychoeducational programme presented a significantly longer period of time until any hypomaniac or maniac type recurrence than those of the control group and they presented fewer relapses after 12 months' follow-up <sup>103</sup> .

1-	No differences have been found between individual family intervention and multi-family intervention with respect to improvement of symptoms <sup>95</sup> .
1-	There are no differences in the clinical improvement between family intervention and non intervention in people with bipolar disorder either at the end of the treatment or after 6 months' follow-up <sup>101</sup> .
1-	There is a greater increase of anxiety levels among those people who receive family intervention than among those who did not receive it <sup>102</sup> .
1-	With respect to the relationships in the family environment (expressiveness, cohesion and conflict), no differences have been found between the family psychoeducation intervention groups for caregivers and non-intervention <sup>103</sup> .
1-	There appear to be no differences between the marital psychoeducation family intervention groups for couples and non-intervention <sup>102</sup> .
1-	Or between family intervention and non-intervention with respect to treatment adherence <sup>102</sup> .
1-	When the multi-family group psychoeducation intervention is compared with non intervention, no differences have been found with respect to the recovery of the patient at the end of the study (28 months) <sup>100</sup> .
1-	There are no differences between systemic family therapy focused on problem-solving and multi-family psychoeducation group therapy in the recovery ratios at the end of the study (28 months) <sup>100</sup> .
1+	Psychoeducation in group format of relations of people with bipolar disorder in euthymic phase, reduces the number of relapses, in particular hypomaniac and maniac relapses, and prolongs the time until these occur <sup>104</sup> .

## Recommendations

B	For people with SMI and a diagnosis of schizophrenia and related disorders, and their families, family intervention should be offered as an integral part of the treatment.
B	In family interventions that are carried out with people with SMI and diagnosis of schizophrenia and related disorders, the intervention should be done in a single-family format.
B	The recommended duration in family interventions aimed at people with SMI and diagnosis of schizophrenia and related disorders must be at least 6 months and/or 10 or more sessions.
A	Psychosocial intervention programmes must be offered that include family intervention with a psychoeducational component and coping and social skills training techniques, added to the standard treatment for people with SMI and diagnosis of non-affective psychosis.
B	Family members and caregivers of people with SMI and a diagnosis of bipolar disorder must be offered group psychoeducational programmes that include information and coping strategies that permit discussions within a friendly emotional climate.

### 5.1.6. Psychoeducational interventions

The psychoeducational type approach is frequently used in interventions with patients affected by schizophrenia and bipolar disorders, both in hospitals and outpatients. This intervention involves transmitting information about the disease to patient and families; it is not always done in an organised manner and the inclusion of family members is not normal practice. It is important to know the effectiveness of these interventions, which are usual in practice.

Problems have been encountered to focus the search for scientific evidence due to the fact that the majority of studies associate psychoeducation as an essential part of family intervention, although the surveys on clinical activity inform us that family incorporation is very scarce and not generalised in clinical practice.

This CPG development group decided to focus the search on psychoeducation programmes for users that were compared with an inactive control group. They included studies that evaluated the impact of the psychoeducation of family members/caregivers in group format on results in patients with bipolar disorders. Those studies that included non-specific cognitive-behavioural interventions were excluded for the psychoeducation of people with bipolar disorders.

An important overlapping is observed between user-orientated psychoeducation and standard treatment when the standard treatment includes transmission of relevant information as well as coping and handling strategies for the disease, both if carried out individually and with the incorporation of family members.

There is a lack of knowledge about whether the mere family involvement in the treatment is per se the determining factor for the improvement of treatment adherence (pharmacological) and these condition the results, or if what is important is to give adequate information, or achieve a change in the transactional patterns<sup>105</sup>. It is difficult to find control groups that incorporate the family without having carried out any specific intervention with them.

The protocolisation and standardisation of psychoeducational intervention (for example, inclusion of contents in a manual, with a specific timeframe) may be a reason for not accepting the intervention for quite a large subgroup of patients, above all if the content does not adapt to the evolutionary moment of the disorder or to the attitudinal state of the patient. Another factor to be taken into account is that when the presentation is more interactive, it incorporates more behavioural components and the content is understood and accepted better, the impact of the intervention is optimised.

Studies that assess exclusively user-orientated psychoeducational programmes do not “continue” with the patient when they end and do not involve support and intervention to incorporate the different issues dealt with in their daily lives. Thus, the long-term assessment of the results may produce evidence of ineffectiveness when compared with interventions that incorporate family members and which, therefore, get “co-therapists” in the home, outside the intervention hours. The relapse ratios seem to be strongly related to the medication adherence, and the question of whether the efficiency of the family psychoeducational interventions is the consequence mainly of the increase in adherence still cannot be answered<sup>104</sup>.

Providing suitable information about the disorder with a view to improving its handling, by patients or by their family members, is an act that is carried out from the moment of the referral, at the time when admission is decided, when the treatment is proposed and prescribed, or when pharmacological treatment is advised, or when a periodical check-up is carried out, etc. Therefore, a good knowledge of the effectiveness of this intervention may help improve the use of resources and clinical practice.

### Question to be answered

- Are psychoeducational interventions effective in people with SMI?
- What are the key components in psychoeducational interventions in people with SMI?
- What is the most adequate level of psychoeducational intervention: individual, group or family?

The review carried out by Lincoln *et al*<sup>107</sup> (18 studies; n = 1543) was designed to assess the long and short-term efficiency of exclusively user-orientated psychoeducation and user and family-orientated psychoeducation. The result variables taken were the reduction of relapses and symptomatic severity, improvement of knowledge about the disorder, medication adherence and global functioning of the patients diagnosed with schizophrenia and related disorders (schizo-affective, delirium disorder, brief psychotic disorder and schizotypal disorder). Both interventions were compared with normal treatment or non-specific intervention without proven efficiency. The studies included had to satisfy the requirement that psychoeducation (understood as the transmission of relevant information about the disorders and its treatment whilst better coping is promoted) was the main element of the intervention.

Bauml *et al*<sup>108</sup> carried out a study (n=101) in a European context whose objective was to evaluate the effectiveness of parallel bifocal psychoeducational intervention and its long-term effect. People diagnosed with schizophrenia and their family members were randomised either to group psychoeducational intervention, both groups separately, or to the control group that consisted in normal treatment.

Three RCTs were included in the NICE bipolar disorder CPG<sup>7</sup>, two of which (n = 170) by Colom *et al*<sup>109,110</sup>, compare the effect of a complex group psychoeducation programme (including psychoeducation on bipolar disorder and training in communication improvement and problem-solving) with a non-directive support intervention control group in addition to the psychopharmacological treatment. The programmes consisted in 20 sessions of psychoeducation each week with a 24-month follow-up, and with euthymic patients.

Perry *et al*<sup>111</sup> performed a RCT (n = 69) comparing an individual psychoeducational programme on people who suffer bipolar disorder that incorporated training in recognition of prodromes and pharmacological treatment compared with pharmacological treatment alone. The intervention lasted for 3 to 6 months with an 18-month follow-up.

### ***Psychoeducation for people with SMI and diagnosed with schizophrenia and related disorders***

#### *Psychoeducation vs. non-intervention*

Psychoeducation, when compared with non-intervention or non-specific intervention, does not produce a significant drop in relapses or readmissions (follow-up of more than 12 months) (3 RCT; n = 144; p = 0.07)<sup>107</sup>. SR (1++)

There are no data to support that psychoeducation represents a reduction in symptoms at the end of the programmes (6 RCT; n = 313; p = 0.08) or in follow-ups at 7 to 12 months (3 RCT; n = 128; p = 0.14)<sup>107</sup>.

Psychoeducation improves the knowledge of the disease when this knowledge is assessed at the end of the programmes (4 RCT; n = 278; p = 0.00) but there are no data from the follow-up periods<sup>107</sup>.

No evidence has been found that indicates that psychoeducation has any effect on improving social functioning when measured at the end of the programmes at 7 to 12 months' follow-up (2 RCT; n = 112; p = 0.32)<sup>107</sup>.

There are no data that indicate that psychoeducation achieves an improvement in treatment adherence at the end of the programmes (2 studies; n = 171; p = 0.31)<sup>107</sup>.

#### *Pyschoeducation with incorporation of family vs. pyschoeducation without family vs. Standard Treatment (ST)*

SR (1++) Only psychoeducation that incorporates the family produces a significant reduction in relapses or readmissions after 7-12 months' follow-up (6 RCT; n = 322; p = 0.32); this is not the case when psychoeducation exclusively focuses on the patient (2 RCT, n=101; p=0.30)<sup>107</sup>.

#### *Parallel group pyschoeducation of users and family members*

RCT (1+) Of the 48 patients who remained in follow-up for 7 years, the group that followed a parallel group pyschoeducational programme for users and for family members had less rehospitalisations (54%) compared with the 88% that existed in the control group (readmission ratio per patient of 1.5 and 2.9 respectively; p<0.05)<sup>108</sup>.

#### *Pyschoeducation for people with SMI and a diagnosis of bipolar disorder*

RCT (1+) Complex pyschoeducation programmes (that include pyschoeducation on bipolar disorder, communication improvement and problem-solving training) reduce the number of relapses in 2 years, compared with a non-directive group intervention of the same intensity (n = 170; RR = 0.71; 95% CI: between 0.6 and 0.84)<sup>109,110</sup>.

No data are observed that support the fact that complex pyschoeducation reduces the number of readmissions after 2 years' follow-up, when compared with a non-directive group intervention of the same intensity (n = 170; RR = 0.47; 95% CI: between 0.17 and 1.3)<sup>109,110</sup>.

RCT (1+) Pyschoeducation interventions that incorporated prodrome recognition training reduces relapses in maniac phase [n = 69 (27% vs. 57% in the control group); WMD = -1.97; 95% CI: between -3.2 and -0.74], although there was no reduction in relapses in the depressive phase after 18 months' study (n = 68; WMD = 1.1; 95% CI: between -1.41 and 3.61)<sup>111</sup>.

No data are found to support that the pyschoeducation programme with prodrome recognition reduces the number of hospitalisations 12 months after treatment onset, compared with standard treatment (n = 68, RR = 9.93; 95% CI: between 0.66 and 1.31)<sup>111</sup>.

## Summary of evidence

1++	Pyschoeducation, compared with non-intervention or non-specific intervention, does not produce a significant decrease in relapses or readmissions, an improvement of symptoms or of social functioning, or improves treatment adherence, in people with schizophrenia <sup>107</sup> .
1++	Pyschoeducation improves the knowledge of the disease in people with schizophrenia <sup>107</sup> .
1++	In people with schizophrenia, and when the family is incorporated into the pyschoeducational intervention, the relapses or readmissions are reduced <sup>107</sup> .
1+	The effects of parallel group pyschoeducation with users and family members reduces the number of readmissions, which are effective up to 7 years after the intervention <sup>108</sup> .
1+	Complex pyschoeducation programmes (which include pyschoeducation on bipolar disorder, training in communication improvement and in problem-solving) reduce the number of relapses in 2 years in people with bipolar disorders. However, there is no evidence to indicate that it reduces the number of readmissions <sup>109,110</sup> .
1+	Pyschoeducational intervention that incorporated prodrome recognition training in people with bipolar disorders, reduces relapses in maniac phase, but not in depressive phase <sup>111</sup> .
1+	The pyschoeducational programme that incorporated prodrome recognition reduces the number of hospitalisations in people with bipolar disorders <sup>111</sup> .

## Recommendations

A	Quality information must be provided about the diagnosis and the treatment, giving support and handling strategies to people with SMI and diagnosis of schizophrenia and related disorders, to family members and to the people with whom they live.
A	Pyschoeducational programmes that are offered to people with SMI and diagnosis of schizophrenia and related disorders, must incorporate the family.
B	Group pyschoeducational programmes aimed at people with SMI and a diagnosis of bipolar disorder must incorporate specific psychological techniques, carrying them out in a relatively stable period of their disorder and always as a supplement to the psychopharmacological treatment.
√	The pyschoeducational programmes for people with SMI must be integrated as an additional intervention in an individualised treatment plan, whose duration will be proportional to the objectives proposed, considering a minimum of 9 months' intensive programme and the need for undefined refresher sessions.

### 5.1.7. Cognitive rehabilitation

A high percentage of people with schizophrenia show low efficiency in different aspects of cognitive processing, such as processing speed, attention maintenance, work memory, verbal learning, cognitive functioning or social cognition. These cognitive alternatives also limit learning in other psychosocial interventions and rehabilitation programmes, as well as in social and labour functioning.

Therefore, cognitive rehabilitation consists in an “intervention that focuses on improving cognitive functioning by applying repeated practice of cognitive tasks or by the training of strategies for compensating cognitive impairments”<sup>106</sup>.

Over the last decade, different cognitive training approaches have been developed to improve cognitive impairments in people with schizophrenia, which have following different methods<sup>106</sup>.

- Repetitive exercises of cognitive tasks presented in a computerised or paper and pencil version.
- Compensatory strategies, which imply the learning of strategies to organise information (for example, categorization; or adaptative strategies, with use of reminders or other environment aids.
- Behavioural and didactic learning techniques, such as positive reinforcement instructions, etc.

These methods have been used alone or combined in different training programmes, such as:

- IPT (*Integrated Psychological Therapy*), by Brenner *et al* {Brenner, 1994 1073 /id}
- CRT (*Cognitive Remediation Therapy*), by Delahunty y Morice<sup>112</sup>
- NEAR (*Neuropsychological Educational Approach to Rehabilitation*), by Medalia *et al*.<sup>113</sup>
- CET (*Cognitive Enhancement Therapy*), by Hogarty *et al*<sup>114</sup>
- CAT (*Cognitive Adaptation Training*), by Velligan *et al*<sup>115</sup>
- NET (*Neurocognitive Enhancement Therapy*), by Bell *et al*<sup>116</sup>
- APT (*Attention Process Training*) by Sohlberg & Mateer<sup>117</sup>
- *Attention Shaping*, by Silverstein *et al*<sup>118</sup>
- *Errorless learning*, by Kern *et al*<sup>119</sup>

#### **Question to be answered**

- Are cognitive rehabilitation interventions efficient in people with SMI and cognitive impairment?
- Which is the most adequate format of these interventions for people with SMI and cognitive impairment?

The NICE schizophrenia CPG<sup>8</sup> addresses this question and includes the systematic review by Pilling *et al*<sup>47</sup>, which also contains 5 RCTs. Furthermore, the NICE CPG development group adds another 2 RCTs, making a total of 7 RCT (n = 295).

Roder *et al*<sup>93</sup> carry out a SR of 29 RCTs (n = 1367) where they compare Integrated Psychological Therapy (IPT) with standard treatment and/or placebo. The review differentiates 7 high-quality studies (n = 362) (of which only one is excluded in the NICE CPG<sup>8</sup>), with controlled studies, including randomisation of patients to different treatment groups, fixed doses of antipsychotics or statistically controlled changes in medication, clearly defined blind assessments and complete explanation of the data of the different symptomatic and functional domains that were assessed. The data referred to in this evidence assessment related to this study will be the data from this high quality group of studies, unless specified otherwise.

12 RCTs are included (n = 543) in the SR by Krabbendam y Aleman<sup>120</sup> and the inclusion criteria of the studies were that they had to assess the efficacy of cognitive remediation in patients

with schizophrenia and that the treatment should involve the practice or learning of cognitive skills in individual or group format. Those studies that assessed the impact of operating behavioural techniques such as modelling were excluded, except when some type of behavioural reinforcement was combined with cognitive remediation. Interventions limited to training in one single cognitive task were also excluded. The effects of the intervention were compared with placebo, another intervention or standard treatment. The training method must be different to the tests used to measure. Seven studies were excluded from this review as they did not include control condition (of which 4 had also been excluded by the NICE CPG<sup>8</sup>), and 12 studies, because the intervention involved training in one single paradigm or the task training was also used as an assessment measure.

In the meta-analysis performed by McGurk *et al*<sup>121</sup>, which included 26 RCTs (n = 1151), the studies included are controlled and randomised, and they use a psychosocial intervention aimed at improving the cognitive function. The assessment had to include neuropsychological measures that had the potential of reflecting generalisation, rather than assessing the trained task.

The only RCT<sup>122</sup> included in this question combines data from 121 patients with schizophrenia or schizoaffective disorders, randomly assigned either to Cognitive Enhancement Therapy (CET) (n = 67) or to Enhanced Support Therapy (EST) (n = 54) and they are treated for 2 years. The patients were stabilised and satisfied social-cognitive and neuro-cognitive disability criteria to take part in the study.

In the NICE Schizophrenia CPG<sup>8</sup> no consistent evidence was found to suggest that cognitive remediation improved the cognitive functions indicated or the symptoms in people with schizophrenia. It was also observed that the evidence was insufficient to determine improvements in the mental state at the end of the treatment, and suggest that patients with schizophrenia improve at the end of the treatment in areas such as visual memory, verbal memory, independent life or non-verbal reasoning.

The final recommendation of that CPG is that there is not sufficient evidence so as to recommend the use of cognitive remediation in routine treatment of people with schizophrenia. However, subsequent reviews, which include more studies and more patients, seem to show more favourable results for cognitive rehabilitation. 26 articles were included in the review by McGurk *et al*<sup>121</sup>, of which two<sup>123,124</sup> were excluded from the NICE schizophrenia CPG<sup>8</sup>. Of the 7 articles included in the review made by the NICE CPG, 4 are included in the SR by McGurk *et al*<sup>121</sup> and a total of 14 RCTs are performed after the NICE CPG.

There seems to be an overlapping of the studies included between the NICE schizophrenia CPG and the articles by McGurk *et al*<sup>121</sup> and Krabbendam & Alemán<sup>120</sup>, with greater study inclusion capacity in the last two perhaps because they apply less restrictive criteria, especially in the case of the study by McGurk *et al*<sup>121</sup>. The review by Roder *et al*<sup>93</sup> is worth a separate mention, as it deals with IPT, an integrated programme that includes cognitive rehabilitation, social skills and problem-solving strategies, and whose field is clearly different to the field framed by the NICE Schizophrenia CPG<sup>8</sup>.

This CPG development group has chosen to use the three reviews mentioned above<sup>93,120,121</sup> as the basis, as they are more recent, including articles that had not been published when the NICE Schizophrenia CPG<sup>8</sup> was written, and because it addresses all types of psychosocial interventions aimed at improving cognitive functioning.

There is no homogeneous theoretic framework about the way in which cognitive rehabilitation interventions improve cognition and social functioning areas, so the interventions incorporate

specific elements depending on the existing paradigm. On the one hand, there are interventions based on the rehabilitating paradigm (repetition) and others based on the compensating paradigm. Furthermore, it is not the same as focusing the measurements in molecular cognitive functions (cognitive functions that can be atomised and analysed as a simple answer system), performance in certain tests, or in psychosocial functioning, which requires generalisation.

The applicability to the Spanish health system of this type of intervention is limited by the number of hours required for their application, which makes it difficult to include them in the normal practice in the Mental Health Centres, compared with specific units. Furthermore, these are techniques that require specific capacity-building of the staff and their effect is moderate: the distal objective is the improvement in social functioning, an aspect that other interventions also address such as, for example, social skills training. There is also a risk of taking resources from other interventions.

### ***Cognitive rehabilitation in people with SMI and a diagnosis of schizophrenia and related disorders***

Cognitive rehabilitation produces the following effects (ES data according to the *effect size* by Cohen)<sup>125</sup>.

- SR (1+)                      With reference to global cognition in the meta-analysis performed by Krabendam & Aleman, it is suggested that cognitive rehabilitation may improve the development of tasks (ES = 0.45; 95% CI: between 0.26 and 0.64) but no significant difference has been detected in cognitive improvement according to the number of sessions (if there are < 15 sessions compared with > 15 sessions) (p=0.978)<sup>120</sup>, MacGurk *et al.*<sup>121</sup> also indicate that cognitive rehabilitation improves global cognition (significant for 6 of the 7 cognitive domains assessed) (n=1.214; p<0.001), and psychosocial functioning (n=615; p<0.05) and the symptoms (n=709; p<0.001).
- SR (1+)                      Patients who received IPT (programme that combines neuro-cognitive intervention focusing on social skills in people with schizophrenia) vs. control group was greater for the global effect of the therapy during the treatment (n=170; p<0.01) and showed improvement in the 3 domains assessed: neurocognition (ESw = 0.48; 95% CI: between 0.27 and 0.70), psychosocial functioning (ESw = 0.62; 95% CI: between 0.33 and 0.92) and psychopathology (ESw = 0.49; 95% CI: between 0.26 and 0.72) (p<0.01)<sup>93</sup>.
- SR (1-)                      However, patients who only received sub-programmes of IPT of cognitive differentiation, social perception and verbal communication obtained greater effects in the neurocognitive domain (RCT = 12; ES = 0.72; 95% CI: between 0.51 and 0.90) and less effects in the psychosocial functioning domain (RCT=7; ES = 0.38; 95% CI between 0.13 and 0.61)<sup>93</sup>.
- SR (1+)                      McGurk *et al.*<sup>121</sup> also indicate that the cognitive rehabilitation programmes, which provided adjuvant psychiatric rehabilitation, showed greater improvements in the psychosocial functions (p < 0.01) than those that did not provide psychiatric rehabilitation.

