DOMICILIARY HOSPITALISATION AS AN EFFECTIVE ALTERNATIVE TO TREAT PATIENTS WITH AN ACUTE PSYCHIATRIC CRISIS, COMPARED TO THE TRADITIONAL METHOD

FINAL DEGREE PROJECT

JANUARY 2023

SUB-ACUTE PSYCHIATRIC UNIT AND THE
DOMICILIARY HOSPITALISATION TEAM
HOSPITAL SANTA CATERINA, PARC
HOSPITALARI MARTÍ I JULIÀ

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This project is dedicated to all those special people, the ones who throughout my journey have encouraged me to move forward; family, friends, and Doctoritas, it is a pure pleasure being able to share this life with you.

In addition, I would like to show my gratitude to all those who have guided me along this process, from the snowy Norwegian mountains to the warm sunshine of Girona. You are light; without you, this would not have been possible.

I would also like to express my sincerest thanks to my tutors; Isabel and Rafel, conjointly with the Psychiatric Sub-Acute Unit of Santa Caterina, Marc Sáez and Irene Bosch. Last but not least, I would like to emphasise an acknowledgement to the home hospitalisation team, Ramon and Nayef, from whom I have had the privilege of learning what true medicine is all about.

Finally, I would like to make a special mention to the patients and their families. You are courageous, and it is an honour to be able to help.

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ABBREVIATIONS

The following are the abbreviations discussed throughout the document:

- DH: Domiciliary Hospitalisation modality of treatment
- DHT: Domiciliary Hospitalisation team
- TH: Traditional Hospitalisation modality, referred to inpatient stays all inside the hospital's domain.
- AMHD: Adult mental Health Disorder
- IFUP: Individual follow-up program
- CSMA: Mental Health Centre
- MiJMC: Martí I Julià Medical Centre
- IAS: Institut d'Assistència Sanitària (Healthcare Institute)
- ICD – 10: International Classification of Diseases 10^{th} edition
- UK NHS: United Kingdom National Health System
- XSMA: Xarxa de Salut Mental de Girona (Girona mental healthcare network)
- CH: Clinical History
- HoNOS: Referring to the Health of Nations Outcome Score
- SDAS: It is s the Social Dysfunction and Aggression Scale
- CSQ: The Client Satisfaction Questionnaire
- ISMI: Internalised Stigma of Mental Illness Inventory
- MANSA: Manchester Short Assessment of Quality of Life
- TAC: Communitarian Assertive treatment
- EIPP: Early Intervention in Psychosis Team
- THC: Cannabis, delta-9-tetrahidrocannabinol
- Oh: Alcohol
- Bzd: Benzodiazepines
- ER: Emergency room
- Trt: Treatment
- CEIC: Comitè d'Ètica d'Investigació Clínica
- WHO: World Health Organisation
- CAP: Primary attention healthcare centre
- GMA: Mutual help group
- CRG: Psychosocial rehabilitation centre

ABSTRACT

BACKGROUND AND OBJECTIVES

Domiciliary Hospitalisation (DH) is presented as an alternative to traditional hospitalisation (TH) when it comes to treating patients during an acute psychiatric crisis, providing assessment to the patients in their home, understood as its social environment and family.

Nevertheless, even though there are multiple studies developed regarding the treated topic, no conclusive data is obtained from them. Therefore, with this present study, we aim to assess the effectiveness of the DH model, and its impact on further patient outcomes, finding and producing evidence of it.

METHODS

This study is designed as a longitudinal prospective cohort study population-based, and will be carried out in the Xarxa de Salut Mental of Girona's region, based in Parc Hospitalari Marti I Julià, located in Girona. The study will be held between February 2024 and August 2026, including the recruitment period, the follow-up, and the post-discharge assessments.

Comparison is set between the population from those areas, aged from 18 to 65, receiving DH or standard hospitalisation, and the other populations, who can only be treated with the traditional method. For the analysis, we will compare our variables on the first day of treatment (T1), right before discharge (T2), 6 months after discharge (T3), and 12 months after discharge (t4), in all groups.

The main objective is to assess Domiciliary Hospitalisation as an effective alternative to traditional hospitalisation by obtaining positive clinical and functional outcomes. In addition, secondary aims are reducing the inpatient admissions to the acute and subacute unit and the readmission rate, as well as creating a linkage to the mental health system and achieving safety, acceptance, and satisfaction both for the patient and the family, and a reduction in the burden and mental health stigma.

KEYWORDS: Domiciliary Hospitalisation, Traditional hospitalisation, acute mental health crisis, linkage to mental health services, effectiveness, positive clinical and functional outcomes, reduction of inpatient admission and readmission, satisfaction and acceptance, reduction of stigma and burden, family integration.

INTRODUCTION

It is a well know truth that patients suffering from an acute psychiatric crisis need to be assessed and taken care of by a professional team. In the recent years, the traditional psychiatric model for acute crisis resolution has been shifting into a whole new entity, in which the patient and family adopt a crucial, active, and decisive role in the treatment and rehabilitation, transforming it into a cooperative process between the different elements, hence building it up. Therefore, the patient-doctor-family alliance becomes the pinnace of the process, toward achieving the optimal bond.

Due to these new reforms, a new concept has been born; deinstitutionalisation, referring to a shifting process, able to trespass the established traditional way, in which patients do have hospital admission in the psychiatric acute ward, followed by their stay in the subacute unit, and once the episode has been solved, assess the patient, and provide him with the tools to re-enter back to society. In front of this new situation, deinstitutionalisation arises as a new service net, in which the construct of quality life takes importance, changing the perspective of treatment, and founding it on the personal needs of the patients and their surroundings. The aim of this new currency is primordially based on the recovery and rehabilitation of the person.

Continuing with this modality, Domiciliary Hospitalisation (DH) has bloomed as ministering those patients suffering from an acute mental health crisis, constituting an alternative to the traditional method. The aim of it is to approach the situation in the domiciliary environment, preventing the disruption of the patient's comfort zone, and including the family and social spheres as part of the intervention.

There are deficiencies in the traditional hospitalisation method, and for that reason, we propose this study, as well as to improve the quality of mental health assistance. All in all, DH is an intervention that could be useful as an alternative to the traditional method, obtaining favourable outcomes, and intending to reduce hospital admissions and re-admissions.

EVIDENCE AND STUDY JUSTIFICATIONS

There are several arguments from professionals and patient movements to treat people in the community and not in the hospital (1). Literature indicates that DH may help reduce hospital admission days and increase the treatment satisfaction of patients and their relatives. Moreover, it can help to address some social and environmental triggers, that can contribute to a crisis, by learning coping skills, and preventing future crises to happen (1,2).