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b The values of the effect size of Cohen (*d*) vary between: small effect (*d* = 0.2), medium (*d* = 0.5) and large (*d* = 0.8 up)

With reference to the type of training, the interventions that include the design of (compensatory) strategies offered better results than those that did not do so or than those based on (rehabilitating) repetition for the psychosocial functioning area but not for the cognitive area (ES = 0.52, 95% CI: between 0.25 and 0.78) vs. (ES = 0.34; 95% CI: between -0.03 and 0.70)<sup>120</sup>. SR (1+)

The data provided with respect to the maintenance of the effect of the programmes, after they end, indicate that: SR (1+)

In the review by McGurk *et al*<sup>121</sup> the post-treatment results are maintained for 8 months (p <0.001); and in the Roder IPT it shows that the effects observed are maintained in the follow-up phase 8 months after the programmes end (p<0.05)<sup>93</sup>.

In the study conducted by Hogarty *et al* where *Cognitive Enhancement Therapy* (CET) is compared with enhanced supportive therapy, a greater effect is observed in favour of CET with respect to the processing speed measurements (p = 0.012), social cognition (p = 0.002), cognitive style (p = 0.007), and social adjustment (p = 0.006), but not for neurocognition (p = 0.195)<sup>122</sup>. It is also indicated that the effect is maintained for 36 months after the end of the intervention. RCT (1++)

### Summary of evidence

1+	Cognitive rehabilitation improves global cognition (maintained after 8 months' follow-up), psychosocial functioning and the symptoms <sup>121</sup> .
1+	Cognitive rehabilitation programmes that also provide psychiatric rehabilitation, improve the psychosocial functions <sup>121</sup> .
1+	Cognitive rehabilitation can improve the development of tasks <sup>120</sup> .
1+	No significant difference has been detected in cognitive improvement according to the number of sessions of cognitive rehabilitation <sup>120</sup> .
1+	The interventions that include design of (compensatory) strategies offered better results than those that did not do so, or those that were based on (rehabilitation) repetition, for the psychosocial functioning area, but not for the cognitive functioning area <sup>120</sup> .
1+	The IPT is higher for the global effect of the therapy during the treatment phase and in the follow-up phase (after 8 months) <sup>93</sup> .
1+	The IPT is more effective in the neurocognition, psychosocial functioning and psychopathology domains <sup>93</sup> .
1-	The application of only the IPT subprogrammes of cognitive differentiation, social perception and verbal communication obtained greater effects in the neurocognitive domain and less effects in the psychosocial functioning domain <sup>93</sup> .
1++	When Cognitive Enhancement Therapy (CET) is compared with enhanced supportive therapy, a greater effect is observed in CET respect to the processing speed, social cognition, cognitive style and social adjustment measurements, but not for neurocognition. These results are maintained 36 months after the end of the intervention <sup>122</sup> .

## Recommendations

B	People with SMI and diagnosis of schizophrenia and related disorders that have cognitive impairment must be offered cognitive rehabilitation programmes.
B	Cognitive rehabilitation programmes aimed at people with SMI and cognitive impairment must be integrated into more extensive psychosocial rehabilitation programmes.
C	From the cognitive rehabilitation interventions or programmes aimed at people with SMI, it is advisable to choose those that include or are accompanied by “compensatory” interventions, in other words, changes in strategy, and training in coping skills or techniques.

### 5.1.8. Other psychotherapies: morita therapy, drama therapy, distraction therapy and hypnosis

#### *Morita therapy for people with SMI*

Morita therapy is a systematic psychotherapy based on Eastern psychology. The therapy was created to treat neurosis and its use has been extended to schizophrenia although, to date, its efficacy has not been systematically verified. The therapy includes a structured behavioural programme to promote relationships with others and consequently, greater social functioning.

There is a systematic review carried out by He *et al*<sup>126</sup> (11 RCT, n = 1041) which analyses the effects of morita therapy in hospital environments for people with SMI and a diagnosis of schizophrenia and related disorders, comparing them with standard care in connection with social functioning (daily living activities-DLA) and mental state (negative symptomatology, measured through SANS and the general mental state, according to scores obtained in the BPRS). The studies included vary with respect to the number of treatment phases and the treatment duration.

Standard care consists of pharmacological treatment, and the results are grouped into short-term (up to 12 week), medium term (13 to 52 weeks), and long term (>52 weeks).

This type of therapy is not a common normal OK practice and it is not very well-known among professionals of the Spanish National Health System, as it has its origins in an Asiatic culture (in particular, Japan and China). Sufficient studies have not been found, either, and there are no data about its practice that can be applied to people with SMI in different cultural contexts.

#### *Distraction techniques for people with SMI*

Distraction techniques were considered to be coping strategies involving a diversion. This can be a passive distraction technique, such as watching television, listening to music, using headphones or practicing relaxation. Alternatively, the distraction can involve activities, such as playing an instrument, writing, reading, gardening, walking or some other form of exercise. Other distraction techniques include socialisation, suppression of unwanted thoughts and problem-solving for future events<sup>127</sup>.

Crawford-Walker *et al*<sup>128</sup> (5 RCTs, n = 186) examine the clinical effects of distraction techniques to divert attention from hallucinations in people with schizophrenia or related disorders. In this SR the distraction techniques are compared with standard care (type of care that a person

would normally receive and which includes interventions such as medication, hospitalisation, community psychiatric nursing input and/or day hospital, other psychological treatments (problem solving therapy, psycho-education, cognitive-behavioural therapy, family therapy or psychodynamic psychotherapy) or social treatments (including social skills training and life skills training). In this study, about 30% of all the people included left before study completion. Distraction techniques did not seem to promote or hinder leaving the study early. It could be argued that the distraction techniques failed to engage participants in studies in a more meaningful way than the control activities. The distraction technique is a practice used in the field of mental health in Spain, which requires specific professional training.

### ***Drama therapy for people with SMI***

Drama therapy is a form of treatment that encourages spontaneity and creativity. It can promote emotional expression, but does not necessarily require the participants to have insight into their condition or psychological-mindset.

In the study conducted by Ruddy *et al*<sup>129</sup> (5 RCT, n =120) they compare drama therapy with standard treatment. All the studies were conducted with hospitalised patients with schizophrenia, compared the intervention and standard hospital care. Due to the deficiencies of the reports, very few data could be used from the 5 studies, and there were no conclusive findings about the harm or benefits of drama therapy for hospitalised patients with schizophrenia. There are differences between the description of psychodrama in China, which is where some of the studies included in this review originate from (Qu *et al*<sup>130</sup>, and Zhou & Tang<sup>131</sup>). It must also be taken into account that the results reflect different versions of drama therapy (psychodrama, social drama and role-playing) which makes it difficult to generalise the results of these studies to western drama therapy.

### ***Hypnosis for people with SMI***

The American Psychological association defines hypnosis as “the procedure during which a health professional or researcher suggests that a client, patient or subject experience changes in sensations, perceptions, thoughts or behaviour”.<sup>132</sup>

Izquierdo & Khan<sup>132</sup> (3 RCTs, n = 149) assess hypnosis in patients with schizophrenia, comparing it with standard treatment (the normal level of psychiatric care that is provided in the area where the trial is carried out: medication, hospitalisations, family intervention, etc.) or other interventions. The hypnosis intervention consisted in one single 90-minute session. Results are only provided in this SR when hypnosis is compared with ST or relaxation related to mental state (these data come from thesis)<sup>133</sup>, as those articles that had large losses (>50%) during the follow-up were excluded.

#### **Question to be answered**

- Are morita therapy, drama therapy, distraction therapy or hypnosis effective in people with SMI?

## **Morita Therapy**

### *Morita therapy (MT) + standard treatment (ST) vs ST*

- SR (1-) There are no differences between morita therapy + ST vs. ST related to short-term improvement of negative symptoms (measured according to the SANS scale) (1 RCT, n = 50; RR = 0.89; 95% CI between 0.41 and 1.93) However, significant differences have been found in favour of MT in the medium term (1 RCT, n = 42; RR = 0.25; 95% CI between 0.08 and 0.76)<sup>126</sup>.
- Results have been obtained in favour of morita therapy + ST related to mental state, according to the BPRS scale, in medium term (1 RCT, n = 76; reduction >25% to 30% in BPRS; RR = 0.35; 95% CI: between 0.14 and 0.89; NNT = 5, 95% CI : between 4 and 25)<sup>126</sup>.
- Morita therapy + ST significantly improved the capacity to carry out daily living activities (social functioning) in the short term compared with standard treatment alone (1 RCT; n = 104; WMD = -4.1; 95% CI between -7.7 and -0.6), and in the medium term (n = 48, WMD: -10.50; 95% CI between -12.50 and -8.50)<sup>126</sup>.

## **Distraction techniques (DT)**

- SR (1-) There are no differences between DT + standard treatment (ST) vs. health promotion + ST, related to the short term improvement of the mental state (measured through the BPRS scale) (1 RCT; n = 60; WMD = 1.60; IC 95%: between -0.49 and 3.69)<sup>128</sup>.

## **Drama therapy**

### *Dramatherapy + ST vs. group therapy + ST*

- RCT (1-) The results indicate that there is no significant improvement of the mental state of hospitalised people with schizophrenia who have received drama therapy as an intervention, compared with group therapy ( n = 24; RR: 0.5, 95% CI: between 0.05 and 4.81)<sup>130</sup>.

### *Psychodrama + medication + hospital stay vs. medication + hospital stay*

- RCT (1-) In the study conducted by Zhou & Tang<sup>131</sup>, improved levels of self-esteem were found in favour of the psychodrama group (measured through the SES scale) than in the control group (n = 24; WMD = 4; 95% CI: between 0.80 and 7.20).

## **Hypnosis**

### *Hypnosis vs. ST*

- RCT (1-) No evidence is found to indicate that hypnosis improves the mental state after a week of intervention measured with the BPRS scale (1 RCT; n =60; WMD = -3.63; 95% CI: between -12.05 and 4.79)<sup>133</sup>.

### *Hypnosis vs. relaxation*

No improvement or deterioration OK of the mental state has been found between hypnosis and relaxation, assessed with the BPRS scale, after a week of intervention (1 RCT; n = 60; WMD = -3.38; 95% CI+ between -11.40 and 4.64)<sup>133</sup>. RCT (1-)

### Summary of evidence

1-	In morita therapy applied to people with schizophrenia, no significant results have been found with respect to the improvement of negative symptoms, or the improvement of the mental state <sup>134</sup> . However, significant differences have been found in favour of morita therapy in the medium term <sup>135</sup> .
1-	Morita therapy + standard treatment improve the mental state in the medium term <sup>136</sup> .
1-	Morita therapy improves the capacity to carry out daily living activities in people with schizophrenia in the short <sup>137</sup> and medium term <sup>138</sup> .
1-	There are differences between the distraction technique and standard treatment related to improving the mental state of people with schizophrenia <sup>139</sup> .
1-	Drama therapy did not show any improvement in the mental state of hospitalised people with schizophrenia <sup>140</sup> .
1-	Drama therapy can help improve the self-esteem of people with schizophrenia <sup>131</sup> .
1-	There is no evidence to indicate that hypnosis improves the mental state in people with schizophrenia <sup>133</sup> .

### Recommendations

	Sufficient evidence has not been found to make recommendations related to morita therapy, drama therapy, distraction therapy and hypnosis in the treatment of people with SMI.
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## 5.2. Social interventions

These are interventions, activities and community support structures whose aim is to facilitate social integration into the context. Social interventions include different types of strategies and programmes. This CPG includes daily living programmes, residential programmes in the community and programmes directed to leisure and spare time.

### Question to be answered

- Do social insertion programmes –daily living skills programmes, residential programmes in the community, or programmes directed to leisure and spare time- improve the evolution of the illness and the quality of life of people with SMI?

### 5.2.1. Daily living skills programmes

The daily living skills training programmes referred to in this section are instrumental skills that can include aspects such as self-care, handling money, organising the house, domestic chores, and even interpersonal skills. The aim of acquiring these skills is to facilitate rehabilitation, maintenance and adaptation of the people with SMI to their normal environment, and, within each person's possibilities, for them to be able to lead a more independent life.

Tungpunkom & Nicol<sup>141</sup> conducted an SR including 4 RCTs (n = 318) which assesses the effectiveness of daily skills training programmes, comparing them with standard programmes or other programmes, in people with severe mental illness. Different articles by Robert Libermann<sup>142-145</sup> have also been reviewed. This author has several publications in this field, and they have been rejected as they refer to social skills training and not to instrumental skills, which is the focus of this question.

SR (1-) The results found do not indicate differences between people who have been trained in the daily living skills programme, compared with people who have received standard intervention, regarding the following aspects<sup>141</sup>

Domestic activities (n = 10; RR = 0.24; 95% CI: between 0.001 and 4.72).

Self-care (n = 10; RR = 1.00; 95% CI: between 0.28 and 3.54)

Positive symptoms of the PANSS (n = 38; WMD = -0.80; 95% CI between -4.38 and 2.78).

Negative symptoms of the PANSS (n = 38; WMD = 1.90; 95% CI between -1.75 and 5.55).

General psychopathology of the PANSS (n = 38; WMD = 0.00; 95% CI -3.12 to 3.12).

Quality of life (n = 32; WMD = -0.02; 95% CI: -0.01 to 0.03).

### 5.2.2. Residential programmes in the community

These programmes consist of alternative housing where people with SMI live either temporarily or permanently and whose aim is to train them in those skills required for them to independently adapt to daily life, insofar as possible. In these structured spaces they are provided with a resource where their personal and social deficiencies are compensated, in order to improve their physical health, self-care, responsibility with the treatment, cognitive functioning, social functioning and participation in community activities, avoiding relapses, readmissions and use of health services.

Literature distinguishes two types of approaches: *supported housing*, where the independent housing in the community is accompanied by support and monitoring by community mental health services, and *residential continuum* where it is the actual service or agency that provides the clinical care, the person is progressively located at levels of differing support and supervision intensities<sup>146,147</sup>. The most common residential programmes in Spain are independent flats, supervised flats, mini-homes and supervised places in hostels and housing in alternative families<sup>148</sup>. All of this falls within a coordinated socio-health functional model.

*Supervised flats* are a community housing and social support resource located in flats or houses where several people, with sufficient level of independence and with Severe Mental Illness, live together, and who do not have sufficient family support to live independently. They offer, on a temporary or indefinite basis and depending on the needs of each case, housing, personal and social support, support to integration, and flexible and continued supervision.

*Mini-homes* are small community residential centres with around 20 places, destined for people with severe mental illness and with their personal and social autonomy impaired. Their main objective is to temporarily or indefinitely provide housing, maintenance, care, personal and social support, support to community integration, to people who do not have family and social support or who, due to their degree of psychosocial impairment, require the services of this type of residential centre.

*Supervised places in hostels* are hostels where, in order to avoid marginalisation processes, housing as well as the coverage of basic needs are offered to people with severe mental illness with a good level of autonomy and a very independent lifestyle, but with no family support or economic resources.

There is a systematic review conducted by Chilvers *et al* 149 with respect to which, despite obtaining 139 quotes, after selecting the studies and assessing their quality, none were found that satisfied the inclusion criteria established in the review, so no conclusions could be drawn.

Although no data have been found in systematic reviews or controlled clinical trials that provide any proof, there is information to indicate that different residential programmes are able to maintain a considerable number of people with SMI in the community, as occurs with the work carried out by Fakhoury *et al* 150. These authors conduct a review of 30 studies (mainly descriptive) where the efficacy of the community residential programmes for SMI patients is assessed. In this study, positive results are found with respect to the improvement of functioning and social integration, and greater satisfaction of the patients, compared with patients from mid and long stay units. Descriptive (3)

Furthermore, in the cross-sectional and descriptive study by López *et al* 151-155, the community residential programme for people with SMI in Andalusia is analysed. Practically all the devices and residents attached to this programme were assessed in this study (16 *homes*, 67 flats and 399 residents). The results of this work, among others, indicate that there is an improvement in the user's satisfaction with supervised housing ( $n = 327$ ;  $p = 0.035$ ) and the pharmacological treatment adherence increases ( $n = 372$ ;  $p < 0.001$ ).

### 5.2.3. Programmes aimed at leisure and spare time

The objective of these programmes is to help people with SMI recover, fostering social relations and the use of free time, fostering participation in community atmospheres and meeting activities, holidays and activities of personal enrichment.

These activities are, per se, a tool and a result at the same time insofar as social integration is a component of the quality of life and this is one of the results to be obtained with psychosocial interventions<sup>156</sup>. This concept of “recreational rehabilitation” has been proposed as a counterpoint to other instrumental rehabilitation interventions, such as occupational or residential interventions, and the characteristic that distinguishes them is that they are designed for one’s own satisfaction<sup>157</sup>.

No SR or RCT has been found that refers to the importance of social integration through alternatives that organise leisure and free time as a systematised study. There is a longitudinal study by Petryshen *et al*<sup>158</sup> that measures the efficacy of a leisure and free time programme, aimed at socially isolated individuals aged 18 to 65, with Severe Mental Illnesses and with a follow-up period of one year. The study has certain limitations with respect to the size of the sample (n = 36), the fact that there is no comparison therapy or group and that it is applied to people with high motivation levels.

The results indicate that significant differences have been found respect to:

- Before and after (3)
- General satisfaction with life: (p<0.001)
  - Reduction of solitude: ( p<0.001)
  - Promotion of self-esteem ( p<0.05)
  - Satisfaction with social relations (p<0.05)
  - Satisfaction with leisure activities (p<0.05)
  - Social functioning (p<0.001)

There is certain professional knowledge, based mainly on daily clinical practice of the symptomatic improvement of some people with SMI after their participation in programmes that structure the execution of constructive leisure activities.

Despite the lack of evidence about the efficacy of these programmes, this type of interventions and resources exist today and they can be accessed through the Spanish national health system or social services. The mental health and social services professionals have the skills to carry out these interventions; however, there are great differences between the different autonomous communities and between rural and city areas, respect to resources and to the programmes offered.

### Summary of evidence

	<b>Daily living skills programmes</b>
1-	There are no differences between people who have been trained in the daily living skills programme compared with those who have received standard intervention, related to domestic activities, self-care, positive and negative symptoms, general psychopathology and quality of life <sup>159,160</sup>
	<b>Residential programmes in the community</b>
3	Community residential programmes improve social functioning, social integration and the degree of satisfaction of patients compared with rehabilitation programmes in medium and long-stay units <sup>150</sup>
3	Community residential programmes produce an improvement in the user’s satisfaction and increases pharmacological treatment adherence. <sup>151-155</sup>

	<b>Programmes directed to leisure and spare time</b>
3	Leisure and free time programmes in people with SMI and with deficiencies perceived in their social relations help improve the general satisfaction with their lives, it reduces the perception of solitude, fosters self-esteem, improves satisfaction with social relations, with leisure activities and improves social functioning <sup>158</sup> .

### Recommendations

√	Daily living skills training programmes could be offered to people with SMI in order to improve their personal independence and their quality of life.
D	For people with SMI who require support to remain in their accommodation it is advisable that the community residential offers include more extensive psychosocial programmes.
D	People with SMI and deficiencies perceived in their social relations should follow community leisure and spare time programmes.
√	During the monitoring of the individualised therapeutic programme, it is advisable to systematically assess the need to use the spare time programmes and offer them to people with SMI who require them.

### 5.2.4. Programmes aimed at employment

Over the last decades in all Mental Health programmes, the employment-oriented programmes and devices for people with SMI are considered to be strategic and form part of the basic rehabilitation objectives.

Labour insertion is an instrument to achieve full social integration in conditions of personal autonomy and participation in the community. It also responds to a right, and to an ethical question derived from the permanent exclusion from the work market. The need for labour insertion programmes to include health and social care aspects in their methods, and not just occupational training aspects, is admitted.

Work, in the recovery process, is not just an activity that develops generalizable competences and improves personal functioning, but it is also an element for social exchange and economic independence. Remuneration and salaries are considered a key motivational element for a person to stay in a job. In any case, due to the different experiences, it is common to place emphasis on motivation and personal choice and take into consideration, from the onset, personal interests and objectives.

Despite the obvious need for these resources, there is no generalised or approved practice. Labour insertion resources have a different typology and experience varies from one country to another. This is due to the differences between the health and social services systems, the different regulations that govern access to employment, social-cultural differences and the actual labour market.

By way of analysis, there are two approaches to address a labour rehabilitation intervention. One is the *train-then-place* or *supported employment*, which places emphasis on the stability and recovery of skills in prior programmes that permit subsequent generalisation. The other, *place-then-train*, which places emphasis on immediate occupation of a job, activating the learning and monitoring programmes in the job<sup>161</sup>.

The different formulations orientated to labour insertion can be grouped into three types of instrumental programmes: supported employment, social enterprises and vocational rehabilitation<sup>162</sup>. These programmes are not antagonist conceptions as they can be complementary and respond to different degrees of difficulty both individual (stability, employment prior to the illness, labour and social skill, etc.), and availability of human resources, as well as to situations derived from the labour market.

Vocational rehabilitation (or labour rehabilitation) starts up social skills training and professional preparation programmes for the subsequent incorporation into a job. They adapt both to the special difficulties of the candidate and to their counselling, support and monitoring needs in the job, and they can incorporate occupational learning workshops with occupational activities. They risk losing their efficiency and just providing training and repetitive learning if there is no perspective of immediate incorporation into employment, either sheltered or ordinary.

The concept of social enterprise is a concept that encompasses (although with certain risks) different business figures whose objective is to create employment for people with difficulties for the competitive market. The regulation that governs them forces individual capacity-building and adjustment programmes and compensates individual and structural difficulties with supportive measures which can be economic (grants, rebates), contract of employment (times and conditions), as well as in supportive human resources: *Social Firms* (UK and Germany), and *Cooperatives* (Italy).

In Spain, the predominant figure has been the Special Employment Centre (Spanish acronym CEE) (with which the expression “sheltered employment” is identified), created for the group of disabled people through the Law on Social Integration for the Disabled<sup>163</sup>. The CEE is understood in law as transition employment to the ordinary market, but in many cases, due to either structural difficulties, the rigidity of the labour market, and the lack of supportive programmes to the ordinary market, they remain as definite sheltered employment and sometimes marginal employment.

Supported employment is directed at immediate placement in the competitive market, accompanied by training and individual monitoring measures at work, as well as support to the employer, with no definite time interval to guarantee maintenance of the job. This approach places emphasis on quick access and attention to personal preferences and motivations; on considering that there is not need for long processes of evaluation and re-training, which, in some cases, are a factor of demotivation; and that the personal stability process is accelerated if care and labour aspects are integrated at the same time, enabling them to overcome difficulties.

Of all the employment support models, the one that has been investigated into the most is individual placement and support (IPS)<sup>164</sup>.

In this way it can be considered that the interventions to be addressed by this CPG will include not only sheltered employment, labour rehabilitation interventions including sheltered workshops, special employment centres, etc., but also include employment support.

#### **Question to be answered**

- Which employment-related intervention format improves labour market insertion of people with SMI?

The NICE Schizophrenia CPG<sup>8</sup> includes the SR by Crowther *et al*<sup>165</sup> and also 2 other RCTs<sup>166,167</sup>. The inclusion criteria used in the NICE CPG<sup>8</sup> refer to people with a diagnosis of

SMI (schizophrenia, affective schizophrenia and bipolar disorders). Studies, whose population consisted of people with low intellectual level/mentally retardation, or abuse of substances as first and only diagnosis, were excluded. The studies included vary with respect to the follow-up period (from 5 months to 4 years), losses, diagnosis and age (19-46 years).

The systematic review elaborated by Crowther *et al*<sup>165</sup>, which includes 18 RCTs<sup>168-185</sup>, is designed to assess the efficiency on employment of pre-vocational training (PVT) and sheltered employment (SE), compared with each other and with standard treatment (ST).

With respect to people with SMI and a diagnosis of bipolar disorder, data have been found in the NICE Bipolar Disorder CPG<sup>7</sup> that include data from the NICE Schizophrenia CPG<sup>8</sup> and add another 3 RCTs that are useful due to the specific nature of the studies, but lack applicability to the subgroup of SMI with a diagnosis of bipolar disorder, as they include SMI with little representation of this diagnosis in the samples (5%-43%).

Bond *et al*<sup>186</sup> perform an SR, which includes 11 RCTs on sheltered employment studies which are very faithful to the *Individual Placement and Support*, (IPS) on patients with SMI, in order to assess their efficacy in achieving competitive employment.

Mueser *et al*<sup>187</sup> performed a RCT where the relationships between preferences, satisfaction and maintenance of employment are examined in a sample of 204 patients with SMI. The patients were randomised between IPS, a psychiatric rehabilitation programme and standard treatment. The patients assigned to the IPS programme, those who obtained employment that coincided with their prior preferences with respect to the type of work desired, obtained higher levels of satisfaction and longer duration of the employment. This relationship was not observed in the other two programmes.

In the RCT (n = 40) developed by McGurk *et al.*<sup>188</sup> in people with SMI and with a prior history of labour failure, they were assigned randomly either to a sheltered employment programme or to another employment programme fostered with cognitive training. The labour results were measured after 2 to 3 years. The results obtained indicate that patients in the sheltered employment programme with cognitive training obtained greater access to employment (69% vs. 14%), maintained more jobs, worked more weeks, more hours and with better salaries than patients who were only offered sheltered employment (p<0.001).

Finally, two multi-centre studies have been included, one performed in the USA and the other at six European sites. The American multi-centre study, designed to compare the cost-efficiency of the current atypical and conventional antipsychotics (CATIE), assessed, in 1411 people with SMI and a diagnosis of schizophrenia, the existing relationship at the onset of the study between the participation in competitive employment or other vocational activities, and the availability of psychosocial rehabilitation services. This study indicates that the greater participation in labour rehabilitation services was associated with the participation in competitive employment (OR = 1.3, p< 0.05) and to a greater extent with non-competitive employment (OR = 1.52; p < 0.0001)<sup>189</sup>.

In the other multi-centre study carried out at six European sites, 312 people with SMI were randomised (80% with a diagnosis of schizophrenia and schizo-affective disorders and 20% with bipolar and other disorders) to a sheltered employment programme (EP-IPS) or pre-vocational training (PVT). An 18-month follow-up was carried out as well as an analysis for intention to treat, in order to evaluate the efficacy of the IPS programme in Europe and examine if its effects are modified by the local state of the labour markets and social benefits<sup>164</sup>.

All these studies include patients who satisfy similar SMI criteria to those used in our setting. However, the studies originate mainly from the United States, where the peri-environmental factors (legislation, economic and social protection situation, unemployment rate, social and health structures, etc.) are considered important and are very different to the Spanish context. The interventions can be similar to those carried out in Spain, although faithfulness to the IPS model is difficult in the few places where there are labour insertion programmes or services; it is more similar with respect to standard treatment and pre-vocational training.

The authors of the studies point out the difficulty of working with community samples that are heterogeneous and that include people who do not want to work, and the difference that exists with patients in employment programmes, that may represent a self-selected sample. Furthermore, the employment rates obtained are low, even with the more effective programmes (except for the EP-IPS programmes with high fidelity to the model, with which the majority of the participants, >50% obtain employment), and employment is not a personal or valid objective for all people with SMI.

There are authors who point out that a general unemployment rate of over 10% in the society has a clear and negative effect on the acquisition and maintenance of employment in the population with SMI, and in our context this case arises<sup>190</sup>. However, although the incorporation into an employment programme is a personal decision, after the information and appropriate consent, the acquisition and maintenance of the role of worker favours a normalising process in the person and improves independence, so the implementation of employment orientated programmes appears to be important and necessary.

#### *Pre-vocational training (PVT) vs. standard treatment (ST)*

- RCT (1-)                    There is no evidence in favour of PVT when maintaining competitive employment after 8 months, compared with standard hospital treatment in a small study (n = 50; RR = 0.79; 95% CI between 0.63 and 1.00)<sup>168</sup>.
- RCT (1-)                    No differences are observed in obtaining competitive employment after 18 months between PVT and community treatment (n = 28; RR = 1.18, 95% CI: between 0.87 and 1.61)<sup>169</sup> and 24 months (n = 215; RR = 0.95; 95% CI: between 0.77 and 1.17)<sup>170</sup>.
- RCT (1-)                    The PVT favours obtaining some type of employment when compared with standard hospital treatment (n = 59; RR = 0.42; 95% CI between 0.26 and 0.68)<sup>168</sup>.
- RCT (1-)                    No differences were observed in hours worked per month between PVT and standard hospital treatment (n = 28; hours = 36.8 and 31.6 average hours respectively; p = 0.92)<sup>171</sup>.
- RCT (1-)                    There is certain evidence that PVT users earn significantly more money a month than those that receive standard hospital treatment (\$176 and \$97.3 on average, respectively; p <0.01)<sup>172</sup>.
- SR (1+)                     There is no difference respect to the level of participation of users in programmes when the PVT programmes and standard hospital treatment are compared (n = 78; RR = 0.5; 95% CI: between 0.05 and 5.25)<sup>165</sup>.
- There are no differences between PVT and community treatment in any form or data related to employment<sup>165</sup>.

When PVT is compared with standard community treatment, there are no differences in the programme finalisation rate (n = 284; RR = 0.95; 95% CI between 0.52 and 1.7)<sup>165</sup>.

Despite finding a lower ratio of hospital readmission among patients who received PVT (n = 887; RR = 0.79; 95% CI between 0.65 and 0.95), this difference was no longer significant when a random effect model was used due to the high heterogeneity in 3 studies (n = 887; RR = 0.71; 95% CI between 0.48 and 1.04)<sup>165</sup>, so the evidence is insufficient to determine if there are significant differences between PVT and ST in hospital readmission ratios.

*Pre-vocational Training (PVT) vs. PVT + alternatives (clubhouse, economic reinforcement, psychological intervention, transitional employment)*

In the work by Beard *et al*<sup>170</sup> no significant differences have been found between the PVT according to the clubhouse model (device where and from where they offer: a) social activities, b) daily job instructions in teams, c) transitional employment for 3-4 months until phases a and b are completed, and placement in a job with adaptation and support) compared with standard community treatment, with respect to obtaining competitive employment and any other employment variable, with a 3 to 12 month follow-up (n = 215; RR = 0.95; 95% CI: between 0.77 and 1.17). RCT (1-)

There are less readmissions in the PVT-clubhouse group, compared with the standard community treatment (n = 215; RR = 0.69; 95% CI: between 0.46 and 0.96)<sup>170</sup>. RCT (1-)

The 6-month study by Bell *et al*<sup>176</sup>, a paid part-time sheltered job intervention, in the context of a hospital, from caretakers to administrative staff, with 50-minute weekly group support, shows a larger number of people in any type of employment in the PVT group + alternatives (economic reinforcement), compared with just PVT (n = 150; RR = 0.40; 95% CI: between 0.28 and 0.57), and they also earned significantly more money a month (\$192 and \$32 respectively; t = 7.56; p = 0.0001). The competitive work was not a result studied. RCT (1+)

The participants in the paid sheltered work group presented greater permanence (n = 150; RR = 0.53; 95% CI: between 0.39 and 0.71; NNT = 3), less number of hospital readmissions (n = 150; RR = 0.55; 95% CI between 0.31 and 0.96; NNT = 6) and less scores in symptoms (measured on the PANSS scale; p < 0.02) than the PVT group<sup>176</sup>.

In the studies by Kline & Hoisington<sup>177</sup>, and Blankerz & Robinson<sup>178</sup>, PVT and psychological techniques were carried out. In the study by Kline & Hoisington<sup>177</sup> there is a 1.5 hour group intervention for 12 weeks, when discussions are held on labour values and which is aimed at reducing anxiety. In the Blankerz & Robinson study<sup>178</sup> counselling is applied as well as social technique learning and group sessions with reinforcement by partial objectives. Both studies presented favourable results with respect to obtaining competitive employment (n = 142; RR = 0.86; 95% CI between 0.78 and 0.95; NNT = 7); but heterogeneity was observed in the studies (p = 0.007). When the re-analysis was performed with a random effects model, no significant differences were found (n = 142; RR = 0.76; 95% CI between 0.44 and 1.33). RCT (1+)

RCT (1+) Those that received PVT + additional psychological intervention presented difficulties in favour of obtaining “some type of employment” (n = 122, RR = 0.89; 95% CI between 0.81 and 0.97; NNT = 9) and “some form of employment or education at the end of the study” (n = 122, RR = 0.85; 95% CI between 0.52 and 0.77; NNT = 3)<sup>178</sup>.

No differences were observed between PVT + psychological intervention and the control respect to clinical improvement (n = 142; RR = 0.85; 95% CI between 0.33 and 2.18)<sup>178</sup>.

RCT (1+) Patients with prior labour failure integrated in the sheltered employment programme with cognitive training presented greater probability of having worked (69.6% vs. 14.3%), having maintained more jobs, worked more weeks, more hours and with higher salaries than patients who were only offered sheltered employment (p<0.001)<sup>188</sup>.

RCT (1+) The study by Bond & Dincin<sup>179</sup> provides data when it compares transitional employment with accelerated entry (with no pre-vocational training, paid employment at least 2 days per week) with gradual entry into sheltered employment. A difference is observed in favour of accelerated entry (n = 131; RR = 0.88; 95% CI: between 0.78 and 1.00). Users with accelerated entry into transitional employment did not achieve better employment data (n = 131; RR = 0.96; 95% CI: between 0.69 and 1.33), however they earned significantly more money.

#### *Sheltered employment (SE) vs. standard treatment (ST)*

RCT (1+) Sheltered employment shows a significantly larger number of people in competitive employment after 24 and 36 months (n = 256; RR = 0.88; 95% CI: between 0.82 and 0.96; NNT = 9), but not after 12 months<sup>180</sup>.

Users in sheltered employment programmes showed a greater probability of holding some type of employment after 12 months (n = 256; RR = 0.79, 95% CI between 0.70 and 0.90; NNT = 6), and also earn significantly more money per month than the controls (\$60.5 vs. \$26.9, p <0.05)<sup>180</sup>.

Sheltered employment did not show any significant differences with the controls in participation ratio (n = 256; RR = 0.75; 95% CI: between 0.55 and 1.01) nor in a smaller number of readmissions (n = 256; RR = 0.83; 95% CI: between 0.63 and 1.1)<sup>180</sup>.

Observational (3) The greater participation in labour rehabilitation services was associated with the participation in competitive employment (OR = 1.3, p < 0.05) and to a greater extent with non-competitive employment (OR = 1.62; p < 0.0001)<sup>189</sup>.

RCT (1+) Compared with standard treatment programmes, the patients included in the individual placement and support programme, IPS, had a greater probability of obtaining competitive employment (75.0% vs. 27.5%) or any kind of paid work (75.0% vs. 53.6%) (p<0.0001)<sup>187</sup>.

Patients included in the individual placement and support programme, IPS, who obtained jobs that coincided with their previous preferences on the type of work desired, obtained higher levels of satisfaction ( $p = 0.01$ ) and the job lasted for longer ( $p < 0.05$ ) than those where the job did not coincide with their preferences. This relationship was not observed among patients in psychiatric rehabilitation programmes or in standard treatments<sup>187</sup>.

*Sheltered employment (SE) (including individual placement and support, SE-IPS) vs. pre-vocational training (PVT)*

Significant differences were observed in favour of SE in the number of people with competitive employment after 4, 12 and 18 months. After 12 months, 34% of the patients in SE were employed compared with only 12% of the PVT group ( $n = 484$ ;  $RR = 0.76$ ; 95% CI: between 0.64 and 0.89;  $NNT = 5$ )<sup>165</sup>. SR (1+)

The IPS (Individual Placement and Support) variant of sheltered employment also showed a larger number of people with competitive employment than pre-vocational training, after 4, 12 and 18 months. 30% and 12% respectively were employed after 12 months ( $n = 295$ ;  $RR = 0.79$ ; 95% CI between 0.70 and 0.89;  $NNT = 6$ )<sup>165</sup>.

A review with 11 studies that were very similar to the IPS model showed a greater ratio of competitive employment among people who followed IPS, compared with the other control vocational interventions (61% and 23% employed, difference in averages 38% (range 20% to 55%))<sup>186</sup>. SR (1++)

There is evidence to indicate that IPS achieves a higher number of patients who work more than 20 hours per week compared with the controls (43.6% and 14.2%, respectively)<sup>186</sup>.

The SE-IPS models obtain their first jobs more quickly than the controls (138 days vs. 206), double the time with work per year (12.1 vs. 4.8 weeks/year) and keep competitive work for longer (22.0 vs. 16.3 weeks)<sup>186</sup>.

Patients in sheltered employment worked more hours in competitive work than those who received PVT ( $p < 0.001$ )<sup>181</sup>, ( $p < 0.001$ )<sup>182</sup>, ( $p = 0.03$ )<sup>183</sup>; and they also earned significantly more money than those that were in PVT: ( $p < 0.05$ )<sup>184</sup>, ( $p = 0.019$ )<sup>185</sup>, and ( $p < 0.001$ )<sup>181</sup>; although in another study the differences were not significant ( $p > 0.05$ )<sup>182</sup>. RCT (1+)

Compared with the psychiatric rehabilitation programmes, the patients included in the IPS programme had greater probability of obtaining competitive employment or any other form of paid employment respectively ( $p < 0.0001$ )<sup>187</sup>. RCT (1+)

There are no differences in maintenance in programmes between SE and PVT<sup>181-185</sup>. None has been found either related to global functioning (measured with the GAF), or self-esteem (measured with the Rosenberg scale)<sup>181</sup>. RCT (1+)

Patients included in IPS programmes, after 18 months' follow-up presented greater probability of having worked at least one day than the vocational programmes (55% vs. 28%), lower number of dropouts (13% vs. 45%) and re-hospitalisations (20% vs. 31%). It was also observed that the local employment rate had a substantial influence on the efficacy of the IPS programme ( $p < 0.016$ )<sup>164</sup>. RCT (1+)

## Summary of evidence

1-	The evidence is insufficient to determine if pre-vocational training confers an additional benefit to the labour expectations of people with SMI when we compare it with standard treatment, with respect to maintenance of competitive employment <sup>168,170,171,173,174</sup> .
1-	PVT favours obtaining some type of employment when compared with standard hospital treatment <sup>168</sup> .
1-	There are no differences with respect to hours worked per month between PVT and hospital ST, for people with SMI <sup>171</sup> .
1-	The incorporation of payment into PVT produces a limited but significant improvement of the results <sup>172</sup> . The incorporation of payment into PVT produces a limited but significant improvement of the results <sup>172</sup> .
1+	There is no difference with respect to participation level of users in programmes when PVT programmes are compared with standard hospital treatment <sup>165</sup> .
1+	Neither PVT nor community ST improve the programme finalisation rates <sup>165</sup> .
1+	PVT does not improve the hospital readmission ratios <sup>165</sup> .
1-	There are no differences between PVT (clubhouse model) vs. ST in relation to achieving competitive employment <sup>170</sup> .
1-	There are less hospital readmissions in the group that participated in PVT-clubhouse than in the group that received standard treatment <sup>170</sup> .
1+	The participants in the paid sheltered work group presented greater permanence, lower number of hospital readmissions and lower scores in symptoms than those who only received PVT <sup>176</sup> .
1+	Those who received PVT + additional psychological intervention presented differences in favour of obtaining “some form of employment” and “some form of employment or education at the end of the study” <sup>178</sup> .
1+	There are no differences between PVT + psychological techniques vs. control group with respect to clinical improvement <sup>178</sup> .
1+	Patients with prior labour failure integrated in the sheltered employment programme with cognitive training presented greater probability of having worked, having maintained more jobs, worked more weeks, more hours and higher salaries than patients who were only offered sheltered employment <sup>188</sup> .
1+	Users with transitional employment and accelerated entry did not achieve better employment data than users with transitional employment and gradual entry, but they did earn more money <sup>179</sup> .
1+	The sheltered employment group showed a significantly larger number of people in competitive employment after 24 and 36 months, as well as greater probability than the ST group of being in some type of employment and of earning more money <sup>180</sup> .
1+	Sheltered employment did not show significant differences with respect to the control group in participation ratios or in number of readmissions <sup>180</sup> .
3	The greater access and participation in labour rehabilitation services was associated with a greater probability of achieving competitive employment, and to a greater extent, non-competitive employment <sup>189</sup> .

1+	The people included in the individual placement and support programme (IPS) obtained greater probability of competitive employment, some type of paid work, higher levels of satisfaction, longer duration of the employment than those people where the job did not coincide with their preferences <sup>187</sup> .
1+	There is strong evidence that SE (including SE-IPS) is superior to PVT in Improving the expectations of competitive employment and hours worked per week <sup>165</sup> .
1++	The SE-IPS models speed up the possibility of obtaining a first job and double the time worked per year, maintaining the competitive work for longer <sup>186</sup> .
1+	People in sheltered employment worked more hours in competitive work than those who receive PVT <sup>183</sup> .
1+	People in sheltered employment earn more money than those in pre-vocational training <sup>181,182,184,185</sup> .
1+	There are no differences between SE (including SE-IPS) . vs. . PVT in global functioning <sup>181</sup> .
1+	People included in sheltered employment programmes and pre-vocational training present greater probability of having worked, having lower abandonment and readmission figures. The local employment rates also affect the efficacy of the sheltered employment programmes <sup>164</sup> .

## Recommendations

A	Sheltered employment programmes are necessary for people with SMI who express their desire to return to work or get a first job. Programmes based on placement models are recommended, with a short preliminary training period, immediate placement, and with frequent individual support.
C	Sheltered employment programmes aimed at searching for normalised employment must not be the only programmes related to labour activity that are offered to people with SMI.
D	It would be recommendable for the psychosocial rehabilitation centres that look after people with SMI and diagnosis of schizophrenia and related disorders, to include employment integration programmes.
B	When employment insertion programmes are offered to people with SMI, the preferences on the type of job to be carried out must be assessed and taken into account.
B	For people with SMI and diagnosis of schizophrenia and related disorders, who has a history of previous job failure, it would be advisable to incorporate cognitive rehabilitation as a part of the employment programmes they are going to participate in.
√	The mental health teams, in coordination with the institutions and other social agents involved, must advise about all types of employment resources, aimed at gainful occupation and production, and adapted to the local employment opportunities. Likewise, they must be orientated towards interventions that put into motion different devices adapted to the needs and to the ability level of people with SMI, to increase stable and productive occupation expectations.