Another interesting phenomenon is that professionals can better respond to the needs of patients and their relatives if they meet them in their social environment since these professionals are different and less dominated by inequalities of power when crises are managed in the patient's own homes (10). Support between equals is fundamental for many people in their process of recovery (11).

On the contrary, hospital inpatient admissions can be harmful and stigmatizing to patients, and the relationship between patients and their families can be set apart, which has a negative effect because their support is often crucial (3).

Multiple studies are pointing out the positive results of home treatment interventions. Taking Norway as a referent system, in which DH is a methodology that has been widely implemented, we can appreciate how the use of DH teams together with the municipalities has been expanded, and anyone who needs it is offered a user-controlled place (4, 5, 6). The specialist health service has an outward-looking and flexible approach, resulting in fewer people needing to be admitted to hospitals. It is crucial to understand that their patient's vision is very empathic, emphasizing the fact that it is fundamental to know what is important for the patient as a whole (7). Greater user involvement and user satisfaction are key goals, and they consider the patient as the expert regarding their life. Their views and needs will therefore determine what happens, being entitled to decide the treatment that is best for them, drown up in cooperation with the professionals and the providing services concerned, and setting the goals and measures needed to achieve them (2).

Other examples to illustrate this are a group of studies we have selected. The first one is performed in Southampton (8), demonstrating that after the implementation of the NHS plan in 2000 of the DHT all around the country, it showed a potential promise as a means to increase DH model fidelity and reduce inpatient service use, as well as to reduce relapse rates for people leaving DH care (9). In addition, another Italian study notes that this alternative provides a quicker

examination and easier, faster patient discharge, as well as other benefits such as user satisfaction (3).

Following on and considering the path that psychiatric reform has taken over the years, tearing down the physical walls of the asylums, and making mental health visible again in society, we must understand one thing, and that is that this reform is an unfinished process. It is in constant change, and it is always at risk, being today's Mental Health Stigma a proof of that. It is important to be conscientious of our society, and to fight for quality and an efficient healthcare, especially for the most vulnerable groups of people. Therefore, we must care for, and specifically protect and treat mental health (9,33,34).

We believe that research in this field is needed to offer quality assistance services and to aid those patients and their families. Also, economic, and political pressure encourages community mental healthcare to develop further. In addition, inquiring about and exposing the new psychiatric reforms is a way of facilitating their correct adaptation and acceptance among the general population, to obtain the maximum quality of life for those people with mental disorders and their families, who will be satisfied with their environment, and thus will contribute to their recovery (36, 10).

CLINICAL AND HEALTHCARE IMPACT

According to the WHO, one in four people will experience a mental health problem in their lifetime. In Catalonia, mental disorders are estimated to affect 23.7% of the population older than 17 years old at some point (11). Biological, socio-economical, cultural, and environmental factors contribute to this, and therefore all of them should be considered (3).

The pandemic, with the confinement and limitation of the free movement of all citizens, has had a psychological impact both on people with previous mental health problems and on the general population, with an increase in the prevalence of mental health problems (6). It is especially notorious, particularly in vulnerable population groups such as hospitalised people, those with a previous mental illness, the ones experiencing difficult situations caused by isolation, those who have suffered domestic violence, the ones affected by the effects of the economic crisis, health professionals and those in the residential and social sphere, and the ones who have lost family and friends without being able to say goodbye (4, 5).

The impact is so far-reaching that numerous analysis positions mental health disorders among the first chronic illnesses declared to be suffered by the Catalan population, and which seriously affect people's quality of life. For instance, the ESCA 2020 (7) finds statistically significant differences in the population aged 4-14 years (*figure 1*), in which the prevalence of the population likely to suffer from a mental health problem has increased statistically significantly, particularly among families from the least advantaged class. Among adults (*figure 2*), 26.6% of women and 19.2% of men suffer from depression, anxiety, or another mental disorder, being higher in men with a lower level of education. What is more, the most important European epidemiological study on the prevalence of mental disorders, the *ESEMeD-SAMCAT 20028* already showed that 23.7% of the population over 17 years of age in Catalonia would suffer from some mental disorder during their lifetime, with women being more likely than men (27% and 20% respectively) (11).

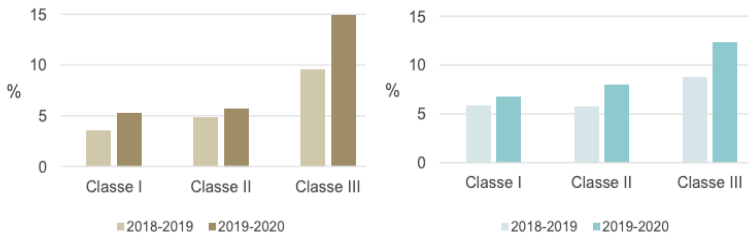

Figure 1: Graphic showing the Catalan population aged 4-14 years old likely to suffer from a mental health problem, by social class and sex. Girls are represented in brown graphics and boys in blue. The social class is represented as: Classe I-advantaged class, Classe II-Medium advantaged class, and Classe III-least advantaged class. Additionally, a darker tone represents 2019-2020 statistics, whilst a pale one reflects 2018-2019. Source: *Esca 2018-2020* (4).

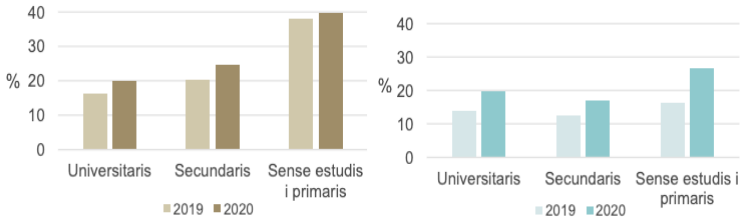

Figure 2: Graphic showing the Catalan population aged more than 15 years old likely to suffer from a mental health problem. The left brown graphics represents women and the right ones in blue men. Each category is divided into university studies (Universitaris), Secondary studies (Secundaris), and Primary studies or neither (Sense estudis i primaris). Source: *ESCA 2018-2020* (4).

According to the mental health data appearing in *Memòria of 2021* (12), carried out by the *Servei Català de la Salut*, centred in the Sanitary Region of Girona, there were 2.162 hospital attendances, 160.871 ambulatory, and 22. 862 concerning drug addictions, having a total of 1.391 contacts with the acute unit of psychiatric hospitals, 397 contacts with the subacute unit, and 374 with general hospitals regarding mental health (4). Also, the five main diagnoses were schizophrenia and other psychotic disorders first, followed by mood disorders, drug-related

disorders, delirium, dementia, and other cognitive and amnesic disorders, and finally alcohol-related disorders (5), as shown in *Figure 3*.