### 5.2.5. Other therapeutic interventions: art therapy and music therapy

Music therapy and art therapy are creative interventions, used together with other more common treatments, in the rehabilitation process and treatment of people with Severe Mental Illnesses. There is still a lively debate about whether the curative aspect of this type of interventions lies in the process of making music or art, or in the actual relationship that is established between the therapist and the patient, or in an interaction between both elements.

#### ***Music therapy for people with SMI***

Music therapy is “a systematic intervention process where the therapist helps promote the patient’s health via musical experiences and the relationships that are developed by means of such experiences, as dynamic forces of change”<sup>191</sup>. It is often perceived as a psychotherapeutic method in the sense that it addresses intra- and inter-psycho processes through the interaction with music as a means of communication and expression. The objective of therapy is to help people with severe mental illnesses develop relationships and address questions that they may not be able to develop or address by words.

There is a SR by Gold *et al*<sup>192</sup> (4 RCTs, n = 321)<sup>193-196</sup>, which examines the effects of music therapy on people with schizophrenia, in the short term (duration of less than 20 sessions) and medium term (20 or more sessions). The treatment varies between 7 and 78 sessions.

#### ***Art therapy for people with SMI***

According to the British Association of Art Therapists, artistic materials for self-expression and reflection are used in art therapy, in the presence of a trained art therapist. The general objective of the professionals is to enable the patient to make a change and grow up on a personal level, using artistic materials and in a safe and facilitating atmosphere<sup>197</sup>. Art therapy allows patients to explore their interior world in a non-threatening manner, through a therapeutic relationship and the use of artistic materials. It was carried out mainly in psychiatric units for adults and was designed to work with people with whom verbal psychotherapy would be impossible.

Ruddy *et al*<sup>198</sup>, in the SR carried out by them, compare art therapy and standard treatment with standard care alone, in people with schizophrenia. Only 2 studies (n = 137) satisfied the inclusion criteria in this review. These studies did not include sufficient participants so as for the results to be significant, and clear conclusions could not be drawn with respect to benefits or harm of art therapy based on them.

It is difficult to estimate the availability of this intervention; however, there are descriptions for its use in people with schizophrenia, individually or in groups, in outpatients and hospitals, as well as in the private sector<sup>199</sup>.

#### **Question to be answered**

- Do therapeutic interventions, such as art therapy and music therapy, improve the evolution of the illness and the quality of life of people with SMI?

## Music therapy

### Music therapy + standard treatment (ST) vs. ST

Music therapy as a complement to standard treatment is superior to ST only RCT (1-) in the medium term with respect to the improvement of the global state (n = 72, RR = 0.10; 95% CI between 0.03 to 0.31)<sup>193</sup>.

In an intervention of less than 20 sessions, no significant differences are found in favour of music therapy with respect to the mental state in the medium term (n = 69); average final score in the PANSS scale, WMD = -0.36; 95% CI: between -0.85 and 0.12)<sup>194</sup>; however, when the intervention includes more than 20 sessions, there are differences in favour of music therapy (1 RCT; n = 70; average final score in the BPRS scale, WMD = -1.25; 95% CI: between -1.77 and -0.73)<sup>193</sup>.

Music therapy favours the improvement of negative symptoms (3 RCTs, n = 180); average final score in the SANS scale (WMD = -0.86, 95% CI: between -1.17 and -0.55)<sup>193,195,196</sup>.

There is no improvement of social functioning in the music therapy RCT (1-) group when 20 or more sessions are applied (1 RCT; n = 70; average final score in the SDSI scale, WMD = -0.78; 95% CI: between -1.27 and -0.28)<sup>193</sup>.

No differences are found in favour of music therapy with respect to the patient's satisfaction in the medium term (less than 20 sessions) (1 RCT; n = 69; average score of the CSQ scale, WMD = 0.32; 95% CI: between -0.16 and 0.80)<sup>194</sup>.

Music therapy does not improve the quality of life (measured with the SPG) with an intervention of less than 20 sessions (1 RCT; n = 31; WMD = 0.05; 95% CI between -0.66 and 0.75) when compared with ST alone<sup>196</sup>.

## Art therapy

The mental state measured with the SANS scale slightly improved in favour SR (1-) of the art therapy group (n = 73; 1 RCT; WMD = -2.3; 95% CI: between -4.10 and -0.5)<sup>198</sup>.

Social functioning (measured with the SFS scale) in the short term, did not show any clear differences between the groups in final scores (n = 70; 1 RCT; WMD = 7.20; 95% CI: between -2.53 and 16.93); and quality of life, measured with the Perc QoL scale, did not indicate the effects of art therapy (n = 74; 1 RCT; WMD = 0.1; 95% CI: between -2.7 and 0.47)<sup>198</sup>.

## Summary of evidence

1-	Music therapy as a complement to ST improves the global state in the medium term <sup>193</sup> .
1-	Music therapy produces a positive effect on the improvement of the negative symptoms of people with schizophrenia <sup>193,195,196</sup> .
1-	Interventions of music therapy with more than 20 sessions improve the mental state and social functioning of people with schizophrenia <sup>193</sup> .

1-	There are no differences between music therapy and ST with respect to patient satisfaction in the medium term <sup>194</sup> or the improvement of the quality of life <sup>196</sup> .
1-	Art therapy may produce an improvement in the mental state of people with schizophrenia. However, there are no differences with respect to social functioning or improvement of quality of life <sup>198</sup> .

### Recommendations

C	Music therapy and art therapy could be offered to people with SMI and schizophrenia and related disorders as a therapeutic complement to other types of interventions.
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## 5.3. Service level interventions

The different community care models are based on the need to help people with SMI have access to health resources and to coordinate the different interventions. After a global deinstitutionalisation process, a series of community services have been developed (Community Mental Health Centres- CMHC, day centres, etc.)<sup>8</sup>, which will be reviewed in this section. In Spain, this process came hand in hand with the General Law on Health<sup>200</sup> and represented the emergence of a new care culture, characterised by a shift of the care centre from the psychiatric hospital/mental hospital to the community<sup>11</sup>.

The multi-disciplinary and inter-disciplinary teams (community mental health teams, CMHT), characterised by the involvement of all the mental health care professional categories (nursing, psychology, psychiatry, occupational therapy and social work), have become the most prevalent way of organising work in Europe and United States. The most elementary form of the CMHT provides a whole range of interventions including contributions from psychiatry, psychology, nursing, social work and occupational therapy, for a geographic area of reference, giving priority to adults with SMI<sup>201</sup>. The concerns about the functioning of the CMHT have arisen about the following aspects<sup>8</sup>.

- Impact on the community, violence, etc. of people with SMI.
- Quality of life of patients with SMI and their caregivers.
- Lack of clear evidence about the benefits of the organisation in CMHC.
- Scarce knowledge of the component that would make the functioning more effective.

The development of additional services in the community has resulted in an increase in the complexity that people with SMI encounter when they try to access services that were previously available in hospitals, and precisely some of the problems of this population is the limited initiative, the difficulty to request help and the problems they encounter to be linked up with community services. The recognition of the need to coordinate these different services is what has given rise to the Case Management (CM), and consequently, a new health profession: the case manager<sup>202</sup>. Thus, over the last 20 years other types of services have been generated that can be classified into 2 categories<sup>8</sup>.

- Services with highly defined objectives: intervention in crisis, home care, labour rehabilitation or early intervention.
- Services aimed at covering a wide range of patient's needs, such as Assertive Community Treatment (CAT) or Case Management.

A series of Case Management systems<sup>202</sup> have arisen over the last two decades. The first of the approaches was the “agent” that does not fulfil clinical functions and it is not necessary for him/her to have skills in this regard. The “clinical” model of CM was developed, in recognition of this fact and trying to provide the person in charge of clinical functions with skills in areas such as psychoeducation and psychotherapy. A community programme was created in the seventies as an alternative to the hospital: Programme for Assertive Community Treatment, which has become an extensive therapeutic approach and goes beyond the agent system or clinical system<sup>203</sup>. In the United Kingdom, these teams have been called Assertive Outreach Teams. The CAT is implemented by a multi-disciplinary team with basic characteristics<sup>204</sup>.

- Low personnel/patient ratio (for example, 10:1)
- Services supplied in the community, not in the surgery.
- Cases shared by the team, not assigned individually. 24-hour coverage. 7 days a week.
- Services provided by the team, not external.
- Unlimited in time.

There are other forms of intervention derived from MC and CAT such as <sup>8</sup>

- Care Programme Approach (CPA), with these bases:
  - Systematic methodology to assess the social and health needs. Care plan that identifies the social and health care required for a series of providers.
  - Appointment of a case manager to maintain close contact with the user and monitor and coordinate the care.
  - Regularly programmed reviews, updates and modifications agreed by consensus of the care plan.
- Intensive Case Management (ICM) characterised by a burden of less than 20 patients per case manager (normally one psychiatrist).

The ICM (Intensive case management) model was developed to cover the needs of high-frequency patients, reducing the actual personnel/patient ratio of the agent MC and reaching limits similar to those of the CAT. The difference here is that in the CAT the cases are shared by the team, whilst in ICM they continue to be assigned individually to the case manager, as in the agent CM. Successive modifications have been made to models such as strengthening or rehabilitating, granting a greater role to the patients’ preferences and to their capacities.

Community care of patients with SMI is often structured around the resources that provide care during the day. As Marshall *et al* <sup>205</sup> recall, the term “day care” is better defined by recalling its functions and associating them with the structures that provide them: an alternative to hospitalisation, shorten the hospital stay and promote recovery and maintenance in the community. These three functions can be implemented from three different resources: day hospitals, employment services and social resources.

This chapter, and in general this CPG, do not address questions related to acute treatment (hospital) of the patients or to alternatives (community), such as crisis-intervention teams, home or day hospital treatments.

In order to unify terminology in this CPG, the terms used in the Rehabilitation Recommendations of the Spanish Association of Neuropsychiatry <sup>11</sup> have been adopted, and reference will be made to:

- Psychosocial Rehabilitation Centres, equivalent to the functions of Day Centre
- Rehabilitation Hospital Units, equivalent to Medium-stay Units, Therapeutic communities, etc.

#### Question to be answered

- Which service supply system –day centres and/or psychosocial rehabilitation centres, community Mental Health centres, Assertive Community Treatment, Intensive Case Management (ICM), non-acute day hospitals or Case management (CM)- is more effective in people with SMI?

In the NICE Schizophrenia CPG<sup>8</sup> different service level interventions are addressed, which are included in this CPG, such as:

- Non-acute hospital day care, based on a review which, in turn, includes 8 RCTs, of which 4 are selected.
- Community mental health centres (CMHC) (3 RCTs, n= 334).
- Assertive community treatment (ACT) (22 RCTs, n = 372). The comparer is standard treatment, hospital rehabilitation or standard Case Management (CM).
- Intensive case management (ICM) (13 RCTs, n = 2546).

#### *Day centres and/or psychosocial rehabilitation centres*

There is another, later, systematic review than the NICE CPG<sup>8</sup>, that of Catty *et al*<sup>206</sup>, where, despite having identified more than 300 quotes, no randomised clinical trials on non-medical day centres were found.

#### *Community Mental Health Centres (CMHC)*

Referring to the CMHC, there is a systematic review developed by Malone *et al*<sup>204</sup> which includes 3 RCTs (n = 587) where these centres are compared with a standard hospital service that generally assessed patients in surgeries and outpatients, with less emphasis on multidisciplinary work.

In the review of the CMHC studies, there is agreement in almost all the points assessed: which is understandable if we bear in mind that both the NICE Schizophrenia CPG<sup>8</sup> and the review by Malone *et al*<sup>204</sup> use 3 studies, 2 of which are common to both reviews<sup>201,202</sup>.

The following considerations must be made:

- There is divergence in the results shown with respect to hospitalisations, favourable to CMHC in the study by Malone *et al*<sup>204</sup> and neutral in the NICE Schizophrenia CPG<sup>8</sup>. Both results are obtained from the same RCT<sup>202</sup> so the only explanation is that the NICE Schizophrenia CPG has handled unpublished supplementary data, as it specifies that it has done in the case of this study.
- The NICE Schizophrenia CPG<sup>8</sup> also considers that patients originating from the study by Tyrer *et al*<sup>201</sup> were more serious and with more probabilities of readmission, so it chose not to add the data to those of the article by Merson *et al*<sup>202</sup> and present them independently, whilst in the review by Malone *et al*<sup>204</sup>, they were added.

- The satisfaction data originating from the study by Merson *et al*<sup>202</sup> are only taken into account in the SR by Malone *et al*<sup>204</sup>, as in the NICE Schizophrenia CPG it considers that the tool used to extract them was not valid, so these data are excluded.

This CPG development group has chosen to taken into account the data provided by the NICE schizophrenia CPG and the SR by Malone *et al* indicating their methodological divergences as in the majority of their findings, there is agreement.

### ***Assertive Community Treatment (ACT), Intensive Case Management (ICM) non-acute Day Hospitals and Case Management (CM)***

With respect to ACT, ICM, non-acute Day Hospitals and CM, the discrepancy that exists in literature referring to whether there is a reduction or not of hospitalisation is already classical.

To respond to the section on ACT and non-acute Day Hospitals, the data obtained from the NICE schizophrenia CPG<sup>8</sup> are provided.

There have been studies that have followed the NICE schizophrenia CPG<sup>8</sup> including the review by Burns *et al*<sup>207</sup> (it includes 29 RCT) where the efficacy of ICM was assessed when preventing hospitalisation compared with standard treatment or CM with low intensity. The review by Marshall *et al*<sup>205</sup> also exists, which analysed the effectiveness of CM compared with standard care in people with SMI (11 RCTs, n > 1300).

The different ways of providing psychiatric and social care in different countries limits the generalisation of the findings of this type of research. Local and international contexts affect the extrapolation of the findings to different settings<sup>208</sup>. With respect to the applicability in our context of the evidence found, there are several problems:

- The different health frameworks of the United States and United Kingdom (countries where the majority of the studies have been conducted), which determine differences on establishing what is the standard treatment with which the majority of the experimental interventions are compared.
- The different supportive systems and social welfare, which determine differences with respect to the needs and the areas for which an intervention has to be designed.
- The different names of interventions (Assertive Outreach, in the United Kingdom); Assertive Community Treatment in the United States) and the different versions of the same intervention adapted to each context (Case Management, Intensive Case Management).

These limitations in the applicability are translated into practical aspects. For example, Malone *et al*<sup>204</sup> recall, when talking about the generalisation of result of the CMHC studies, that care must be taken, as community care in mental health has spread substantially and it is very likely that traditional therapy is quite close to what is considered as treatment with CMHC teams. Thus, additional studies can be associated with smaller differences between these two forms of care.

The majority of the service level configurations and interventions referred to in this chapter are, to a greater or lesser extent, implemented in our context, so the impact must be focused on the implementation of Assertive Community Treatment teams. Indeed, care, in the majority of the Spanish NHS territory is focused on the CMHC, the availability of psychosocial rehabilitation centres, rehabilitation hospital units, etc. varies from one area to another, but it can be considered as generalised for the entire territory.

This CPG development group considers that the impact of the implementation of ACT teams must be high because it would improve the care of patients who, if this service did not exist, would not be attended by the system (they are left outside), and would permit providing more efficient care for those patients who overload the short-stay units. People with SMI constitute a relatively small population but they represent a considerable burden for the Spanish NHS and for their families.

The specific problems of the design of this type of studies to assess the service level interventions are related to the following difficulties:

- The difficulty in defining these interventions with precision.
- Variations relating to the application of one same model (or fidelity to the model).
- Variations between different settings and different moments, with respect to standard care with respect to what it is compared with.
- The frequency with which some interventions and others overlap depending on the place.

### 5.3.1. Day Centres and/or Psychosocial Rehabilitation Centres

No randomised clinical trials have been found that assess these services <sup>206</sup>

### 5.3.2. Community Mental Health Centres (CMHC)

#### CMHC vs. ST

##### *Use of services*

SR (1-) In the NICE schizophrenia CPG<sup>8</sup>, it indicates that there is insufficient evidence to determine if the CMHCs reduce hospital admissions when compared with standard treatment (n = 100; RR = 0.711; 95% CI: between 0.42 to 1.19 and n = 155; RR = 0.88; 95% CI: between 0.76 and 1.01) These results agree with those found in the SR by Malone *et al*<sup>204</sup> (n= 587; 3 RCT; RR = 0.81; 95% CI: between 0.7 and 1.0).

No differences have been found, either, with respect to the use of emergency services (n = 587; 3 RCT; RR = 0.86; 95% CI: between 0.7 and 1.1) or respect to the reduction of contacts with Primary Care (n = 587; 3 RCTs; RR = 0.94, 95% CI: between 0.8 and 1.1)<sup>204</sup>.

##### *Deaths*

SR (1-) There is not sufficient evidence to determine if the CMHC are associated with a reduction in the death ratios (n = 100; RR = 0.54, 95% CI: between 0.5 and 5.78; and n = 155; RR = 0.89; 95% CI: between 0.06 and 13.98)<sup>8</sup>. It has not been found either in the SR by Malone *et al*<sup>204</sup> (n = 587; 3 RCT; RR = 0.47; 95% CI: between 0.2 and 1.3) in the medium term assessment (3 to 12 months).

### *Loss of contact*

With respect to the risk of loss of contact in the population cared for in CMHC compared with ST, it seems to indicate that there is insufficient evidence to determine this association (n = 100; RR = 1.24; 95% CI: between 0.49 and 3.16 and n = 155; RR = 1.04; 95% CI: Between 0.60 and 1.79)<sup>8</sup>. Similar results to those obtained in the study by Malone et al.<sup>204</sup> (n = 253; RR = 1.10; 95% CI: between 0.7 and 1.8).

SR (1-)

### *Mental state*

In the data indicated in the NICE Schizophrenia CPG, which are those provided by the study by Merson *et al.*<sup>202</sup> respect to the evolution of the mental state in the population cared for in CMHC compared with ST, no differences are observed between the two interventions (n = 100; WMD = - .80; 95% CI between -5.74 and 4.14).

RCT (1-)

### *Social functioning*

There is no evidence to determine if the CMHC is associated with an improvement of social functioning according to the Social Functioning Questionnaire scale (n = 100; WMD = 0.70; 95% CI: between -1.18 and 2.58)<sup>8</sup>.

SR (1-)

### *Service satisfaction*

In the CMHC group there was a smaller number of people who were dissatisfied compared with the participants who received ST (n = 87; RR=0.37; 95% CI: between 0.2 and 0.8)<sup>204</sup>.

SR (1-)

## 5.3.3. Assertive Community Treatment (ACT)

### **ACT vs. Standard treatment (ST)**

#### *Use of services*

Patients who receive ACT have more probabilities of remaining in contact with services than those that receive community ST (number of losses in follow-up: n = 1757; RR = 0.62; 95% CI: between 0.52 and 0.74)<sup>8</sup> and the probabilities of admission also decreases compared with ST (n = 1047; RR = 0.71; 95% CI: between 0.52 and 0.97; NNT = 7; 95% CI: between 4 and 100)<sup>8</sup>.

The ACT decreases the probabilities of hospital admission compared with rehabilitation based in the hospital (n = 185; RR = 0.47; 95% CI: between 0.33 and 0.66; NNT = 3; 95% CI: between 3 and 5)<sup>8</sup>.

SR (1-)

SR (1++) The ACT is associated with a reduction average of 40% in the use of beds<sup>8</sup>.

SR (1-) The ACT is associated with an increase in satisfaction with the services compared with ST (Client Satisfaction Scale: n = 120; WMD = -0.56; 95% CI: between -0.77 and -0.36)<sup>8</sup>.

#### *Housing and work*

The ACT reduces the probability of users becoming “homeless”, compared with ST (n = 374; RR = 0.22, 95% CI: between 0.09 and 0.56; NNT = 10; 95% CI between 7 and 20)<sup>8</sup>.

Patients who receive ACT have more probabilities of living independently than those that receive community ST (not living independently at the end of the study: n = 362; RR = 0.70; 95% CI: between 0.57 and 0.87; NNT = 7, 95% CI : between 5 and 17)<sup>8</sup>.

People who receive ACT have less probabilities of being unemployed at the end of the study than those that receive community ST (n = 604; RR = 0.86; 95% CI: between 0.80 and 0.91; NNT = 8; 95% CI: between 6 and 13)<sup>8</sup>.

#### *Symptoms and quality of life*

SR (1-) People who receive ACT improve their mental state more than those who receive standard community care, but the difference is small in terms of clinical significance (BPRS/Brief Symptom Inventory/Colorado Symptom Index: n = 255; WMD = -0.16; 95% CI: between -0.41 and -0.08)<sup>8</sup>.

“Homeless” people who receive ACT have probabilities of experiencing clinically significant improvements in the quality of life, compared with those that receive ST (General Well-being in Quality of Life Scale: n = 125; WMD = -0.52; 95% CI: between -0.99 and -0.05)<sup>8</sup>.

### 5.3.4. Intensive Case Management (ICM)

#### *ICM vs. Standard Case Management (CM)*

ICM is associated with an increase in contact with the services, compared with that provided with standard CM (number of losses in follow-up after 2 years: n = 1060; RR = 0.54, 95% CI: between 0.39 and 0.74)<sup>8</sup>.

SR (1+) There is no significant difference between ICM and standard CM in terms of numbers of participants who lose contact with their case manager (n = 780; RR = 1.27; 95% CI: between 0.85 and 1.90)<sup>8</sup>, or in terms of readmission rates, either (n = 747; RR = 0.95, 95% CI: between 0.85 and 1.05)<sup>8</sup>.

There is not sufficient evidence, either, in terms of pharmacological treatment adherence (n = 68; RR = 1.32, 95% CI: between 0.46 and 3.75)<sup>8</sup>. SR (1-)

With respect to mental state no differences have been found between ICM and standard CM with respect to mental state (BPRS/CPRS endpoint score n = 823; WMD = 0.02; 95% CI: between -0.12 and 0.16)<sup>8</sup> or to social functioning (*Disability Assessment Schedule/Life Skills Profile* = 641; WMD = -0.08; 95% CI: between -0.24 and 0.07)<sup>8</sup>. SR (1+)

ICM functions better when participants tend to use hospital care a lot. When the use of a hospital services is high, the ICM can reduce it (p=0.001), but no effect is produced when the use of hospital care is low<sup>207</sup>. SR (1+)

Respect to ICM teams that are organised in agreement with the ACT model, they were more likely to reduce the use of hospital care (p=0.029), but this finding was not encountered when the personnel levels recommended for ACT were analysed<sup>207</sup>.

### 5.3.5. Non-acute Day Hospitals

There are no differences between non-acute day hospitals and outpatients treatment for people with SMI with respect to the number of follow-up losses (at 18 months: n = 80; RR = 1.75; 95% CI: between 0.56 and 5.51)<sup>8</sup> admission rates (at 12 months: n = 162; RR = 0.86; 95% CI: between 0.61 and 1.23; at 24 months n = 162; RR = 0.82; 95% CI: between 0.64 and 1.05)<sup>8</sup>, and mental state (*Symptom Check List-90*: n = 30; WMD = 0.31; 95% CI: between -0.20 and 0.82)<sup>8</sup>. SR (1+)

There is not sufficient evidence, either, to be able to determine if there is any difference between non-acute day hospitals and outpatients treatment for people with SMI with respect to social functioning (*Community Adaptation Scale*: n = 30; WMD = -0.03; 95% CI: between -0.30 and 0.24)<sup>8</sup>.

### 5.3.6. Case Management (CM)

#### *Case Management vs. Standard treatment (ST)*

People included in Case Management are more likely to remain in contact with the services, compared with those who receive ST (n = 1210, Peto odds-ratio = 0.70; 99% CI: between 0.50 and 0.98)<sup>205</sup>. SR (1+)

There are no differences with respect to mortality in patients between either intervention (n = 1341; Peto odds-ratio = 1.29; 99% CI between 0.55 and 3.00)<sup>205</sup>.

People who were in the CM group were approximately twice as likely to be admitted into a psychiatric hospital (n = 1300; Peto odds-ratio = 1.84; 99% CI: between 1.33 and 2.57) as patients who received ST<sup>205</sup>.

With respect to imprisonment, the CM had no clear effect ( $n = 757$ ; Peto odds-ratio = 0.90; 99% CI: between 0.36 and 2.28)<sup>205</sup>, but it does seem more favourable to improve medication adherence ( $N = 71$ ; Peto odds-ratio = 0.25; 99% CI: between 0.06 and 0.97)<sup>205</sup>.

There was no difference between CM and ST in the improvement of the mental state ( $n = 126$ ; WMD = 0.461; 99% CI between -4.9 and 5.9)<sup>205</sup>, social functioning (SMD = -0.097; 99% CI CL -0.47 -0.27;  $N = 197$ ) or quality of life ( $N = 135$ ; SMD = 0.096; 99% CI: between -0.35 and 0.54)<sup>205</sup>.

## Summary of evidence

	No randomised clinical trials have been found to assess the efficacy of the day centres and/or psychosocial rehabilitation centres <sup>206</sup> .
1-	No statistically significant differences were found between CMHC and ST in the reduction of hospital admissions, or in the loss of contact in the population cared for in the CMHC <sup>8,204</sup> .
1-	There are no differences between CMHC and ST with respect to death ratios <sup>204</sup> .
1-	There seem to be no differences either between CMHC and ST with respect to the evolution of the mental state in the population cared for in CMHC <sup>202</sup> .
1-	It is not clear that the CMHC is associated with an improvement in social functioning when compared with ST <sup>8</sup> . However, there does seem to be a smaller number of dissatisfied people in the group of CMHC than the ST <sup>204</sup> .
1++	The ACT in people with SMI, compared with ST, is associated with more likelihood of remaining in contact with the services, and reducing hospital admissions <sup>8</sup> .
1-	The ACT reduces the probabilities of hospital admission compared with hospital-based rehabilitation <sup>8</sup> .
1++	The ACT reduces the use of beds, it decreases the risk of becoming “homeless”, greater probability of independent living, a reduction in the risk of being unemployed and an improvement of the mental state <sup>8</sup> .
1-	The ACT is associated with an increase in satisfaction with the services <sup>8</sup> .
1-	“Homeless” people who receive ACT are likely to experience clinically significant improvements in quality of life <sup>8</sup> .
1+	ICM is associated with an increase in contact with the services when compared with the CM <sup>8</sup> .
1+	There are no differences between ICM and Case Management with respect to losses of contact with their case manager <sup>8</sup> .
1+	When ICM is compared with Case Management there is no evidence to indicate that an improvement takes place in the readmission rates, the mental state or social functioning in people with SMI <sup>8</sup> .
1-	There is no evidence to indicate that ICM, in people with SMI, compared with Case Management improves treatment adherence <sup>8</sup> .
1+	ICM functions better when participants tend to use hospital care a lot. When the use of hospital services is high, the ICM can reduce this, but no effect is produced when the use of hospital care is low <sup>207</sup> .

1+	Respect to ICM teams organised in agreement with the ACT model, they were more likely to reduce the use of hospital care, but this finding was not encountered when analysing the personnel levels recommended for ACT <sup>207</sup> .
1+	There are no differences between non-acute day hospitals and outpatients treatment for people with SMI, with respect to readmission rates, mental state and social functioning <sup>8</sup> .
1+	People who receive Case Management are more likely to remain in contact with the services and improve medication adherence <sup>205</sup> .
1+	There are no differences with respect to social functioning, improvement of mental state, quality of life, imprisonment between CM and ST in people with SMI <sup>205</sup> .

## Recommendations

B	When people with SMI need to be readmitted several times into acute units, and/or there is a past history of difficulties to engage with the services with the subsequent risk of relapse or social crisis (as for example becoming a “homeless” person) it is advisable to provide assertive community treatment teams.
√	The continuity of the treatment must be favoured via the integration and coordination of the use of the different resources by the people with SMI, maintaining continuity of care and interventions, and in the psychotherapeutic relations established.
√	Care must be maintained from the perspective of the CMHC as a configuration of the most commonly implemented services in our context, based on teamwork, on service integration and not losing the perspective of being able to integrate other ways of configuring the services that might be developed.
√	When the needs of the people with SMI cannot be covered from the CMHC, continuity of assistance must be given from units that provide day care, and whose activity is organised around the principles of psychosocial rehabilitation, whatever the name of the resource are (Day Centres, Psychosocial Rehabilitation Centres, etc.).
√	A certain level of care can be offered to people with SMI whose needs cannot be satisfied by resources that provide day-care in rehabilitation orientated residential resources whatever the name of the resource are (hospital rehabilitation units, medium stay units, therapeutic communities, etc.)

## 5.4. Interventions with specific subpopulations

### 5.4.1. SMI with dual diagnosis

Substance abuse is, for different reasons, a frequent comorbidity in people with SMI and entails a worsening of the clinical condition, of their clinical management and prognosis. One of the consequences of dual diagnosis is an increase in non-treatment adherence and abandonment, more relapses, suicides, contagion of viric diseases via parenteral way, home abandonment, disruptive behaviour with aggression, legal problems, less economic resources and less social support<sup>52</sup>.

Psychiatric and drug-dependent treatments have traditionally been separate and may differ in theoretic cases and implementation methods. In those places where the Mental Health and Drug Dependent networks have been or are administratively separate, the psychiatric or psychosocial treatment of SMI and treatment programmes for drug dependences have been offered separately, in parallel or in sequence, with the possibility of neither being optimised on having to negotiate the patient with two separate teams. On other occasions, the presence of both diagnoses compromised the parallel care, requiring the tempering or control of the “other problem” by a network, to incorporate it to the second (control of drug addiction to be able to be incorporated into specific psychosocial rehabilitation programmes “without” the handicap of active drug addition; or, on the contrary, rejection in treatment for drug dependency units until clinical stability has been achieved).

Thus, the efficacy of integrated programmes for the treatment or reduction of substance abuse in patients with SMI is being questioned. The objective is to know the evidence of the importance of providing addiction treatment programmes and psychosocial rehabilitation programmes by one single coordinated team to achieve the objectives of both programmes.

In this question, no difference has been established between the studies aimed at diagnostic groups that, a priori, may have different characteristics (for example, bipolar disorder). For that SMI subgroup, RCT have been found included in selected reviews such as Weiss *et al*<sup>209</sup> and Schmitz *et al*<sup>210</sup>, whose data have been treated globally.

The evidence review rejected the study of the use of other psychosocial techniques that patients with SMI and dual diagnosis may receive on specific occasions, such as cognitive-behavioural therapies, social skills training or motivational interview, whose efficacy will be assessed in other sections.

#### Question to be answered

- What type of treatment has proven to be most effective in people with SMI and substance abuse: integral or parallel treatment?

Cleary *et al*<sup>52</sup> developed a SR that included 25 RCTs which assesses the effect of psychosocial interventions in the reduction of the consumption of substances in patients with SMI.

Likewise, Morse *et al*<sup>211</sup> performed a RCT (n = 149) with 24-month follow-up on people with SMI and substance abuse, as well as “homeless”. They were randomised either to an integrated ACT or standard ACT programme or to standard treatment. This study has an important bias risk as it does not specify the losses in the groups.

Finally, in the RCT by Cheng *et al*<sup>212</sup> (n = 460 and with 3-year follow-up), the integrated intervention was assessed with sheltered housing at a medical care centre for “homeless” veterans with SMI and/or substance abuse (not specifying percentage of psychiatric diagnoses of substance abuse of the sample).

In some of the studies assessed, the intervention of the control group exceeds what in our context would be standard treatment, which would favour the lack of appearance of differences between the interventions compared. An absence of data from quality studies has also been encountered, showing that integrated treatments are more effective than non-integrated treatments, although both interventions show efficacy compared with the standard treatment for dual SMI patients.

Another relevant aspect is that these scientific studies originate exclusively from Anglo-Saxon countries and generate doubts about the extrapolation to our context, as in our context there are no integrated assertive community treatment teams/programmes for dual pathology; although there are integrated treatment teams.

In our context there are few services with integrated treatment programmes for dual patients and starting them up systematically and in a generalised way would represent an increase in resources, when in many fields there are parallel networks with programmes that are already functioning.

The motivation factor is important in these studies and differences are observed with respect to the moment of the intervention. There are authors that suggest that the heterogeneity could be reduced, studying interventions and results related to specific treatment stages (support and skills development both for handling and for preventing relapses)<sup>213</sup>

### ***People with SMI and substance abuse***

No differences were found between long-term integrated treatment (36 months) and standard treatment (which includes the same interventions except for assertive community treatment, which were developed by different teams) respect to the use of substances (n = 85; 1 RCT; RR = 0.89; 95% CI: between 0.6 and 1.3)<sup>52</sup>.

With reference to abandoning the treatment it is also observed that no differences have been found, either, between the long-term integrated treatment (36 months) and standard treatment (n = 603; 3 RCT; RR = 1.09; 95% IC: between 0.8 and 1.5)<sup>52</sup> and the same occurs with respect to the number of rehospitalisations (n = 198; 2 RCT; RR = 0.88; 95% CI: between 0.6 and 1.2)<sup>52</sup>.

Regarding to integrated assertive community treatment (ACT) and standard ACT, no significant results were observed in favour of either the interventions regarding satisfaction at 24 months, although there are significant results between both interventions when compared with standard treatment (p = 0.03)<sup>211</sup>. No differences have been found, either with respect to housing stability at 24 months although they do exist between both interventions when compared with standard treatment (p = 0.03)<sup>211</sup>. RCT (1-)

## RCT (1-)

There are signs that indicate that integrated clinical services and supported housing approach is more favourable than standard treatment in “homeless” patients with diagnosis of SMI and/or substance abuse, in results of substance consumption at 36 months, using a multiple imputation system for handling lost data (use of alcohol  $p = 0.047$ ; intoxications  $p = 0.053$ ; consumption days  $p = 0.028$ ; spending on alcohol and drugs  $p = 0.048$  <sup>212</sup>.

The integrated clinical service and supported housing approach appears to be more favourable too compared with case management and with standard treatment in “homeless” patients with diagnosis of SMI and/or substance abuse, with a shorter stay in institutions ( $p < 0.05$ )<sup>212</sup>.

## Summary of evidence

1+	There are no differences between long-term integrated treatment (36 months) and standard treatment (that included the same interventions, except for Assertive Community Treatment, which were not developed and coordinated by the same team, but by different teams) with respect to the use of substances <sup>52</sup> .
1+	There are no differences between long-term integrated treatment (36 months) and standard treatment with respect to abandonment of treatment and rehospitalisations <sup>52</sup> .
1-	There are no differences between integrated assertive community treatment (ACT) and standard ACT with respect to satisfaction and housing stability at 24 months, although there is between both interventions when compared with standard treatment <sup>211</sup> .
1-	The integrated clinical services and supported housing approach improves the consumption of substances when compared with standard treatment, in homeless patients with diagnosis of SMI and/or substance abuse at 36 months <sup>212</sup> .
1-	Integrated clinical services and supported housing approach seems to be more favourable compared with CM and with standard treatment in “homeless” patients with diagnosis of SMI and/or substance abuse, respect to a shorter stay in the institutions <sup>212</sup> .

## Recommendations

B	People with SMI with dual diagnosis must follow psychosocial intervention programmes and drug-dependent treatment programmes, both in an integrated manner and parallel.
B	The treatment programmes offered to people with SMI with dual diagnosis must have a multi-component nature, be intensive and prolonged.
C	For people with SMI and dual diagnosis and in a homeless situation, the treatment programmes should incorporate sheltered housing as a service.
√	When the care for people with SMI and dual diagnosis is provided in parallel, it is necessary to guarantee continuity in the care and coordination among the different health and social levels.

## 5.4.2. “Homeless” with SMI

The term “homeless” refers to the mixture of states that includes those who literally have no roof (rooflessness), those that have no stable home (houselessness) or those who live in precarious or inadequate conditions<sup>214</sup>.

The prevalence of schizophrenia in homeless people is variable although higher quality studies have established the prevalence in this population within a range of between 4% and 16%, with an average of 11%. The highest rates corresponded to the younger subgroups, to women and to the chronically homeless. In 2002, one review concluded that schizophrenia is 7 to 10 times more frequent in homeless people than in the population with stable housing<sup>215</sup>. Data are included in this review from a Spanish study that offers figures situated within a lower range<sup>216</sup>. A more recent review<sup>217</sup> offers greater heterogeneity in its results, with figures of 12% average prevalence of psychotic disorders in a range of 2.8% to 42.3%. Another important fact is that, of this population, only one third receives treatment<sup>214</sup>.

The attention to “homeless” people and who have SMI, is based on the combination of the services that provide housing and those that provide clinical care; this combination has two approaches: the traditional approach, called the continuum housing model in Anglo-Saxon literature, which is based on the offer of a range of housing provided by the same team that provides the clinical care, favouring the users’ progression towards more independent housing as they gain clinical stability. More modern approaches (*supported housing*) propose considering housing separately from clinical stability, based on normalised community housing and independent clinical services that give support when required<sup>147</sup>.

On the other hand, there are proposals that give preference to housing (housing first), with no prior clinical stability requirements or no drug consumption<sup>218</sup>.

The clinical care for the subgroup of “homeless” patients can be structured into three overlapping programmes and interventions<sup>219</sup>:

- Outreach services aimed at “homeless” people who resist looking for treatment by themselves.
- Case Management and ACT Services that are based on personalised relations as a means of accessing the services.
- Housing and community work to facilitate stability in housing.

Assertive community treatment is worth a special attention as a way of addressing the problem. In this section reference will be made to the specific ACT modalities aimed at dealing with “homeless” people. These ACT programmes often present modifications with respect to the original programme to address the specific need of this patient subgroup<sup>218</sup>.

### Question to be answered

- Which intervention is more efficient in people with SMI and “homeless”?

In the RCT by McHugo *et al* 147 (n = 121) 2 community ICM (Intensive Case Management) programmes are analysed, that differ in the way they approach the housing intervention (integrated vs. parallel).

In the study by Tsemberis *et al* 220 (n = 225) the sample to be studied is assigned either to the continuity of care group (housing and clinical care following *continuum* model) or housing with no clinical conditioning factors (*housing first* model).

The systematic review by Coldwell & Bender<sup>221</sup>, where 6 RCTs and 4 observational studies are assessed (940 and 4854 patients, respectively), ACT is compared with standard Case Management or standard treatment in “homeless” people.

Nelson *et al*<sup>222</sup> carries out another SR with 16 assessments of controlled studies on housing and support for people who have been homeless. In this study, ACT, Case Management and supported housing are compared with each other. No information is provided about the magnitude of the effect.

Caplan *et al*<sup>223</sup> (n = 112) randomise the sample (all receive ICM) and assign it to an individual residential housing programme without clinical personnel or housing with 6 to 10 residents with individual room and assigned clinical personnel.

There are several problems regarding the generalisation and application of the results of these studies, which have been conducted in Anglo-Saxon countries:

- The variability in the prevalence of psychotic disorders in the homeless population, already mentioned.
- The differences in social and health support between the different areas where they are conducted, with a greater degree of protection in European countries.
- Derived from the above, the problem of the homeless population has determined the need to create specific teams to care for them in certain contexts; this may create differences regarding the comparative intervention and the generalisation of the results to settings such as ours, where the existence of these resources is not so usual.
- Most of the studies focus on the greater efficiency of the ACT compared with CM. In our context there are a few ACT teams disseminated in certain autonomous communities, compared with the absence of teams that focus on the traditional CM model (broker), due mainly, once again, to the different social support and health systems.
- With respect to the housing provision systems, the prevailing model in our context is similar to the model of housing + supporting (assisted flats), whilst the housing in parallel to the clinical care model is difficult to find as there are no agencies that provide economically accessible individual or group housing for people with SMI.

As there are differences between the social environment and the support of homeless people in our context and that of the countries where the studies have been conducted, there will also be differences in the need to develop and/or adapt resources for them. Therefore, the relevance of the intervention for the Spanish social and health system is linked to the prevalence of homeless with SMI, possibly not as high as that of the Anglo-Saxon countries. However, there is a benefit derived from the application of programmes in a group for which the only alternative is conventional treatment. The necessary resources to start up integrated housing and care programmes for homeless people are multiple and involve the start-up of assertive community treatment teams, only available today in some health sectors of some autonomous communities.

### ***People with SM and “homeless”***

RCT (1++) Patients who are in an integrated housing system (housing + clinical services) spend less time homeless (p <0.01), more time in stable residence (p <0.01), in own apartment (p <0.01), have less severe psychiatric symptoms (p <0.05) and show greater general satisfaction with life (p <0.05) than participants in the parallel programme<sup>147</sup>.

Patients who access housing with no prior conditioning factors (housing first model) drop more quickly in the rates of staying in the “homeless” status and stay in stable housing for longer than those who have gone through a period of soberness and treatment acceptance ( $p < 0.001$ ), although there are no significant differences between both groups with respect to psychiatric symptoms and evolution in time ( $p = 0.85$ )<sup>220</sup>. RCT (1+)

### *Housing stability*

Assertive Community treatment (ACT) reduces the “homeless” state in 37% (p = 0.0001) compared with standard Case Management<sup>221</sup>. SR (1++)

The best results in housing stability are obtained by programmes that include housing and support (ES = 0.67), followed by ACT (ES = 0.47)<sup>222</sup>. SR (1-)

### *Hospitalisation*

Assertive Community treatment does not reduce hospitalisation when compared with standard Case Management in “homeless” population (10% reduction) ( $\chi^2 = 0.024$ )<sup>221</sup>. SR (1++)

### *Symptomatology and cognition*

In homeless people with SMI, assertive community treatment reduces the psychiatric symptoms compared with standard Case Management (p = 0.006)<sup>221</sup>. SR (1++)

Living in a group improves the executive functions (measured in agreement with perseverance in WCST), especially in patients with no substance abuse, with an interaction between type of housing, evolution in time and abuse of substances or not ( $p < 0.01$ )<sup>223</sup>. RCT (1-)

## **Summary of evidence**

1++	Patients who are in an integrated housing system (housing + clinical services) spend less time homeless, more time in stable residence and in own apartment, have less severe psychiatric symptoms and show greater general satisfaction with life than participants in the parallel programme <sup>147</sup> .
1+	Patients who access housing without prior conditioning factors (housing first model) drop more quickly in the rates of remaining in “homeless” status and remain for longer with stable housing than those who have gone through a period of soberness and treatment acceptance <sup>220</sup> .
1++	ACT reduces the “homeless” status in 37%, compared with CM <sup>221</sup> .
1-	The best housing stability results are obtained by programmes that include housing and support, followed by ACT <sup>222</sup> .
1++	ACT, when compared with standard Case Management in the “homeless” population, does not reduce hospitalisation <sup>221</sup> .