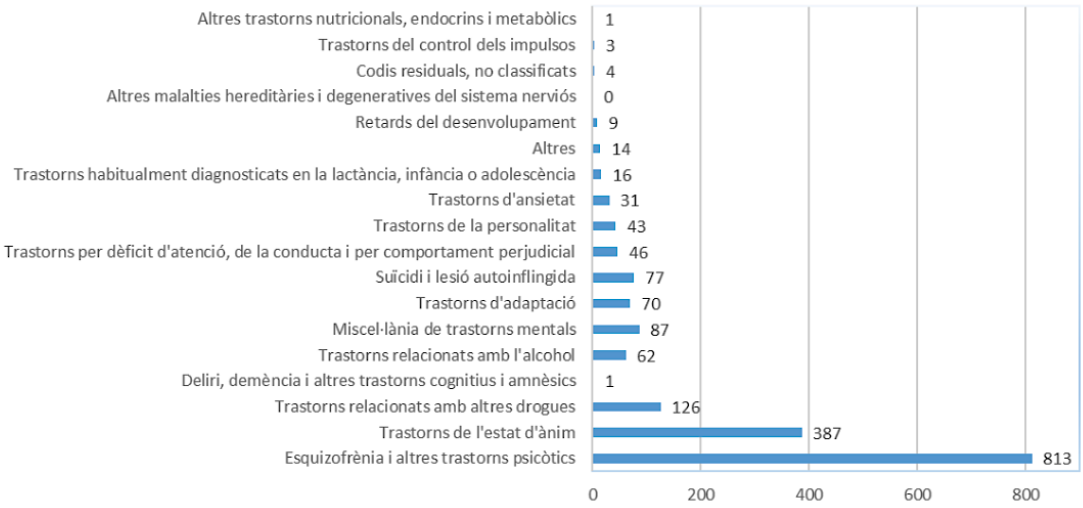

Figure 3: Five main diagnoses during 2021. Source: *Anuari d'Activitat 2021*. Regió Sanitària de Girona **(13)**

To continue, 37% of patients who visited the Adult Mental Health Centre (CSMA) in Catalonia have a severe mental disorder (SMD), and there was a 27% increase in the number of cases with SMD treated in the last five years (12), as represented in *Figure 4.*

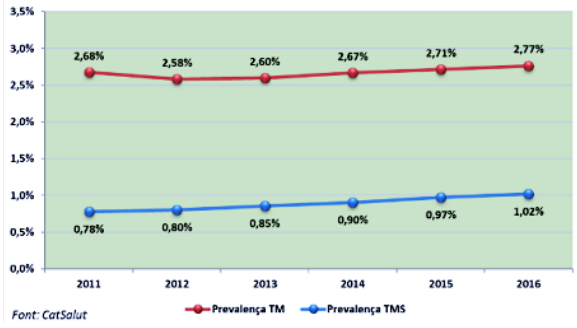

Figure 4: Prevalence of mental health disorder (red) and severe mental health disorder (blue). Source: CatSalut (6)

Taking the hospitalisation data of 2017 in Catalonia, 72.5% of them were acute, and in women up to 76.1%. This fact makes the planning and management of programmed activity considerably more difficult (14). The average acute hospital stays, excluding admissions for stays of 1 day or less, was 17.7 days (17.9 in women and 17.5 in men). The sub-acute units have an average length of stay of approximately two months (55.6 days in women and 58.4 in men).

Regarding readmissions, 10.7% of acute inpatients generated another urgent admission during the 30 days following discharge (10.5% in women and 10.0% in men). On the other hand, 18.1% of those discharged from a sub-acute unit were re-admitted to an acute or sub-acute unit within 90 days of discharge (17.4% of women and 18.7% of men).

Health priorities and system priorities

According to the *Catalan Health Plan* (5), although the general health indicators of the Catalan population are among the best in the countries around us, it is necessary to continue to address some health challenges and priorities. Particularly noteworthy is the impact that the COVID-19 pandemic has had on the general mental and emotional health of the population, especially on people previously affected and young people.

Finally, the new *Health Plan for 2021-2025* establishes priorities aimed at transforming the system, recognizing the need to reduce the fragmentation of the care process to effectively ensure integrated, person-centred care. It also requires improving the systems of communication and clinical and therapeutic coordination between professionals at different levels of care. What is more, it requires the systematic incorporation of new intervention methodologies, strengthening communication and citizen participation. This last point may be essential when dealing with mental health stigma.

In line with the strategy of the *Health Plan (5*), a reform is sought where it is increasingly possible for groups to enjoy more and better physical and emotional well-being to their full potential, proposing an integrated approach to health with the person, considering social determinants, respecting their autonomy and care of the environment. In addition, one of the plan's strategies (9) should be highlighted, the so-called "integration of health care", which aims to guarantee integrated health care for individuals, families, and communities, promoting their quality of life and personal autonomy, placing the person at the centre of the care process, and adopting a health-generating approach. Finally, it also focuses on the transformations to be made in current care networks to support integrated care, intending to transform and adapt the functionality of the health system to meet future challenges.

Healthcare impact

In front of all this data, the WHO maintains that mental health stigma is a global problem, and its elimination must therefore be a priority for all societies. Efforts must be made to combat

prejudice, stereotypes, and discrimination against people diagnosed with mental health problems (8). DH is a good element to do so, but still needs future studies examining the relationship between overall outcomes and evaluating the impact of key aspects of the DH models (15,16).

To assess the healthcare impact this study may have, some data will be disclosed: according to the European *REFINEMENT* study (17,18) (*Figure 5*), Girona's acute outpatient care, concretely DH (mobile related), lags far behind other countries. To ameliorate the situation, DH should therefore be promoted.