1++	In homeless people with SMI, ACT reduces the psychiatric symptoms when compared with standard Case management <sup>221</sup> .
1-	Living in group improves the executive functions, especially in patients with no substance abuse <sup>223</sup> .

### Recommendations

A	For homeless people with SMI who require psychiatric care and psychosocial intervention, it is advisable for both to be supplied together via integral programmes where residential programme/housing is offered.
C	When there is no active substance abuse, it would be advisable to provide grouped accommodation to homeless people with SMI included in integral intervention programmes.
C	When it is not possible to use accommodation and support programmes in the integral psychosocial intervention of homeless people with SMI, the intervention of assertive community treatment team should be offered.

### 5.4.3. SMI and low IQ/mental retardation

There seems to be general agreement about the high prevalence of mental disorders in people with intellectual disability or mental retardation (understood as a person whose intellectual coefficient is 70 or below)<sup>224</sup>, at the same time as less access to specialised mental health services. Several factors may be interfering with this, one of which may be the perception by professionals that psychological interventions may be inefficient due to the cognitive deficits and verbal limitations<sup>225</sup>.

On the other hand, the correct diagnosis of the symptoms, syndromes and nosological entities in this population may be limited by the use of the current diagnostic classification criteria. More specifically, the diagnosis of psychotic disorders (schizophrenia and related disorders, included in SMI) is hindered by the problem of distinguishing real hallucinations from other non-pathological behaviours, such as talking to themselves or to imaginary friends. Added to this is a high prevalence of symptomatology, but limited detection capacity (lack of diagnostic criteria and adapted and validated instruments for this population) of greater psychiatric disorders. The use of diagnostic criteria and instruments adapted to mental retardation has been proposed therefore<sup>226</sup> as a way of improving the reliability of the diagnoses in this population.

#### Question to be answered

- Which psychosocial treatment is more effective in people with SMI and a low IQ?

To be able to answer this question the RCT by Martin *et al*<sup>227</sup> has been included, which compares the efficacy of the ACT model with the standard community treatment, to treat mental illness in light to moderate mental retardation (MR) and SMI.

Due to the little evidence found, which could also answer this question, a series of cases by Haddock<sup>228</sup> (n = 5) have been included, where the people that are described, suffer from light MR and schizophrenia (they are being treated with antipsychotics) and chronic and resistant sensor-

ceptive disorders. This series of cases describes the reliability of cognitive-behavioural therapy adapted to this population, including 2 cases where family intervention was integrated.

Little volume and quality of evidence have been found, regarding the number of studies and types of interventions to be compared. Assuming that the productive symptomatology in people with SMI and learning disabilities (light MR) may be disruptive, chronic and resistant to treatment, the application of effective psychosocial interventions may provide clear benefits, especially when the learning disabilities variable is often a criterion for exclusion when creating programmes, services and studies. In our context and at the present time, the basic conditions do not exist to be able to apply cognitive-behavioural techniques and assertive programmes to the SMI population with learning disabilities.

No differences were found between ACT and standard treatment. Favourable results have been observed in both treatments with respect to covering needs and improving the burden of care and the functioning level of this population. Regarding the quality of life, the results were even favourable for standard treatment, compared with ACT (adjusted difference of standard means vs. ACT -5.27 IC95%: between -9.7 and -0.82;  $p = 0.023$ )<sup>227</sup>. RCT (1+)

Adapted, individual cognitive-behavioural therapy or with family intervention is effective in population with learning disabilities and schizophrenia and can be efficient as a supplementary therapy in treatment of chronic psychotic symptomatology resistant to antipsychotic treatment<sup>228</sup>. Cases series (3)

### Summary of evidence

1+	ACT and standard treatment improve the burden of care and functioning levels in people with SMI and learning disabilities <sup>227</sup> .
1+	The results appear to be more favourable in standard treatment, compared with ACT, respect to quality of life <sup>227</sup> .
3	Adapted, individual cognitive-behavioural therapy or with family intervention is effective in population with learning disabilities and schizophrenia and may be efficient as a complementary therapy in the treatment of chronic psychotic symptomatology resistant to antipsychotic treatment <sup>228</sup> .

### Recommendations

B	For people with SMI and a low IQ, and when there is a presence of persistent productive symptoms, it is recommendable to indicate cognitive behaviour therapy adapted to that condition.
√	To improve the diagnosis of psychiatric disorders included within the concept of SMI in people with a low IQ, adapted criteria and specific and validated instruments must be used.



## 6. Dissemination and implementation

Clinical practice guidelines aim to help professionals and users to take decisions on the most appropriate healthcare. Their development means investing effort and resources, which are sometimes not appropriately used, because they are not sufficiently used by the health professionals and because they do not represent an improvement in the care quality and results in health of the population they are aimed at.

To improve the implementation of a CPG, in other words, introduce it into a clinical setting, it is advisable to design a series of strategies aimed at overcoming the possible barriers for its adoption<sup>5</sup>.

The plan to implement this CPG for psychosocial interventions in Severe Mental Illnesses includes the following interventions:

- Presentation of the CPG by the health authorities to the media.
- Collaboration with scientific societies that have participated in the preparation of this CPG, to review and disseminate it.
- Forwarding the CPG to different databases that compile CPGs for its evaluation and inclusion therein.
- Contact with the Spanish Federation of Associations of Family Members with Mental Illness and other associations of stakeholders to show them the guide.
- Free access to the different versions of this CPG on the GuiaSalud website (<http://www.guiasalud.es>).
- Dissemination of information about the CPG in scientific activities (congresses, conferences, meetings) related to psychiatry, psychology, nursing, social work, occupational therapy...
- Forwarding by post of a three-page information leaflet about the CPG to professional associations, health administration care centres, local associations of health professionals, etc.
- Information about the CPG in magazines and medical daily newspapers of the specialties involved.
- Dissemination of the existence and the objectives of the CPG by means of distribution lists for professionals who are potentially interested in it.



## 7. Recommendations for Future Research

This chapter includes proposals for future research that are suggested in the different sections of the guideline.

### 5.1.1. Cognitive-behavioural therapy

It would be necessary to carry out studies that analyse to what extent the effects of CBT are maintained in people with SMI after the treatment and if refresher sessions are necessary.

More studies are required to assess the characteristics of the population on whom CBT is more effective (people with positive persistent symptomatology and resistant to psycho-drugs) and the characteristics of the intervention that make it more effective with respect to duration and number of sessions.

Quality studies must be carried out to measure the efficiency of social skills training in different sub-populations and their generalised use in other functioning areas.

The utility of the use of motivational interviews in people with SMI must be assessed by research studies, as well as their indications with respect to specific clinical situations (dual disorder, lack of awareness of the illness, collaboration or treatment adherence).

### 5.1.2. Psychodynamic psychotherapy and psychoanalytical approach

Studies must be developed that analyse the efficacy of psychodynamic therapies and psychoanalytical approach in people with SMI with designs that adapt to the peculiarities of their epistemology, to the singular nature of each individual and the Spanish and European area.

### 5.1.5. Family interventions

Family intervention is an important component in the treatment of people with SMI, so there must be well-designed studies that investigate which the components of family intervention are associated with the stability and improvement in the psychosocial functioning in a prolonged manner.

The efficacy of integrated or combined programmes, which include work with the family of people with SMI must be examined to see if it is mediated by the greater treatment adherence / fulfilment or is independent from this.

Due to the lack of studies related to family intervention in population with SMI and bipolar disorders, quality research studies must be carried out that include this population.

### 5.1.7. Cognitive Rehabilitation

It would be useful to investigate which moderating and mediating variables make cognitive rehabilitation interventions more effective in people with SMI and cognitive impairment.

Studies must be conducted to indicate in which areas cognitive rehabilitation is more effective (psychosocial functioning, employability, cognitive performance, reduction of symptoms).

### **5.1.8. Other psychotherapies**

It is necessary to know the efficacy of dramatherapy, distraction therapy and hypnosis by quality research studies and developed within the national and European context.

### **5.2.3. Programmes aimed at leisure and spare time**

It would be advisable to conduct quality research in our field to be able to establish the effectiveness and efficiency of rehabilitation through leisure and free time, of residential programmes and of daily living skills.

### **5.2.4. Programmes aimed at employment**

Studies are necessary to assess the employability of people with SMI, to improve the efficiency of the employment programmes.

It is necessary to research into the influence of environmental factors on employment programmes aimed at people with SMI, and about the way to adapt them to the social-economic, cultural and local reality, as well as to the employment policies.

### **5.2.5. Other therapeutic interventions**

Studies must be developed that determine the efficiency and applicability of art therapy and music therapy in people with SMI to know which aspects must be addressed in the intervention, how the sessions must be structured and the minimum number of sessions necessary to be able to be effective.

## **5.3. Service level interventions**

It would be recommendable to design high-quality studies that compare the different intervention possibilities with respect to existing service configurations in our context (CMHC, psychosocial rehabilitation centre, day centres, rehabilitation hospital unit, ACT teams, etc.) and to the components that can make them more effective, including their impact in areas such as quality of life, person's satisfaction, integration into social networks, etc.

With respect to the population with SMI that are in long-stay units, psychiatric hospital and who – at least in our context- are still in a de-institutionalisation process, it would be advisable to conduct research studies that can indicate which psychosocial interventions are effective as alternatives to hospital centres.

Investigations must be carried out into those people with SMI with whom ACT is not indicated, to find out which alternative integrated programme proves to have greater effectiveness to maintain these people in the community and improve long-term social functioning.

### **5.4.1 SMI with dual diagnosis**

It would be advisable to conduct studies that include people with SMI and dual pathology, to measure the efficiency of different psychosocial interventions depending on the stage of motivation and with respect to the abandonment of programmes or reduction in consumption.

# Appendices



## Appendix 1. Key to evidence statements and grades of recommendations from SING

### Levels of evidence

- 1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias.
- 1+ Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias.
- 1- Meta-analyses, systematic reviews, or RCTs with a high risk of bias.
- 2++ High quality systematic reviews of case control or cohort or studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal.
- 2+ Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal.
- 2- Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal.
- 3 Non-analytic studies, e.g. case reports, case series.
- 4 Expert opinion.

### Grades of recommendations

- A At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.
- B A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+.
- C A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
- D Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+.

Studies classified as 1- and 2- should not be used in the process of developing recommendations due to their high possibility of bias.

### Good practice points

- √<sup>1</sup> Recommended best practice based on the clinical experience of the guideline development group.

Source: Scottish Intercollegiate Guidelines Network. SIGN 50: A guideline developers' handbook (Section 6: Forming guideline recommendations), SIGN publication n° 50, 2001.

<sup>1</sup> Sometimes the guideline development group becomes aware that there are some significant practical aspects they wish to emphasise and for which there is probably no supporting scientific evidence available. Generally, these cases are related to some aspect of the treatment, considered to be a good clinical practice and that nobody would normally question. These aspects are considered good clinical practice points. These messages are not an alternative to evidence based recommendations, but must be only considered when there is not another way to highlight the aspect mentioned above.

## Appendix 2. Information obtained from working groups with family members and people with SMI

Summary of the information obtained by two group interviews held with people affected by mental illnesses and families of this type of people. The aim of these interviews was to identify problems and needs both of people with mental illnesses and of their families. The participants were contacted through different associations of families and/or patients with mental illnesses in Aragon.

### Group of patients:

9 people (4 men and 5 women) participated, who satisfied the Severe Mental Illness criteria, representatives of different groups.

### Group of families:

10 fathers, mothers, brothers or sisters of mental patients (4 men and 6 women) took part.

**Table 1.** Information obtained from the working groups of families and users

	Related to the institution and its interventions.		Related to the social environment	
	PROBLEMS	NEEDS	PROBLEMS	NEEDS
<b>Relatives</b>	<ul style="list-style-type: none"> <li>• There are not sufficient residences for young people with mental problems.</li> <li>• Limited resources in rural areas.</li> <li>• Legal vacuum in involuntary hospital admissions.</li> <li>• Legal Capacity (disability)</li> </ul>	<ul style="list-style-type: none"> <li>• Lack of information for families.</li> <li>• Participate in normalised contexts, such as labour activities.</li> <li>• Adapted employment environments (timetables, etc.)</li> <li>• Crisis intervention at home by health professionals. Only police presence in these interventions leads to an increase in the stigma.</li> </ul>	<ul style="list-style-type: none"> <li>• Social rejection and isolation.</li> <li>• Denial of illness by some members of the family.</li> <li>• Loss of role (family, social, etc.) within the family)</li> </ul>	<ul style="list-style-type: none"> <li>• Participate in normalised contexts of leisure and spare time.</li> </ul>
<b>People with mental illness</b>	<ul style="list-style-type: none"> <li>• Treatments and involuntary admissions.</li> </ul>	<ul style="list-style-type: none"> <li>• Information to user.</li> <li>• Sheltered flats with 24 hours' supervision.</li> <li>• Work (paid and not paid)</li> <li>• More day centres.</li> <li>• More and better access to different types of therapies.</li> </ul>	<ul style="list-style-type: none"> <li>• The stigma of the illness.</li> <li>• Social and family exclusion.</li> </ul>	

## Appendix 3. Template to develop recommendations via formal assessment or well-founded judgement

<b>Question:</b>	
<b>Volume of evidence.</b> Comment on the quantity of evidence available and its methodological quality.	
<b>Applicability and generalisation.</b> Comment to what extent the evidence found is applicable in the Spanish National Health System and to what extent can the results obtained from the studies be generalised to the target population of the CPG.	
<b>Consistency.</b> Comment if there have been conflicting results between the different studies and if so, the reasons why the working group has decided on one option or another.	
<b>Clinical Impact Relevance.</b> Indicate the impact that the intervention could have in our context, in agreement with the population size, magnitude of the effect, relative benefit compared with other options, recourses that would be involved, and balance between risk and benefit.	
<b>Other factors.</b> Indicate, in this space, aspects that may have been taken into account when assessing the available evidence.	
<b>Classification of evidence.</b> Sum up the available evidence with reference to the question to be answered. Indicate the level of evidence assigned.	<b>Level of evidence</b>
<b>RECOMMENDATION.</b> Set out the recommendation that the taskforce understands is derived from the evidence assessed. Indicate degree of recommendation. Point out discrepancies, if any, in the recommendation formulation.	

## Appendix 4. Information for people with SMI and their families

### 1. What is a Clinical Practice Guideline?

This document is an essential part of the composition of a Clinical Practice Guideline (CPG), it includes those contents that the authors believe may be important for the people interested, in order to be able to have information and help cope with and in this health problem.

A CPG is a scientific instrument, comprised of a series of systematically developed recommendations, based on the best evidence available, in order to help clinicians and patients take decisions. Its purpose is to reduce the variability of clinical practice, providing summarised information. Each recommendation is based on the scientific quality of the studies and publications, the professionals' experience and the users' preferences. Deciding which questions on psychosocial interventions in SMI are pertinent and require an answer, searching for information, summing up data and agreeing to the final content have been the work of the Guideline development group over the last few months.

This CPG has been funded through the agreement signed by the Carlos III Health Institute an organisation pertaining to the Ministry of Science and Innovation, and the Aragon Health Sciences Institute, within the framework of collaboration provided for in the Quality Plan for the National Healthcare System.

The CPG is not a substitute for scientific knowledge and the life-long training of professionals on the topic, but rather it is a part of this, another tool for decision-making when doubts arise. For users and families it is a tool that can help them discover the characteristics of the different interventions. Sometimes, our intuitions, practical knowledge and common sense do not coincide with the conclusions of the guideline. This may be due to a lack of knowledge in this area of knowledge or simply to the absence of good quality studies designed to be able to answer our problems. The application of our knowledge to those problems where there is no proof or evidence of the efficacy of the interventions is where the clinician and the user must decide which decisions to make concerning a specific health problem, in a specific scenario or with specific conditions and with respect to one single person.

The preparation of this guideline on Psychosocial Interventions in Severe Mental Illness (SMI) presents additional difficulties as it does not respond to the needs for knowledge on one single and defined mental disorder, due to the lack of consensus about the meaning of the techniques and activities included as Psychosocial Interventions and the different definitions of the concept of Severe Mental Illness.

The majority of the documents and scientific evidence found refer to affective and non-affective psychotic disorders, schizophrenia and related disorders, bipolar disorders and severe and persistent affective disorders; thus they are all specifically defined or framed within the concept of Severe Mental Illness.

There are other CPGs that deal with specific psychiatric disorders and can be found at <http://portal.guiasalud.es/web/guest/home>

## 2. What is SMI

When we refer to Severe Mental Illness (SMI) we are referring to a series of clinical diagnoses that fall within the group of psychoses (mainly Schizophrenia and Bipolar Disorder), but also other related diagnoses.

For the people with these diagnoses to be considered as pertaining to the group of SMI, they must also satisfy two requirements: persistence in time (2 years by consensus) and present serious difficulties in personal and social functioning due to this illness.

Thus, it can be stated that not all people who have been diagnosed with a psychosis (such as, for instance, schizophrenia) enter the group of SMI and that not all people with SMI suffer from schizophrenia. As indicated, apart from the diagnosis, the persistence of the disorder in time and the existence of a disability are required.

## 3. Why do we talk about a bio-psycho-social approach

The main treatment for people with SMI has been pharmacological interventions since its introduction in the 50s. However, the partial and limited control of the symptomatology with the medication, the difficulties for certain patients to adapt to the pharmacological patterns, the need to work in areas such as awareness of the illness, the short and long term side effects, the difficulties in co-existence and the difficulty to carry out a productive activity and be independent, among others, pose the need to use a more far-reaching approach than pharmacological treatment, an approach that permits including biological, psychological and social aspects of the treatment (“bio-psycho-social approach”). So, other psychotherapeutic and psychosocial interventions must be incorporated which, in many aspects, are included in the psychosocial rehabilitation concept.

The sole objective of these interventions and this approach is to improve the personal and social functioning and the quality of life of people with SMI, as well as support their integration. This means doing more than just controlling symptoms and considering overcoming the illness; in other words, foster the possibility of people with SMI to lead a significant and satisfactory life, being able to define their own objectives and finding help to develop them in the professionals. This concept has been called recovery in scientific literature and at the same it becomes a channel and an objective to work with each patient.

These programmes, framed within a bio-psycho-social approach and aiming towards *recovery* have their maximum expression in Community Mental Health, whose aim is to care for patients in their normal environment, contrary to hospital (psychiatric hospital) care. As referred to in other chapters of this manual, this community model is the direct consequence of the changes in mental illness care over the last few decades and that foster a shift from the psychiatric hospital to the community and which have been reflected in, among other documents, the General Law on Health and the Strategies document of the Spanish NHS.

## 4. Regulatory and legal framework

### 1978 Spanish Constitution

The right to health protection is recognised in article 43. Furthermore, in its article 49, it urges the public powers to carry out a prediction, treatment, rehabilitation and integration policy for people with physical, sensorial and psychic disabilities or impairments, to whom they will provide specialised care.

### General Law on Health (Law 14/1986)

This is the law that provides a response to the constitutional requirement to “recognise the right for all citizens and foreigners resident in Spain to obtain the benefits of the health system and to establish the principles and criteria that enable general and common characteristics to be conferred upon the new health system, which will be the basis for the health services in the entire State territory”.

#### Characteristics:

- The focal point of the model are the Autonomous Communities
- Integral concept of health
- Health promotion/illness prevention
- Community participation
- Health Area as the basic nucleus of Health Services

One of the basic guidelines of this law is to promote the actions necessary for the functional rehabilitation and social reinsertion of the patient (Chapter one, art. 6).

This law also includes the fundamental rights (Chapter one, art. 10) and obligations (Chapter one, art. 11) of the users. Some of the section are repealed and developed by Law 41/2002 on the Patient’s Autonomy.

Mental Health has a specific chapter (Chapter III of Title One), which states the following as its basis: “the full integration of the actions relating to mental health in the general health system and placing mental patients on the same status than all other people, promoting care in the community and ambulatory care resources, and indicating that care in a hospital regime if required, should be carried out in the psychiatric units of the general hospitals”. The mental health and psychiatric healthcare services of the general health system will also cover, in coordination with the social services, the aspects of primary prevention and attention to psychosocial problems that accompany the loss of health, in general.

([http://www.boe.es/aeboe/consultas/bases\\_datos/doc.php?coleccion=iberlex&id=1986/10499](http://www.boe.es/aeboe/consultas/bases_datos/doc.php?coleccion=iberlex&id=1986/10499))

### The Health Laws of the different Autonomous Communities

These are responsible, together with the State and other competent public Administrations, for organising and developing all the health actions. Extensive competences in health-related matters are recognised in the different statutes.