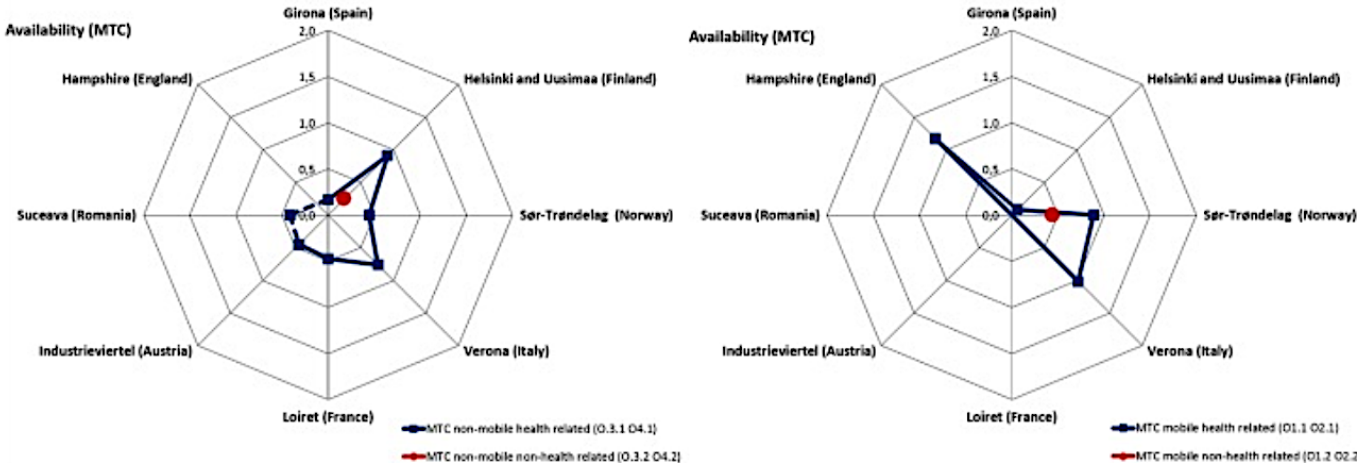

Figure 5: Acute Outpatient care statistics. The right-side figure, in blue coloured, is expressed the mobile health-related rats from the DHT availability. Source: *REFINEMENT* study (17,18).

Other relevant information is that Girona's DH coverage area involves only Gironès Nord and Pla de l'Estany territories, (13,19), with a reference population of 750.000 inhabitants benefiting from the treatment. However, there is an inequality, and that is that the rest of the province's territories cannot be offered this alternative, due to the lack of human resources of the service. This generates a great disparity among the population, as it is also the farthest from the Martí i Julià medical centre (MiJMC), where TH is given in the acute and sub-acute unit, which denotes a clear need to improve the accessibility and expansion of DH, hence saving hospital stays, guaranteeing better results, and significantly reducing costs (14,19).

We aim to create evidence of the current system, highlight DH strengths, promote its further implementation, and find areas for improvement, thus creating a new and effective strategy to ensure the best possible care for all patients. All in all, creating universal and accessible mental healthcare for everyone.

DEFINITIONS

DOMICILIARY HOSPITALISATION

Hospitalisation is a common method used to intensify care for patients experiencing a psychiatric crisis, and for many years, TH has been the indicated care modality. Nevertheless, new alternatives, such as the intensive home treatment called Domiciliary hospitalisation, has bloomed as a viable intervention. The goal is to treat patients experiencing an acute psychiatric crisis in his/her home, understood as their social and family environment. This is recommended as a first-line service when passing all DH criteria items (see *Annex 1*).

DH TEAM

The DH team is a multidisciplinary team consisting of a psychiatrist and two nurses (See *Figures 6 and 7* with Girona's DHT), with all members having received the proper training and additional education regarding family and relational treatment. Professionals can provide (20):

- Assessment: psychiatric diagnostic and risk taxation.
- Psychoeducation: both to the patient and his/her relatives
- Support: in structuring patient's daily life and solving social and financial problems.
- Supportive and cognitive behavioural intervention
- Pharmacotherapy
- Support and empowerment to the patient's informal care system, so they will be able to sustain care
- Support a more gradual transition between inpatient care and low-intensity outpatient care if the patient is admitted to a psychiatric ward.
- Referral, if necessary, to specific treatment settings

Figures 6 and 7: On the left, the DHT attends to the residence of one of the patients. On the right, is the team at the MiJMC.From left to right: Ramon Rovira, Nayef Fadel and Irina Gil. Source: Institut d'assistència Sanitària (10).

MODALITIES OF PROFILES ATTENDED IN THE HOME SETTING THROUGH DH

The DHT must tackle several modalities of profiles, set out hereunder:

1. Diagnostic orientation

Due to the limitations of care in the CSMA, it is often not possible to carry out in-depth exploration and an approach to all the difficulties that the person affected by a mental disorder may present, not being completely clear about the orientation of the case or the real difficulties.

Therefore, a home intervention is carried out, based on guiding the case from the home environment through a psychopathological, family, and social exploration, assessing to the maximum extent the outpatient resources from which (s)he can benefit.

This intervention consists of a series of visits (3-5 in a period of 2-3 weeks) to carry out the orientation. During these visits, an evaluation is made as to whether it is advisable to start a structured home intervention with certain objectives or to end the intervention due to the iatrogenic risk it would entail, thus indicating the abandonment of the home intervention.

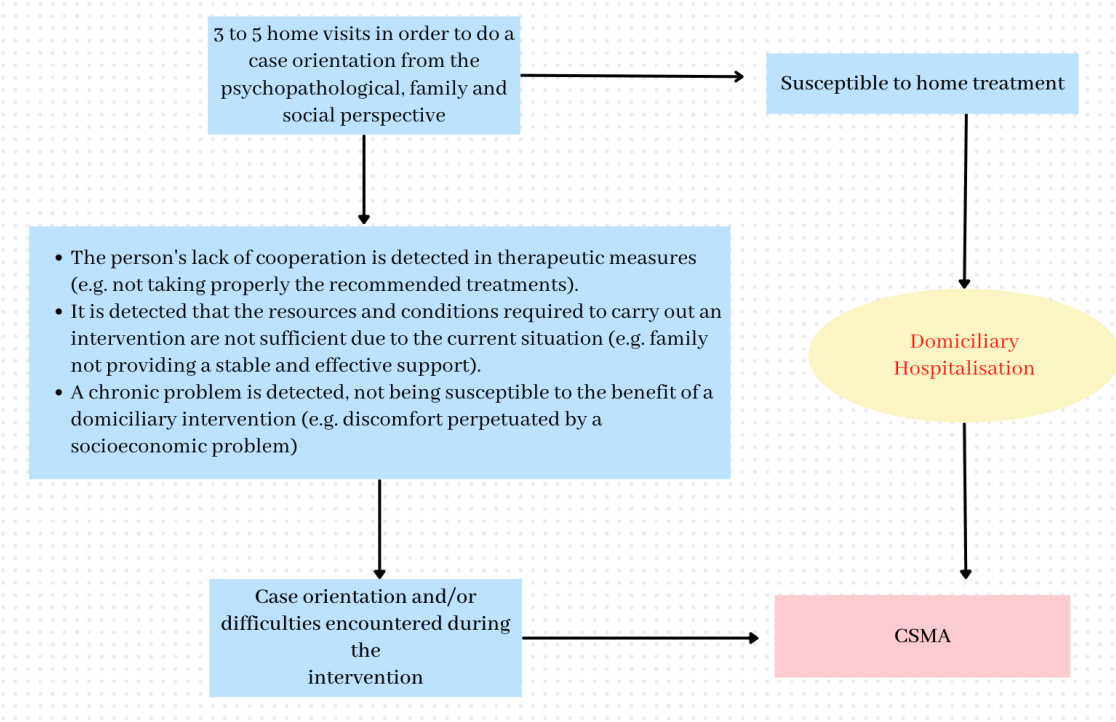

Figure 8: Diagram of diagnostic orientation modality of DH

Criteria for referral for a diagnostically oriented intervention:

- There are difficulties in the complete exploration of the person attended due to the subjective contribution of the patient or difficulties of the ambulatory service.

- Assessment of the real difficulties of the person in their domestic environment and the resources available to them.
- The orientation of the case and the measures provided for improvement are not effective and it is suspected that there are factors that cannot be detected by the CSMA that may provide some explanation for the lack of effectiveness of the therapeutic measures.

2. DH with reduced functionality

Modality of action in the profile of people affected by a severe mental disorder in which functional difficulties that perpetuate the psychological discomfort stand out. These patients may also require supervision of pharmacological intake due to difficulties in the management of treatment, support in maintaining the home, links to outpatient facilities such as day centres, etc.

The initial intervention consists of a psychopathological assessment and an evaluation of functional records in the following areas: self-care, instrumental skills, autonomy, work rehabilitation, and leisure time. This is carried out over a period of 2-4 weeks, with variable weekly visits. Once completed, a profile is determined to determine if it is susceptible to a longer-term support intervention (Intensive Home Care or IFUP).

The activation profile of the Intensive Home Care team would correspond to a person affected by a severe mental health disorder with, additionally, diminished functionality, going beyond the needs of accompaniment or the tendency to isolation, thus requiring a more intensive intervention in terms of organisation, self-care, and instrumental skills. For this reason, a nursing or auxiliary referent is assigned to establish, together with the patient, a long-term work plan (longer than that of the home hospitalisation record), subject to the fulfilment of the objectives determined in the work plan and subject to the evolution of the process. This work plan is drawn up by consensus with the CSMA, the DH team, the Intensive Home Care referent, and the patient. This intervention will be supervised by the DHT, and will receive clinical support on a deferred basis, and in the event of an intercurrent crisis during the rehabilitation process.

In cases where the support is based on the need for more inclusive processes, an IFUP will be sought as a referent for accompaniment and management in the community setting to generate an adequate bonding process. At this point, the DH team will proceed by making liaison visits with the IFUP referent. The objectives to be addressed with this group are established with the CSMA,

the DHT and the patient. Once the ISP intervention plan has been drawn up, the intervention by the DH team will cease, and the clinical follow-up will pass into the hands of the referring CSMA.

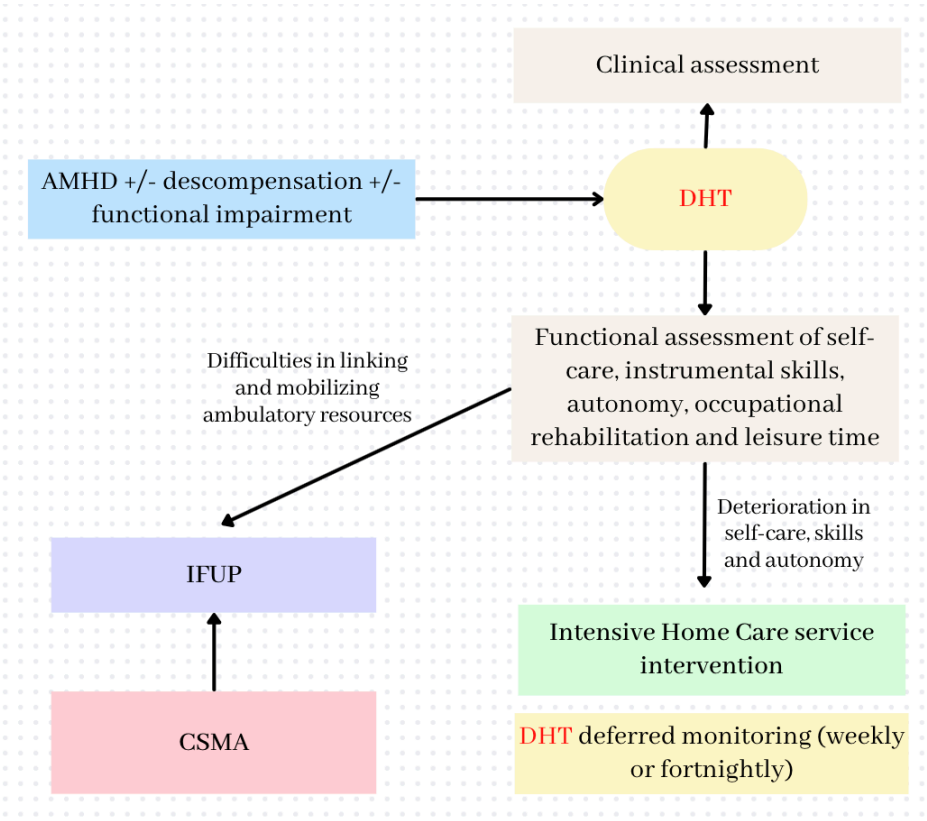

Figure 9: Diagram of DH with reduced functionality modality. DHT-Domiciliary home treatment, IFUP-Individual follow-up program, CSMA- Mental Health centre, AMHD-Acute mental health disorder

3. Acute decompensation

Patients with defined SMD are in a phase of psychopathological decompensation, requiring a high frequency of visits (daily or every 2 days), including supervision of treatment intake, until the crisis is resolved. This intervention is more like what would be done in acute hospital units.

For this approach, the patient must be receptive to therapeutic and pharmacological measures and have solid and stable family support.

In certain cases, an assistant from the Intensive Home Care service may be indicated to ensure that the treatment is taken.

Criteria

-Known SMD with a clear psychopathological decompensation.

-Stable family support

-Willingness to accept all therapeutic measures indicated by the Home Hospitalisation Team and acceptance by the family.