Spanish basic regulatory law on the Patient’s Autonomy and on rights and obligations in clinical documentation information matters (Law 41/2002, 14 November). The aim of this law is to regulate the rights and obligations of patients, users and professionals, as well as of public and private health services and centres, in matters related to patients’ autonomy and clinical documentation

and information.

([http://www.boe.es/aeboe/consultas/bases\\_datos/doc.php?coleccion=iberlex&id=2002/22188](http://www.boe.es/aeboe/consultas/bases_datos/doc.php?coleccion=iberlex&id=2002/22188))

United Nations Resolution 46/119, December 1991, for the protection of the rights of persons with mental illness.

It recognises the right to labour, health, institutional and social non-discrimination of these people.

#### 1996 Madrid Declaration

Developed by World Psychiatric Association, the ethical guidelines that must rule between patient and psychiatrist are indicated, avoiding a compassionate attitude or an attitude exclusively aimed at avoiding injury to oneself or violence to third parties.

Royal Decree 63/1995, 20 January, on management of health benefits of the (Spanish) National Health System, establishes the health benefits directly provided to people by the National Health System. More specifically, it includes mental health care and psychiatric care in one of its sections, covering clinical diagnosis, psychopharmacotherapy and individual, group or family psychotherapy, and hospitalisation where appropriate.

Strategy in Mental Health of the National Health System. Approved by the Interterritorial Council of the National Health System on 11 December 2006.

In this document, we find general and specific objectives, as well as recommendations whose aim is to improve prevention and care of Severe Mental Illness, one of the priority healthcare lines for the Ministry. In addition, there are different community plans that set out development lines for Mental Health, and include care for patients with SMI.

Law of Civil Procedure and Civil Code: They regulate two procedures of interest in Mental Health:

1. The “*non-voluntary hospitalisation due to psychic disorders*” is regulated by Law of Civil Procedure (Law 1/2000, 7 January). Article 763 concerns Mental Health, regulating this procedure. It deals with the hospitalisation of persons who are not able to decide for themselves because of their psychic state, as a necessary therapeutic measure indicated by medical staff, applied with restrictive criteria and for as short a time as possible.

As this represents a privation of the fundamental right of personal freedom, the regulation aims to guarantee this right, among others, so the entire hospitalisation requires judicial authorisation (the authorisation will be prior to the hospitalisation, except when, due to urgent reasons, the measure must be immediately adopted). With the times established by law, “the court will hear the person affected by the decision, the Public Prosecutor’s Office and any other person whose appearance is deemed advisable or is requested by the person affected by the measure. Furthermore, and without prejudice of being able to perform any other test that is deemed relevant for the case, the court must examine for itself the person whose hospitalisation is referred to and hear the judgement of a physician appointed by him or her. In all the actions, the person affected by the hospitalisation measure may be represented and defended under the terms indicated in article 758 of this Law”.

This is a civil procedure and by virtue of strictly medical reasons.

([http://www.boe.es/aeboe/consultas/bases\\_datos/doc.php?coleccion=iberlex&id=2000/00323](http://www.boe.es/aeboe/consultas/bases_datos/doc.php?coleccion=iberlex&id=2000/00323))

Several protocols have been published that set out the involuntary hospitalisation procedure. The majority coincide in urgent cases in general lines, although some points may differ in the different health services:

- Initial approach by the general Emergency services or Primary Healthcare services (on request of the family or of close friends who detect a serious decompensation of the patient, who does not accept any approach of his or her clinical situation).
- With support of security forces if necessary, and
- Transfer to a hospital of reference with psychiatric emergency services where admission is decided upon, following the regulation of article 763 of the aforementioned Law.

2. *Civil Incapacitation and Tutorship*. Incapacitation is the legal mechanism foreseen for those cases where persistent, physical or psychic illnesses or impairments prevent a person from coping on their own, and where the aim is to protect the interests and rights of the incapacitated person, both personally and for hereditary purposes. Its legal regulation is included in articles 199 to 214 and following of the Civil Code and 756 to 763 of the Civil Procedure. The declaration of incapacitation is the competence of the Judge of First Instance, by virtue of verification of the causes that cause incapacity. Causes of incapacitation are persistent, physical or psychic illnesses or impairments that prevent a person from coping on their own (art. 200) and, in the case of minors, when this cause is foreseen to persist after the coming of age (art. 201).

The following are legitimised to start the incapacitation process:

- Spouse or descendants.
- And when absent, ancestors or brothers/sisters of the assumed incapable person.
- The Public Prosecutor when the persons mentioned do not exist or they have not requested it.

Any person is empowered to inform the Public Prosecutor's Office of the facts that may be decisive for the incapacitation.

The incapacitation of minors may only be fostered by those who exert custody or guardianship.

This process gives rise to a judicial judgement, which will determine its extension and limits, as well as the guardianship that the incapacitated person must be submitted to.

- Tutorship: will require the attendance of the guardian for any activity.
- *Curatela* (guardianship): needs the attendance of the tutor only for those acts established in the judgement.

The incapacitation judgement will not prevent any new circumstances that may occur from leaving the scope of the incapacitation without effect or modify it.

Tutorship is the consequence of an incapacitation process, which is established and constituted as a duty that is established in benefit of the tutored person, always under the supervision of the judicial authority. Tutorship is a legal institution whose aim is to guard and protect the person and the goods of the incapacitated person.

The tutor is the representative of the incapacitated person. The following may hold this position:

- Spouse, children, parents, brothers or sisters:
- Any physical person considered appropriate by the Judge.
- Non-profit legal persons, whose purposes include the protection of incapacitated people. The Autonomous Community is one of these legal persons.

### 3. *Other Regulation on Incapacitation and Tutorship:*

- Creation of the Tutorship and Judicial Defence Commission for Adults (Decree 168/1998, 6 October).
- Patrimonial protection of persons with disabilities (Law 41/2003, 18 November).
- Update of the Commission for Tutorship and Judicial Defence of Adults (Decree 13/2004, 27 February).

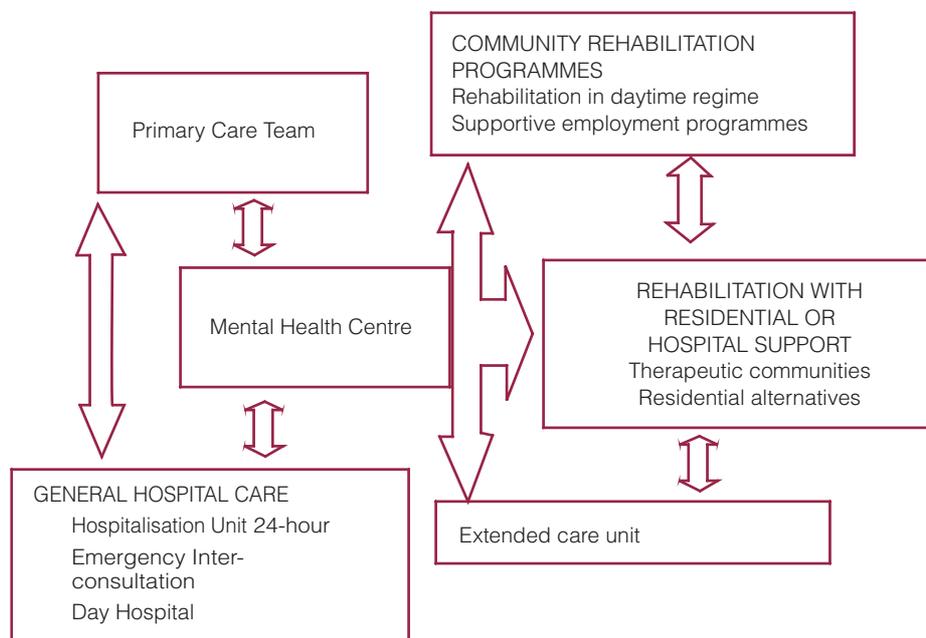
## 5. Therapeutic mechanisms and resources

As recommended in the 2006 Strategic Mental Health Plan, all citizens who require it must have access to a rehabilitation process, and in their territory (Basic Health Area, Health Sector of Autonomous Community), they must have the following devices at their disposal:

- Unit / Centre / Community Mental Health Service
- Hospitalisation unit in general hospital
- 24 hour a day emergency care
- Interconsultation and liaison in general Hospitals
- Daytime hospitalisation for adults
- Children- adolescents daytime hospitalisation
- Children- adolescents hospitalisation in general and/or paediatric hospital
- Community rehabilitation programmes (including community monitoring programmes and/or assertive community treatment programmes or similar)
- Daytime regime rehabilitation
- Rehabilitation with residential or hospital support
- Extended care unit
- Therapeutic community for adults
- Therapeutic community for teenagers
- Residential alternatives with grading support and therapeutic or rehabilitation activity
- Home care programme
- Home hospitalisation (intensive care)
- 24-hour community care (including community monitoring programmes and/or ATC programmes or similar)
- Employment programmes with support

People with SMI may use these resources at different moments of their illness, in some cases successively, in other simultaneously. The way in which the interventions are coordinated and in which circumstances one resource or another is used, may vary from one Autonomous Community to another. In any case, it maintains a series of constant factors that are aimed at what is called continuity of care, and which are based on situating the Community Mental Health Centre in the decision-making centre, with respect to each patient and at there being no interruptions or sudden changes in the level and intensity of the care.

The coordination of these resources and devices must offer a series of psychosocial interventions (objective of this CPG) that must be accessible for users and family members and which are the following:



- Psychoeducation or standard interventions that include information about the disorder, the treatment, training in problem-solving and improvement of communication, including family members or caregivers.
- Family –single family or multi-family- intervention programmes aimed at incorporating the family into the treatment, with a psychoeducational model, with training in problem-solving, handling stress and improving communication skills.
- Specific Cognitive-Behavioural Therapy Programmes for persistent symptomatology (positive and negative).
- Community intervention programmes –in the form of Case Follow-up and Assertive Community Treatment Teams – for those people with SMI with multiple readmissions or reduced monitoring adherence.
- Therapeutic programmes that include alternative accommodation for SMIs complicated with other situations: homeless, great difficulty of family co-existence, extended psychiatric admission, lack of resources and frequent readmissions.
- Assessment programmes and employment insertion for all those people who wish to work, recommending “Supportive Employment” if the objective is competitive work and “Sheltered Employment” and “Occupational Programmes” for all the other occupational objectives.

## 6. Social Benefits for people with severe mental illness

The first thing is to define the scope of this perspective of the treatment, and to do this we must point out that, in social intervention, the rehabilitation concept refers to the improvement of capacities or skills, to the series of supports or conditions necessary for a person to maintain a certain level of functioning, including both improving and maintaining or preventing a worse situation from being prolonged, even temporarily.

Its target of action is not only the specific individual who has a long-term severe mental illness but it also covers the person and the context. The rehabilitation work focuses, therefore, apart from on the user, on the family, friends, supports, social environment and any other relevant elements to satisfy the intervention objectives established in this individualised process.

### Importance of health resources and coordination with social care

The Mental Health Services, in any of its forms, depending on the implementation peculiarity in the different Autonomous Communities (mental health centres, mental health services, mental health teams, mental health units, or any similar entity) are the axis that articulates the care for people with severe mental illness and therefore the parties responsible for the treatments and those that must guarantee continuity of care. Therefore, those that must channel the care with other social devices but base them on the specific care if it is confirmed that the care has to be provided under this principle of continuity.

### How to define continuity of care

The Mental Health Services Care Continuity Programmes are aimed at facilitate the person included therein with the treatment, rehabilitation, care and community support that adapts best to their pathology and their time of life.

This care continuity must be expressed by specifically organising actions that can be divided, in general, into the following intervention groups:

- Mental health services of centres
- General or grass-roots social services
- Hospitals
- Primary health care
- Specific rehabilitation resources in mental health
- Other resources that are linked to the user's situation and that complement their needs for care and promotion of autonomy.
- Family members and users associations
- Normalised resources

### Definition of the social services system

It is the series of services and benefits, which, together with other elements of Social Welfare, aim to:

- Promote and fully develop all people and groups in society, to obtain greater social welfare and a better quality of life, within a setting of co-existence.
- Prevent and eliminate the causes that lead to social marginalisation and exclusion.
- All of this is done through public services and structures of the State Administration, Autonomous Communities and Local Corporations.

## Social protection systems

Pursuant to our Constitution, our country is a Social and Legal State that assures, through its protection systems, certain guarantees to its citizens through basic structures that guarantee basic rights, such as health, employment or housing, through solidarity redistribution processes, based on work revenues and the contributions of each one of the people. This process is carried out through the structures that are based on the National Social Security Institute, which, directly or by competence transfers to the autonomous communities, is responsible for distributing these benefits.

The National Social Security Institute is a Managing Entity attached to the Ministry of Work and Immigration, with its own legal personality and whose job it is to manage and administer the economic benefits of the public Social Security system and recognise the right to healthcare, regardless of the fact that the applicable legislation has a national or international nature.

Its competences include the recognition, management and control of benefits, which, in the case of a person affected by Severe Mental Illness, could be subject to the following:

- Retirement: If the person in question has made the specific, contributions and amounts required in agreement with their working life.
- Permanent disablement: as with retirement, but in this case, not having surpassed retirement age and when specific difficulties combine to hold a job that adapts to their education and training, in the event that it is for the normal work, or for all types of work, in the event that the person cannot carry out an adequate working role.
- Death and survival (widow/widower, orphans, in favour of family members and aid for death): in those cases when the person loses a family member and the situation whereby the applicable legislation gives the right to orphans' benefit, regardless of the age, is recognised.
- Temporary disablement: if a person is working and needs to temporarily interrupt their employment due to the concurrence of an illness.
- Maternity.
- Risk during pregnancy.
- Family benefits (dependent child, birth of third or successive children and multiple birth (contributory and non-contributory level).
- Economic compensations derived from non-disabling permanent lesions.
- The recognition of the right to healthcare.

Each one of the benefits described must be understood as complementary processes to those established in health care and that permit certain protection guarantees for the person affected by a Severe Mental Illness, to permit a certain degree of autonomy and social solvency.

It is important to point out the implicit possibility of recognising the condition of disability for a person with a mental health problem if their capacity to act, their ability and autonomy is reduced. These difficulties can be recognised through the acquisition, through the Specialised Social Services of each one of the autonomous communities, of the relative disability certificate. This condition is reflected procedurally in the Law on Social Integration of the Disabled, and which as a basic process for its acquisition would be:

1. Existence of a disabling illness, of acknowledged chronic nature.
2. Mandatory report of the illness by a physician who will perform a diagnostic appreciation and indicate the specific difficulties.
3. Mandatory report from Social Work referring to the difficulties and needs for social concurrence or support of a third person, who will assess the environment of the person and the social consequences of the specific pathology that affects the person.

4. Request to the relative body of an evaluation of this case. The teams of Grass-roots Social Services Centres will receive the demand. The competence evaluation team of each autonomous community will issue the relative judgement and the disablement condition of the person will be temporarily or definitely recognised.

By virtue of this recognition, the person affected by the SMI may benefit from other social coverage systems:

- If the percentage is higher than 33% disablement, the condition will be recognised and the person affected may make use of tax-related advantages.
- If the percentage is higher than 33% disablement, the condition will be recognised and If their disablement condition exceeds 65% and the person affected has not contributed for sufficient time so as to have a contributory benefit, he or she may have a non-contributory type economic income, set by each autonomous community.

The framework of reference of Spanish Law 39/2006, 14 December, on the Promotion of personal autonomy and care for dependent persons, recognises, among its principles, the universality in the access of all dependent people, in conditions of effective equality and non-discrimination. It also recognises in the actual definition of the dependency situation, the specific characteristics of the people who belong to the group of people affected by a mental illness, indicating that dependency is a “permanent state of people, who, due to reasons derived from age, illness or disability, and linked to the lack or loss of physical, mental, intellectual or sensorial autonomy, require the care of another or of other people or considerable help to perform basic activities of daily living or, in the case of people with intellectual disability or mental illness, other supports for their personal autonomy”. The evaluation and access to these benefits is regulated by each Autonomous Community.

([http://www.segsocial.es/Internet\\_1/LaSeguridadSocial/QuienSomos/InstitutoNacionalde29413/index.htm](http://www.segsocial.es/Internet_1/LaSeguridadSocial/QuienSomos/InstitutoNacionalde29413/index.htm))

#### Functions of the social services professionals

Some competences that are attributed to social services professionals and that act as coordination with the health spaces would be:

- Carry out evaluation tasks and social intervention with the referred users and their families.
- Coordinate with the different resources of the social-health network (General Social Services, training, labour mechanisms, etc.).
- Attend and form part of the Rehabilitation Commission of the area of reference if there are any.
- Participate in the taskforces of each one of the spaces defined. Carry out the assessment of the families, within the assessment protocol of each mechanism.
- Carry out the follow-ups of the assigned users.
- Inform and counsel users on resources, especially those that represent greater normalisation and integration: training, labour, educational, leisure...
- Detect new resources and be responsible for compiling already existing resources.
- Coordinate with the Associations of Families and Users of the Areas of reference of the Rehabilitation Centre, as well as with other types of people’s participation associations.

### Specific regulation

- (SPANISH) LAW 7/1985, 2 April, regulating the bases for the local regime. (BOE no. 80, 3 April 1985) whereby reference is made to specific care competences linked to local type administrations:  
Councils, regions, communities, provinces and other types of similar administrative structures) [http://www.boe.es/aeboel/consultas/bases\\_datos/doc.php?coleccion=iberlex&id=2003/03596](http://www.boe.es/aeboel/consultas/bases_datos/doc.php?coleccion=iberlex&id=2003/03596)
- (SPANISH) LAW on Promotion of personal autonomy and care for dependent people (with special reference to people with mental health problems) Law 39/2006, 14 December, on Promotion of Personal Autonomy and Care for dependent people <http://www.imsersomayores.csic.es/landing-pages/ley-autonomia-personal.html>
- (SPANISH) LAW 13/1982, 7 April, on Social Integration of the Disabled. [http://noticias.juridicas.com/base\\_datos/Admin/l13-1982.html](http://noticias.juridicas.com/base_datos/Admin/l13-1982.html)

## 7. The stigma and Severe Mental Illness and how to cope with it

Despite the advances in the development of human rights, an analysis of social behaviour indicates that there are still discriminatory attitudes towards people with mental illnesses, especially if these are severe, resulting from stereotypes and prejudices that form an often insurmountable barrier for the development of their rights as citizens, for their social integration, and they add new suffering not attributable to the actual illness per se.

- **Stereotypes** are definitions about the illness and its evolution, resulting from partial analyses or false beliefs: incurability, the unpredictability of their actions, non-responsibility, lack of interests, inability to make decisions and a whole life is qualified by one diagnosis or by the symptoms at a time of crisis.
- **Prejudices** are irrational attitudes derived from those beliefs: fear, disdain, aggressiveness, annulment of the other, paternalism, etc.
- **Discriminatory behaviours:** social exclusion actions, segregation, non-access to services, to work, to enjoyment of cultural benefits, leisure, personal enrichment, etc.

**The stigma** is the mark that these beliefs, attitudes and behaviours leave on the person who suffers the illness and on the family. The social origin of this stigma dates back to times gone by, so overcoming it is a slow process and it still has an impact on all social fields, to a greater or lesser extent: families, neighbours, work, media and also in the health fields and mental health professionals.

Thus, the person has to work to overcome the illness in a precarious situation of personal impoverishment that compromises the progresses of the recovery process. As a whole, the group of affected people has no power to recruit influence: either at work, in their environment and sometimes not even in the services. This is one of the reasons for the limited resources in budgets and the slow development of the services.

### Facing the fight against stigmatisation

The fight against the stigma means adopting a conscious and active change in outlook: respect for human rights, personal dignity and the right of people with SMI to develop their potentialities and to contribute to society. Working in this direction is one of the basic responsibilities of the public

Administration, of the health and social services system, of the family and of the social environment, and it is in this direction that progress is being made.

### Support to the person affected

This change in outlook is inefficient if the person suffering the illness is not counted on, as this person must overcome the internalisation of any negative beliefs that he or she may have about him/herself (self-stigma). Positive experiences in this field indicate that progress occurs when the following concur:

- awareness of their own difficulties (psychoeducation)
- development of individual abilities (self-esteem)
- knowledge of one's own rights
- decision-making in agreement with their interests and preferences (*Empowerment*) (self-assertion),

and when this approach is integrated continuously and early on in the care and rehabilitation programmes, counting on the family and situating the anti-stigma action in the actual fields of life (residence, work, leisure...), procuring the collaboration of the environment.

The person can leave his or her role as a patient and integrate significant roles, becoming a neighbour, a worker, a citizen who mixes, has fun, etc. and has his or her own life project. The close knowledge of the environment and stable social exchange decrease rejection.

The impact of the illness on a family presents tragic characteristics at the onset, something that is not unlike the stigma. That is why the family must be actively integrated right from the start in the information processes and in the rehabilitation programmes, establishing suitable strategies regarding the way in which each family has to cope with the illness.