4. Establishment or change of treatment

Patients affected by mental disorders, without symptomatic resolution or established after changes in treatment at the outpatient level, where a change of regimen is considered that requires more continuous supervision than that which can be offered by the CSMA. An example would be a person with solid support and a complex pharmacological regimen (intramuscular administration, introduction of clozapine or simplification of the regimen).

5. Global home approach

People affected by SMD, where at the time of the approach they do not present sufficiently severe clinical symptoms due to involuntary admission, but there is no clear psychopathological improvement and it is suspected that it may be related to some factor in the home environment, which may require a brief but intensive intervention. The format for action would be a twice-weekly approach with an intense focus on each visit, and a global approach (ideally with the family) where the aspects of the person being attended to and their relatives living with (s)he can be assessed.

Finally, the following description was adapted from a document provided by the DHT, courtesy of *R Rovira*.

SEVERE MENTAL DISORDER (SMD)

First, it should be pointed out that up to 40% of psychotic disorders are defined as severe, signifying that they have a great personal impact on the individual sufferer, their family, and friends (12). As a result, people with severe and very common chronic mental illness present very complex problems, not only psychopathological symptoms, but often impacts on their ability to maintain the basic resources in life, which seems to further impact negatively on their illness, and their ability to maintain supportive social relationships. In other words, they have altered the psychosocial functioning and integration into the community, and social barriers, such as stigma, social rejection, insufficiency of attention resources and social support can be originated, consequently increasing the risk of social isolation and exclusion, unemployment, poverty, and homelessness.

ACUTE PSYCHIATRIC CRISIS

Acuteness is determined when the patient is denoting conditions or symptoms of sudden onset and often great intensity since a patient's coping mechanisms are affected to the point that they break down, interfering in the everyday life, and causing affective, cognitive, or behavioural impairment (20).

In front of this situation, the severity of current acute clinical and social problems, and associated risk indicate the need for medical support, becoming a crucial intervention as it relieves suffering whilst helping prevent further deterioration.

PSYCHOSIS

Psychotic disorders are severe mental disorders characterised by a global alteration of the personality that causes sufferers to have abnormal, distorted ideas and perceptions of reality. It is a syndrome embedded in several disorders, including schizophrenia and bipolar disorder with psychotic features. Pathophysiologically, dopamine and glutamate are implicated in, and therefore psychosocial treatments supplement pharmacologic therapy. Other key-role elements involved in the aetiology are environmental factors.

Someone who develops psychosis will have their own unique set of symptoms and experiences, according to their particular circumstances, but in general, three main symptoms are associated with a psychotic episode: hallucinations, delusions and confused and disturbed thoughts. As a result, they may exhibit personality changes and disorganised thinking, unusual or bizarre behaviour, as well as difficulty interacting socially and an inability to carry out activities of daily living. Moreover, during a psychotic disorder, there appears to be an increased risk of suicidal behaviour, especially during the acute episode. It is imperative in this case to take safety measures to prevent the affected person from self-harm (21, 22).

AFFECTIVE DISORDERS

Mood disorders are described by marked disruptions in emotions (severe lows called depression or highs called hypomania or mania). These include bipolar disorder, cyclothymia, hypomania, major depressive disorder, disruptive mood dysregulation disorder, persistent depressive disorder, and premenstrual dysphoric disorder. These are common psychiatric disorders leading to an increase in morbidity and mortality.

The aetiology is in the brain areas responsible for controlling our feelings and emotions, the amygdala and orbitofrontal cortex. Patients with mood disorders have been shown to have an enlarged amygdala on brain imaging, which substantiates the certainty that abnormalities in these areas lead to mood disorders. Ventricular expansion results from repeated episodes of mood disorders. Other contributing factors are the neurotransmitters serotonin and noradrenaline, which are decreased in episodes of depression. Dopamine has also been implicated in mood disorders with research showing that it may be decreased in depression and increased in mania. What is more, certain genes can cause it, as well as hormonal factors such as an increased HPA and TSH activity, and psychosocial factors such as stressful life changes and traumatic events.

Timely diagnosis and treatment of mood disorders can decrease the associated morbidity and mortality, with the use of medication, psychotherapy, brain stimulation therapy and a healthy lifestyle (23).

HYPOTHESIS

With this study, we are seeking to demonstrate our main hypothesis; that domiciliary hospitalisation (DH) is an effective alternative to traditional hospitalisation when treating patients with an acute mental health crisis.

In addition, our secondary hypotheses are that DH is a safe modality, as well as accepted by the patients and relatives, showing higher rates of satisfaction. Furthermore, we aim to prove that a reduction of burden and Mental Health Stigma can be achieved through it.

AIMS AND OBJECTIVES

PRIMARY OBJECTIVE

- The aim of this study is to demonstrate that participants in the DH condition will report the same amount or fewer clinical and functional symptoms than the ones in TH, proving the DH effectiveness.

SECONDARY OBJECTIVES

- To establish that DH can provide a proficient outcome, and therefore determine that DH interventions can reduce the inpatient stay in the TH.
- To evaluate a reduction in the readmission rate after the DH intervention.
- To prove that DH is a safe alternative, by expecting that patients in the DH condition will report the same amount or fewer symptoms of social malfunctioning and aggression than TH patients.
- To estimate higher results compared to TH when contrasting the DH's acceptance and satisfaction of the participants and their relatives.
- To verify that a successful linkage between the patient and the mental health system has been created, translated into the correct attendance at medical appointments post-DH intervention.
- To demonstrate a reduction of the burden (being the disruption to social life, daily routine, and susceptibility to physical illness), both for the out-patients and their relatives.
- To assess a reduction in the stigmatisation inherent to hospitalisation.

METHODOLOGY

STUDY DESIGN

The following research is designed by its characteristics as a population-based prospective cohort study, in pursuance of assessing DH, carried out by the *Xarxa de Salut Mental i Addiccions* (XSMA).

STUDY POPULATION

The population of this study is formed of people with a diagnosis of severe mental illness (see more in *definitions*), the ones referred from the Acute Unit, Subacute Unit, Emergency ward, Adult Mental Healthcare Centre, and the Individualised Follow-up Program. Moreover, we have selected the following disorders for study, due to their prevalence (*figure 10),* classifying them following the next clusters: psychosis and affective disorders (see *Definitions*), using the ICD-10 coding method as a reference (See *Table 1* and *Annex 2*: *Diagnostic groups*):

Table 1: Group classification by categories:

Group 1: Psychosis		**Group 2**: Affective disorders	
Coding reference	Disorder	Coding reference	Disorder
F20	Schizophrenia	F30	Maniac episode
F21	Schizotypal disorder	F31	Bipolar affective disorder
F22	Persistent delusional disorder	F32	Depressive episode
F23	Acute and transient psychotic disorder	F33	Recurrent depressive disorder
F25	Schizoaffective disorders	F34	Persistent affective disorder
F28	Other non-organic psychotic disorder	F38	Other affective disorders
F27	Unspecified non-organic psychosis	F39	Unspecified affective disorders

To be more accurate with the study population, it should be stated that all participants are recruited from *Xarxa de Salut Mental* of Girona's area of coverage. More precisely, our study population involves all of Girona's region, but only those from Gironès and Pla de l'Estany territories will be the selected ones forming the study's sample (*figure 10*) since the DHT can only reach this territory. Therefore, candidates from this area will receive the two modalities of treatment: some of them DH intervention, while the others will proceed with the traditional hospitalisation approach.

The other municipalities from Girona province (Ripollès, Alt Empordà, Garrotxa, Selva Interior, Baix empordà and Selva Marítima), will serve as a control group, only receiving the traditional modality treatment.

Figure 10: Study's selected areas of Girona's province in a dark tone, Gironès and Pla de l'Estany; in a light tone represented the other townships, working as a control group

To continue, in the following tables we will expose the inclusion and exclusion criteria of the study:

Table 2: Inclusion criteria for the study

INCLUSION CRITERIA
1. A psychiatrist must state that admission to a clinical crisis care unit (acute or subacute) is indicated. This decision is based on clinical outcomes, judgments of other professionals, and information from informal caregivers. Additionally, the patient shall also meet the admission criteria for DH treatment (described in *Annex 1*). 2. A patient diagnosed with an onset, acute phase, or exacerbation of a mental health disorder corresponding to a psychosis or affective disorder (see *Table 1*, and diagnostic groups following the ICD-10 (*Annex 2*)). 3. The environmental factors allow the patient to be contained in the home environment. 4. The patient is a resident of Girona's province or the surroundings. 5. Age between 18 and 65 years old. 6. Ability to read and understand Spanish or Catalan language. 7. Written informed consent has been provided by a mental-competent patient, voluntarily.

Table 3: Exclusion criteria for the study

EXCLUSION CRITERIA
1. Absence of patient cooperation with the treatment. 2. Severe aggressivity. 3. Imminent suicidal risk 4. Difficulties in the household: security concerns, issues with home support or homeless patient. 5. The primary diagnosis of the patient is substance use disorder, for which referral to a specialised treatment unit is indicated 6. A hospitalised patient in a psychiatric ward (our target is only the new admissions). 7. Severe comorbidities concerning organic disorders and the need for complex medical interventions. 8. The patient will be excluded automatically under the following circumstances: if there is a demise during the follow-up period or if the patient decides to sign the withdrawal form. 9. Presence of structured autolytic ideation.

STUDY PERIOD

Our study will last from 1st September 2024 to 31st March 2028. The coordination and collection of data to redact the protocol will last 6 months approximately (phase 1). Proceeding, the cohort's follow-up will begin, when all patients will have been recruited, have signed the informed consent form and we will have collected all the baseline information. Then, the groups of cohorts will be formed and followed for 18 months, and after the discharge, a new assessment will be made after 6 and 12 months (Phase 2). After that, data will be processed and interpreted (phase 3), and finally, results will be published (phase 4). Therefore, the study will last 42 months.

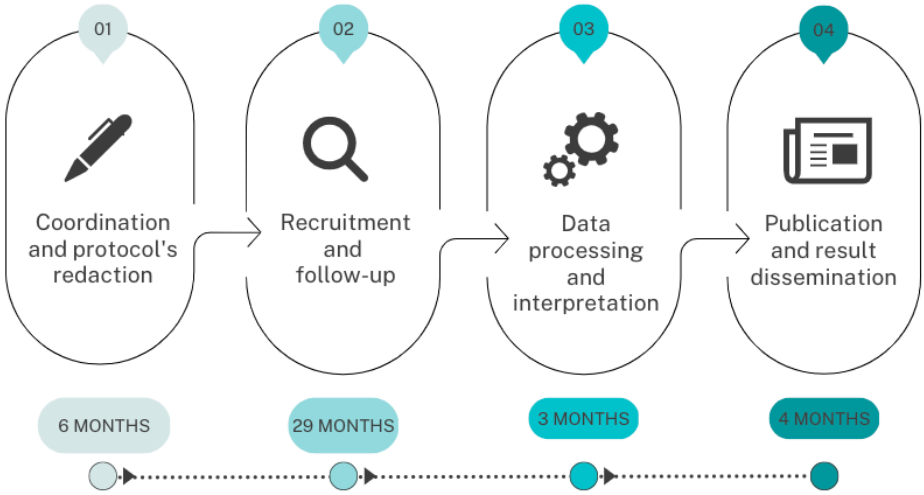

Figure 11: Process graph of the study

RECRUITMENT PERIOD

To enrol participants in the study, a conveniently consecutive non-probabilistic method will be used for the selection. To do so, patients will initially be transferred from the referral devices (Acute Unit, Subacute Unit, Emergency ward, Adult Mental Healthcare Centre (AMHC), and the Individualised Follow-up Program (IFUP)) to the DH team, who will assess whether they are appropriate candidates for DH, if they meet the admission criteria and none of the exclusion criteria for DH (see *Annex 1).* To disclose some data, the average number of admissions per day at DH is 3, considering that 65% of admissions are voluntary, and 80% fulfilling DH inclusion criteria. Therefore, our recruitment and follow-up period have a long duration.

For those patients who meet the criteria, the study inclusion and exclusion criteria will be assessed *(tables 2 and 3),* thus obtaining the study sample (see *Figure 12*).

Patients who do not meet the in- and exclusion criteria will not be included in the study, and will receive any treatment deemed necessary.