**Programmatic Statements:** In all democratic countries, and especially in Europe, there are programmatic statements that foster cross-section policies to fight against stigmatisation that contain the principles to be taken into account in the applicable legislation of each country

#### *Europe:*

- *“Conclusions of the Council of Employment, Social Policy, Health and Consumers”, June 2003, on the fight against stigmatisation and discrimination in connection with mental illness*
- *“European Declaration on Mental Health”. Ministerial Conference of the WHO. Helsinki, January 2005*
- *Green Paper “Improving the mental health of the population. Towards a European Union strategy on mental health” Commission of the European Communities COM(14.10.2005) 484, page 11*
- *“From exclusion to inclusion. The road to promoting social inclusion of people with mental health problems in Europe” Mental Health Europe 2008 Trad. FEAFES*

#### *In Spain*

- *“Strategy in Mental Health of the National Health System” Strategy line 1 “Promotion of mental health of the population, prevention of mental illness and eradication of the stigma associated with people with mental disorder” Ministry of Health 2007*
- *“Model for care of people with severe mental illness” Ministry of work and social affairs. General Catalogue of Official Publications, Chapter 15: Fight against social stigma.*

**Service Management:** The first anti-stigma measure corresponds to the Administration as:

- Provider of quality, accessible, universal, non-excessive, recovery-orientated services, which decisively incorporate advances in treatment, rehabilitation and social integration,
- and leading the start-up of awareness-raising campaigns and maximising surveillance over the respect for the dignity of persons both in the state administration as a whole and in healthcare in particular.

Integrate the anti-stigma approach in community plans

Over the last few years, a lot of progress has been made to fight against the stigma. The family associative movements and self-help associations as well as movements of users and of professionals, have now taken centre stage. The social fabric itself has joined this effort (local administration, NGOs, neighbourhood associations, etc.)

One of the main components is information (knowledge) both from the specialised professional media and through awareness-raising campaigns. Information and awareness-raising campaigns must be combined with social interaction processes that persist in visible actions in society. An information strategy must be cross-sectional, significant and continued, reaching the entire social fabric: the public administration, the judiciary, the health, social, education, cultural, labour (employers, unions) systems, residents and the media. An effective way is the presence and direct participation of the people affected and their families in the education and awareness-raising campaigns...

- *“MENTALIZATE. (change your mindset) Information campaign on mental illness”* (<http://www.feafescyl.org>)
- *Mental health and media: style guide* Spanish Association of Groups of Families and People with Mental Illness (FEAFES) 2003
- *Mental health and media: Handbook for entities* Groups of Families and People with Mental Illness (FEAFES) 2003

On the other hand, mental health professionals are not oblivious to the stigma and they must review their action, eliminating any attitude that fosters this:

- Include reviewable action protocols in the services, which guarantee respect for the dignity and rights of the person: right to be attended to, to choose between options, to be informed of the rights, of the functioning of the services, of the programme to follow and its objectives.
- Use complete models of continuing assessment with the active participation of the persons affected and of their families, avoiding stereotypes in the diagnosis, the use of indiscriminate treatments, establishment of routines and incorporating strategies for handling the stigma that include the family.
- Be disseminating agents in the fight against the stigma.
- Use the resources of the normalised network for training, cultural, leisure and entertainment activities, those of citizens' participation.
- Create intermediate group structures that act as mediators to facilitate participation in the community: theatrical, artistic groups, choirs, sports groups.
- Create a quality image of the intermediate devices and for them to participate in the social network.
- Promote the user's active participation in the rehabilitation services. Foster self-help activities in a group among those affected, exchanging personal experiences and associative movements. However small the experiences, they have the value of being projected to the whole society.

## 8. The role of user and family associations

The Associations of Families and Users have represented an important advance over the last 30 years both due to their contributions in the development of a previously unknown perspective, identifying the needs and rights of people with severe mental illness, and due to the information, support and lobby they carry out. Thanks to these organisations, closely linked to the community care of mental health, it has been possible to foster the creation of new healthcare resources in response to the psychiatric de-institutionalisation in many countries.

The families, who are very often the only more direct support that people with SMI have, now play an active part in the therapeutic process of rehabilitation or recovery, and are considered as just another therapeutic agent. Obviating their involvement in the development and implementation of care programmes would mean ignoring the needs to improve the quality of life of the people affected. Their contribution in the fight against the stigma of mental illness, the demand for accessibility to health and social resources within the parameters of equality and recognition of full rights for people with SMI, has been and is fundamental to continue advancing in the achievement of these objectives.

The creation and consolidation in the entire Spanish territory of groups of psychoeducation or school of families, has helped provide these families with the necessary information and strategies to cope with the difficulties represented by living with a relation diagnosed with SMI. Peers groups, or self-help groups, have also been effective and gratifying for the families. The *Prospect* training method, for example, a programme used in different countries and which was promoted by EUFAMI (European Federation of Associations of Families of People with Mental Illness) appears as an instrument of union and training for the three groups involved: people with mental illness, family members and mental health professionals. The role of these groups, in the international scenario, covers not only mutual help activities and other services, but also the defence of the rights and interests of the group, education for the community, impacting the Mental Health policy-makers, reporting the stigma, and the discrimination, demanding an improvement of the services.

The groups of people with mental illness who, in many countries are identified as groups of consumers or users, follow, in their origins, a similar dynamic to the organisations of family members, although somewhat later. They have progressively played a more influential role in healthcare and legislative policies, as well as in the development of actions to help other people with mental illnesses. These groups have stood out for their educational and social awareness-raising role, due to their actions, reporting practices perceived as negative practices and protecting their rights, and for the development and management of help services.

The Spanish Federation of Associations of Families and People with Mental Illnesses (FEAFES) was created in Spain in 1983, as a state organisation to group together and represent the entire associative movement of families and people with mental illness. The first European Congress of Families was held in June 1990, which led to the foundation of EUFAMI in 1992.

We can sum up the main tasks and contributions of these organisations:

### ***1. Collaboration in the preparation of healthcare, planning policies and legislation***

In the political field, the associative movements of families and people with mental illness have a historical function of demanding improvements in the care of people with mental illness. Currently these movements, in Europe and in other countries, also have an active function in the design, development and assessment of policies, as indicated by the World Health Organisation (WHO) and as included in the actions of the European Commission (Green Paper

on Mental Health and the future European Strategy on Mental Health). Its role in the regulation of the Involuntary Outpatient Treatment (IOT) is also known as well as in the Law on Promotion and Prevention of Autonomy and Care to Dependency, among others.

## **2. Service Providers**

The associative movements are also characterised because they carry out support services. In some countries, such as France or Ireland, the services provided by the associative movement are focused on support and training groups, information services and awareness, demand and denunciation actions. In Spain, as in Great Britain, different social or social-health services are managed, which contribute to covering the needs of users and families where public resources are not sufficient. There, a series of basic services are offered, which vary from information and counselling, awareness-raising and promotion of mental health, legal advice for programmes of psychoeducation, self-help groups, family break activities and home care programmes.

Other services are based on the organisation of activities framed within the psychosocial rehabilitation process, labour rehabilitation, and leisure and spare time activity programmes, as well as on the management of the resources that can carry them out.

## **3. Social awareness-raising**

This is one of the cornerstones of the associative movement. The dissemination and social awareness-raising activities, which these organisations organise and promote, are assumed as a fundamental task both by the actual organisations and by the professionals and politicians, agents and planners. There are many different initiatives and projects aimed at raising social awareness, from the promotion and prevention of mental health, to addressing discrimination and prejudices towards mental illness and people who suffer from it. The aim is to get public administrations (state, regional or local) to assume these initiatives through awareness-raising activities for specific groups (students, professionals, media, employers...). Initiatives to be highlighted due to their impact are the “*Schizophrenia opens the doors*” programme and the “*Zerostigma*” campaign promoted by EUFAMI in 2004. Equally important is the work carried out with the social media through the Style Guide for Media, published by FEAFES, or the participation in studies on stigma (project, “harassment and discrimination faced by people with psychosocial disability in of health services” promoted by Mental Health Europe, MHE).

It is still necessary to join and coordinate the forces of the different players who intervene in the integrated treatment of people with SMI and the support to their families. The aim is no other than to guarantee the healthcare continuity that these people require, with the most effective therapeutic techniques and strategies, providing the most normalised and personalised possible support.

# **9. Addresses and websites of interest**

## **National Associations**

**Spanish Federation of Associations of Families and People with Mental Illness**, grouping together federations and association of people with mental illnesses and their families from the entire national territory. The contact addresses of the member associations in each Autonomous Community can be consulted on their webpage.

<http://www.feafes.com> [feafes@feafes.com](mailto:feafes@feafes.com)  
C/ Hernández Más, 20 – 24. 28053 Madrid  
Tel: 91 507 92 48 Fax: 91 785 70 76

**Spanish Association of Neuropsychiatry**

<http://www.aen.es> [aen@aen.es](mailto:aen@aen.es)  
C/ Magallanes, 1 Sótano 2 local 4. 28015 Madrid  
Tel: 636 72 55 99 Fax: 91 847 31 82

**Spanish Association of Clinical Psychology and Psychopathology**

<http://www.aepecp.net/>  
[aepecp@aepecp.net](mailto:aepecp@aepecp.net)  
C/ Beato Gálvez, 3, pta 4. 46003 Valencia

**Spanish Association of Dual Pathology (AEPD)**

<http://www.patologiadual.es/> [asociacion@patologiadual.es](mailto:asociacion@patologiadual.es)  
C/ Londres, 17. 28028 Madrid  
Tel: 91 361 2600. Fax: 91 355 9208

**National Association of Mental Health Nursing**

<http://www.anesm.net/>  
[anesm1@gmail.com](mailto:anesm1@gmail.com)  
C/ Gallur N° 451, local 5. 28047 Madrid  
Tel: 91 465 75 61. Fax: 91 465 94 58

**Spanish Federation of Associations of Psychosocial Rehabilitation (FEARP)**

<http://www.fearp.org/> Hospital of Zamudio.  
Arteaga Auzoa 45. 48170 Zamudio, Bizkaia

**Sociodrogalcohol. Spanish Scientific Society for Studies on alcohol, alcoholism, and other drug addictions**

<http://www.socidrogalcohol.org/>  
Avda Vallcarca, 180. 08023 – Barcelona  
Tel: 93 210 38 54. Fax: 93 210 38 54

**Spanish Society of Psychomatic Medicine**

<http://www.semp.org.es/> [sempsecretaria@wanadoo.es](mailto:sempsecretaria@wanadoo.es)  
Avda San Juan Bosco 15. 50009 Zaragoza

**Spanish Society of Psychogeriatrics**

<http://www.sepg.es/>  
[jacb@ugr.es](mailto:jacb@ugr.es)  
Department of Psychiatry Faculty of Medicine. Avda. de Ramón y Cajal, s/n. 47011 – Valladolid

**Spanish Society of Psychiatry**

<http://www.sepsiq.org/> [sep@sepsiq.es](mailto:sep@sepsiq.es)  
C/ Arturo Soria, 311 1° B. 28033 – Madrid  
Tel: 91 383 41 45. Fax: 91 302 05 56

**Spanish Society of Biological Psychiatry (SEPB)**

<http://www.sepb.es/>  
[info@sepb.es](mailto:info@sepb.es)  
C/ Arturo Soria 311, 1° B. 28033 Madrid  
Tel: 91 383 41 45

**Spanish Society of Legal Psychiatry**

<http://www.psiquiatrialegal.org/>

**Spanish Society of Psychiatry and Psychotherapy for Children and Adolescents (SEYPNA)**

<http://www.seypna.com> [seypna@seypna.com](mailto:seypna@seypna.com)

C/ Monte Esquinza, 24 4º izq., 28010 – Madrid

Tel: 91 319 24 61. Fax: 91 319 24 61

International Associations

**World Fellowship for Schizophrenia and Allied Disorders**

<http://world-schizophrenia.org>

<http://espanol.world-schizophrenia.org> (in Spanish)

**World Psychiatric Association**

<http://www.wpanet.org/>

**European Federation of Associations of Families of People with Mental Illness**

<http://www.eufami.org>

**American Psychiatric Nurses Association**

<http://www.apna.org>

**HORATIO. European Psychiatric Nurses Association**

<http://www.horatio-web.eu/>

**The European Psychiatric Association**

<http://www.aep.lu/>

**World Association for Psychosocial Rehabilitation**

<http://www.wapr2009.org/index.htm>

**World Federation for Mental Health**

<http://www.wfmh.org/>

**Mental Health Europe**

<http://www.mhe-sme.org>

**National Alliance on Mental Illness**

<http://www.nami.org> [http://www.nami.org/Content/NavigationMenu/Inform\\_Yourself/](http://www.nami.org/Content/NavigationMenu/Inform_Yourself/)

[NAMI\\_en\\_espa%3%B1ol/](http://www.nami.org/Content/NavigationMenu/Inform_Yourself/NAMI_en_espa%3%B1ol/) [NAMI\\_en\\_espa%3%B1ol.htm](http://www.nami.org/Content/NavigationMenu/Inform_Yourself/NAMI_en_espa%3%B1ol.htm)

**American Psychiatric Association**

<http://www.psych.org/>

**Latin America Psychiatric Association**

<http://www.apalweb.org>

Other websites

**Schizophrenia**

<http://www.esquizo.com/>

**Spanish Foundation of Psychiatry and Mental Health**

<http://www.fepsm.org>

**Association of Obsessive-Compulsive Disorder**

<http://www.asociaciontoc.org>

**Psychosis Prevention Programme**

<http://www.p3-info.es/>

**Psychiatry website**

[www.psiquiatria.com](http://www.psiquiatria.com)

**Psychiatry website**

[www.psiquiatria24x7.com](http://www.psiquiatria24x7.com)

## Appendix 5. Abbreviations

ACT	Assertive Community treatment
AEN	Spanish Association of Neuropsychiatry
AHCRPR	<i>Agency for health care policy and research</i>
AHRQ	<i>Healthcare research and quality</i>
APA	<i>American Psychiatric Association</i>
ADL	Activities of Daily Living
CAT	<i>Cognitive adaptation training</i>
BPRS	<i>Brief psychiatric rating scale</i>
CDR	<i>Centre for review and dissemination</i>
CET	<i>Cognitive enhancement therapy</i>
ICD	International Classification of Diseases
CPA	<i>Care program approach</i>
CM	<i>Case Management</i>
CPRS	<i>Comprehensive psychopathological rating scale</i>
CRT	<i>Cognitive remediation therapy</i>
CMHC	Community mental health centre
CSQ	<i>Client satisfaction questionnaire</i>
DAS	<i>Disablement assessment schedule</i>
SMI	Standardised mean deviation
WMD	Weighted mean deviation
DSM	Diagnosis and statistics manual for mental disorders
RCT	Randomised clinical trial
GAAS	Global activity assessment scale
SE	Sheltered employment
SE-IS	Sheltered employment and individual support
PVT	Pre-vocations Training
ES	Effective Size
EST	Enriched support therapy
EWs	<i>Effect size weighted</i>
FCO	Pharmacological treatment
G.I.N	<i>Guidelines international network</i>
GAF	<i>Global assessment functioning</i>
GAS	<i>Global assessment scale</i>
CPG	Clinical Practice Guideline
SK	Social skills
CI	Confidence Interval
95% CI	95% confidence interval
ICM	<i>Intensive case management</i>
IPS	<i>Individual placement and support</i>
IPSRT	Interpersonal and social rhythm therapy
IPT	<i>Integrated psychological therapy</i>
MHSC	<i>Menninger health sickness scale</i>
MSANS	<i>Modified scale for the assessment of negative symptoms</i>
NEAR	<i>Neuropsychological educational approach to rehabilitation</i>
NET	<i>Neurocognitive enhancement therapy</i>
NICE	<i>National institute for health and clinical excellence</i>

NIMH	US National Institute of Mental Health
NNT	Necessary number to treat
WHO	World Health Organisation
NGO	Non-government organisations
OTP	<i>Optimal treatment project</i>
OR	<i>Odds ratio</i>
P	Probability of the results being due to chance
PANNS	<i>Positive and negative syndrome scale</i>
Perc QoL	<i>Lancashire quality of life profile</i>
FP	Family psychoeducation
PORT	<i>Patient outcomes research team</i>
MR	Mental retardation
RR	Relative risk
SR	Systematic review
SANS	<i>Scale for the assessment of negatives symptoms</i>
SES	<i>Self esteem scale</i>
SFS	<i>Social functioning scale</i>
SDSI	<i>Social disability schedule for inpatients</i>
SIGN	<i>Scottish intercollegiate guidelines network</i>
MH	Mental Health
NHS	National Health System
SPG	<i>Skalen zur psychischen Gesundheit</i>
BD	Bipolar disorder
CBT	Cognitive behaviour therapy
ST	Standard treatment:
SMI	Severe Mental illness
WCST	<i>Wisconsin card sorting test</i>

## Appendix 6. Glossary

**Therapy adherence:** Active and voluntary involvement of the patient in a mutually agreed and accepted behaviour course in order to produce a desired therapeutic result.

**Psychosocial rehabilitation centres:** Specific resource, aimed at the population with severe and chronic psychiatric disorders, who have difficulties in their psychosocial functioning and in their integration into the community. The aim is to offer psychosocial rehabilitation and community support programmes that facilitate the improvement of their level of autonomy and functioning, as well as support their maintenance and social integration into the community, in the best possible conditions of normalisation, independence and quality of life.

**Expert collaborators:** Clinical professionals with knowledge and experience on specific subjects of the CPG and ideally with prestige in the field where the guideline is developed. They participate in defining the initial clinical questions and reviewing the recommendations<sup>5</sup>

**Comorbidity in psychiatry:** The World Health Organisation (WHO) defines comorbidity or dual diagnosis as the co-existence in the same individual of a disorder induced by the consumption of a psychoactive substance and a psychiatric disorder.

**Prosocial behaviours:** Acts carried out in benefit of other people; ways of responding to them with sympathy, condolence, cooperation, help, rescue, comforting and delivery or generosity.

**Disability:** According to the WHO “Within the health experience, a disability is any restriction or absence (due to a deficiency) of the ability to carry out an activity in the way or within the margin that is considered normal for a human being.”

**Randomised control trial:** An experimental study in which the participants are randomly assigned to receive a treatment or intervention from among 2 or more possible options.

**Control Group:** A control group in a clinical trial is the group that has not received the intervention of interest and serves as the standard of comparison to evaluate the effects of a treatment.

**Experimental group:** In a clinical trial, the group that receives the treatment under study, in comparison with the reference group that receives placebo or an already known, accepted and established active treatment.

**Interdisciplinary:** Carried out with the collaboration of several disciplines.

**Distal measurements:** Measurements related to distant circumstances in a space-time sense of the intervention under study.

**Proximal measurements:** Measurements related to immediate circumstances in a space-time sense of the intervention under study.

**Multidisciplinary:** Which cover or affect several disciplines.

**Level of evidence:** Hierarchic classification of the evidence according to the scientific rigour of the design of the studies.

**Relapse:** Increase of symptoms of the illness after a period of reduction or elimination of such symptoms. It can be operatively defined as equivalent to “rehospitalisation”, increase in the intensity of the care, increase in psychopathological severity, as reduction of social functioning or even as a need for change in clinical care.

**External reviewers:** Clinical professional with knowledge and experience in the specific subjects of the CPG and ideally with prestige in the field where the guideline is developed. They only participates in the final phase of the guideline, reviewing the provisional draft of the CPG<sup>5</sup>.

**Effect Size (ES):** it is the measurement of the force of the relationship between two variables. Following the recommendations of Cohen, the values are equivalent to:  $D= 0.2$  “small effect”, around  $d = 0.5$  “medium” effect and  $d = 0.8$  on “large” effect, although this interpretation depends on the context. The size of the weighted effect (ESw) will refer to the statistical control exercised on the influence of the different in sample sizes.

**Standard (or normal) treatment:** Treatment that is received in the normal medium that includes medication, hospitalisation, nursing care and that is conditioned by the personal preferences of the people, the criteria of the professionals and availability of resources.

**Hospital rehabilitation unit:** Hospital health mechanism designed to satisfy integrated treatment, rehabilitation and containment functions.

## Appendix 7. Declaration of interest

All the members of the development team, expert collaborators and external reviewers have declared no conflict of interest.

Milagros Escusa Julián, Francisco Galán Calvo, Laura Gracia López, Pedro Pibernat Deulofeu, Ana Vallespí Cantabrana, Juan Ignacio Martín Sánchez, María José Vicente Edo, José M<sup>a</sup> Álvarez Martínez, Daniel Navarro Bayón, Antonio Lobo Satué, Julián Carretero Román, Carlos Cuevas Yust, Begoña Iriarte Campo, Juan Francisco Jiménez Estévez, José Manuel Lalana Cuenca, Marcelino López Álvarez, Mercedes Serrano Miguel, Catalina Sureda García, Oscar Vallina Fernández, have declared no interests.

Francisco Caro Rebollo has received funding (Janssen, Boehringer Ingelheim, Lundbeck, GSK and Novartis) for attending meetings, courses and congresses. He has obtained fees (Janssen) as a speaker at courses and conferences. He has also received economic aid to participate in research projects (Bristol Myers-Squibb, AstraZeneca, Esteve / Novartis, Janssen, Lilly).

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