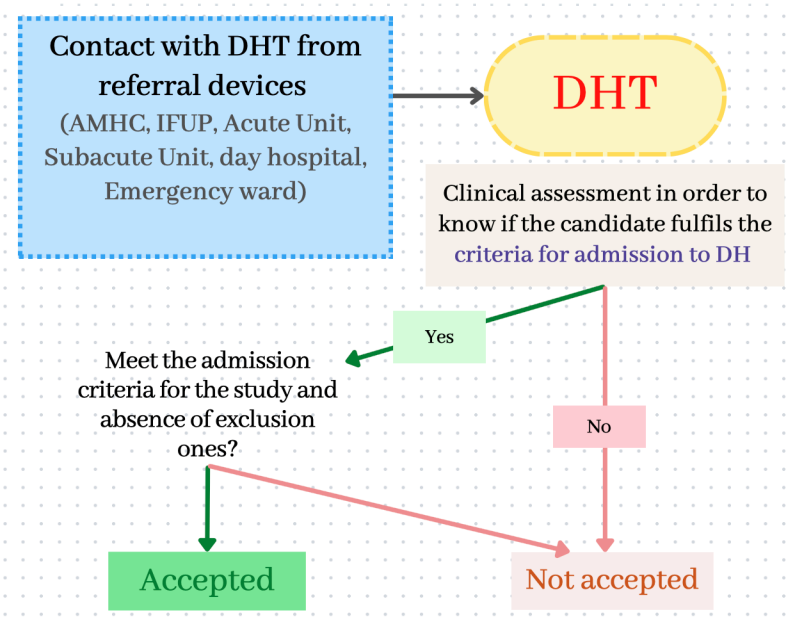

Figure 12: Recruitment process

CONSENT AND MENTAL COMPETENCE

To proceed with the informed consent procedure, once the patients have been admitted, researchers will contact the DHT and professional care providers, to find wheatear the patient's mental health competence is acceptable to give informed consent for the study. In the affirmative case, after 24h hours, a clinician will assess again the patient's competence, to be able to participate in the study, as described in the Oviedo Convention.

In case of any doubt regarding the patient's mental ability to decide during this first evaluation, there will be a new evaluation within 1 week. If the patient is still not declared mentally competent to give informed consent, (s)he will not be included in the study.

Only those patients whose capacity to decide is corroborated affirmatively, meeting the inclusion criteria and none of the excluded ones will be contacted by the research team. To do so, information concerning the study and their data usage from Xarxa de Salut mental database will be delivered to the patient and his/her relatives, through an informative interview with a health professional and a folder containing all the information (see *Annex 3*). Furthermore, another interview will be held within a 1-day difference, with a view to answering all possible doubts the patient may have developed, informing about the treatment, and finally, the collection of the written informed consent will take place (*Annex 4*).

It is very important to point out that only after having provided the written informed consent, the baseline interview and the data collection from the Hospital's database will be done.

In those cases when the patient hesitates about providing the document, (s)he will have 5 more days to decide whether (s)he will enrol in the study. If a patient decides not to provide informed consent, (s)he will be not included in the study and will be provided with any treatment deemed necessary.

A consent withdrawal form (*Appendix 5*) is provided upon acceptance of informed consent and is always available by contacting the healthcare professionals. Patients' denial of or withdrawal from participation in the present trial will not be detrimental to future treatment.

SAMPLE SIZE

To estimate the sample size, using a two-sided test, with an alpha level equal to 5%, a statistical power equal to 80%, assuming a moderate/high efficacy of DH, and a drop-out rate of 10%, we will need 96 subjects. This sample will be divided into three: the first group, corresponding to DH with 20 subjects, due to the lack of human resources of the DH teams, and the other two groups, corresponding to TT and control, of 38 subjects each.

Computations were carried out with Prof. Marc Saez's software based on the package 'pwr' of the free statistical environment R (version 4.2.2).

STUDY VARIABLES

INDEPENDENT VARIABLES

In terms of grouping the study variables, we have created the following two clusters. The first is according to the treatment modality received, and the second is based on the undergoing condition (see *Table 1).*

1- TREATMENT

Domiciliary Hospitalisation (DH) treatment

DH is a treatment modality that addresses the patient's care in a home setting. The aim is to not disrupt the patient's normal life, causing minimal interference. It is thanks to this that the collaboration and utilisation of his/her social system can be used and implemented as part of the intervention. Consequently, hospitalisation is evaded, and therefore mental stigma is reduced.

Girona's DHT is located in the MiJMC, within the sub-acute unit. It is composed of a psychiatrist and two nurses, and a part-time administrative assistant (a social worker from the CSMA), but with the support of a psychologist, other psychiatrists and all the administration staff behind, and it provides hospital home service to those members who require intensive care (16). The average duration of the service is about 3-4 weeks (at medical discretion), and its availability is based on weekdays, from 8:00 am to 19:00 pm, with full telephone availability 24 hours a day, all week.

The procedure for accepting the case is as follows (*figure 13*): the referral devices (AMC, IFUP, Acute Unit, Subacute Unit, day hospital, emergency ward), contact the DHT, making a description of the situation. With this information, the DHT assesses the candidate with its inclusion and exclusion criteria (*Annex 1*). In the affirmative case, the research team, depending on the inclusion and exclusion criteria of the study (Figures *2 and 3*), will decide as to whether to admit the patient, and if so, the admission will proceed.

Once inside the admission group, in the first contact professionals are addressed to the patient, as well as the most involved members of the patient's social sphere. This first approach aims to determine the achievements expected, how to obtain them, the discussions of the problems and goals to be addressed, and finally, who is responsible for each part of the scheme.

During the following visits, the DHT will assess the patient at home. The interventions made are the medical regime, medical interventions to prevent relapses and increase adherence, relative support, and assistance for daily tasks if required.

It is crucial that the patient takes an active role in the process, as this has shown multiple benefits, such as increased responsibility and awareness of the disease, increased adherence during the process, and greater preparedness for future crises caused by environmental triggers, by developing new coping skills. In addition, the integration of the family must be ensured to achieve the best results (24).

The frequency of the visits will be determined by the necessity, acuteness, and clinical expertise of the DHT, and the intervention will endure until the crisis has been solved, finishing with the discharge. Furthermore, if the situation is prompted, both patients and relatives can contact the professional team whenever needed, via WhatsApp or even a telephone call. The subsequent procedure will be decided according to the professional's criteria, choosing the most suitable approach (14,20). If the situation is outside the scope, acute or sub-acute hospital admission may be required. In this case, the event will be accounted for, and once the inpatient admission is

controlled, the patient will be sent home and will be followed up again by the DHT, who will monitor the situation until its complete recovery.

Then, the patient will undergo a follow-up, which will be carried out until 18 months have elapsed since the first day of the DH intervention. During this period, the patient will be referred to the CSM and will have a scheduled visit (according to the protocols) no more than 15 days after discharge. Later, if all goes well and no other needs are required, this follow-up period will be concluded, and the patient will simply have to undergo a re-inspection at 6 and 12 months after the follow-up, with a single medical interview. Nevertheless, there is the possibility of readmission during this follow-up period, which will have to be accounted for, and the intervention will have to be re-administered. Finally, if the patient is not admitted, a report will be made, and other options will be assessed, such as hospitalisation, day hospital, etc.

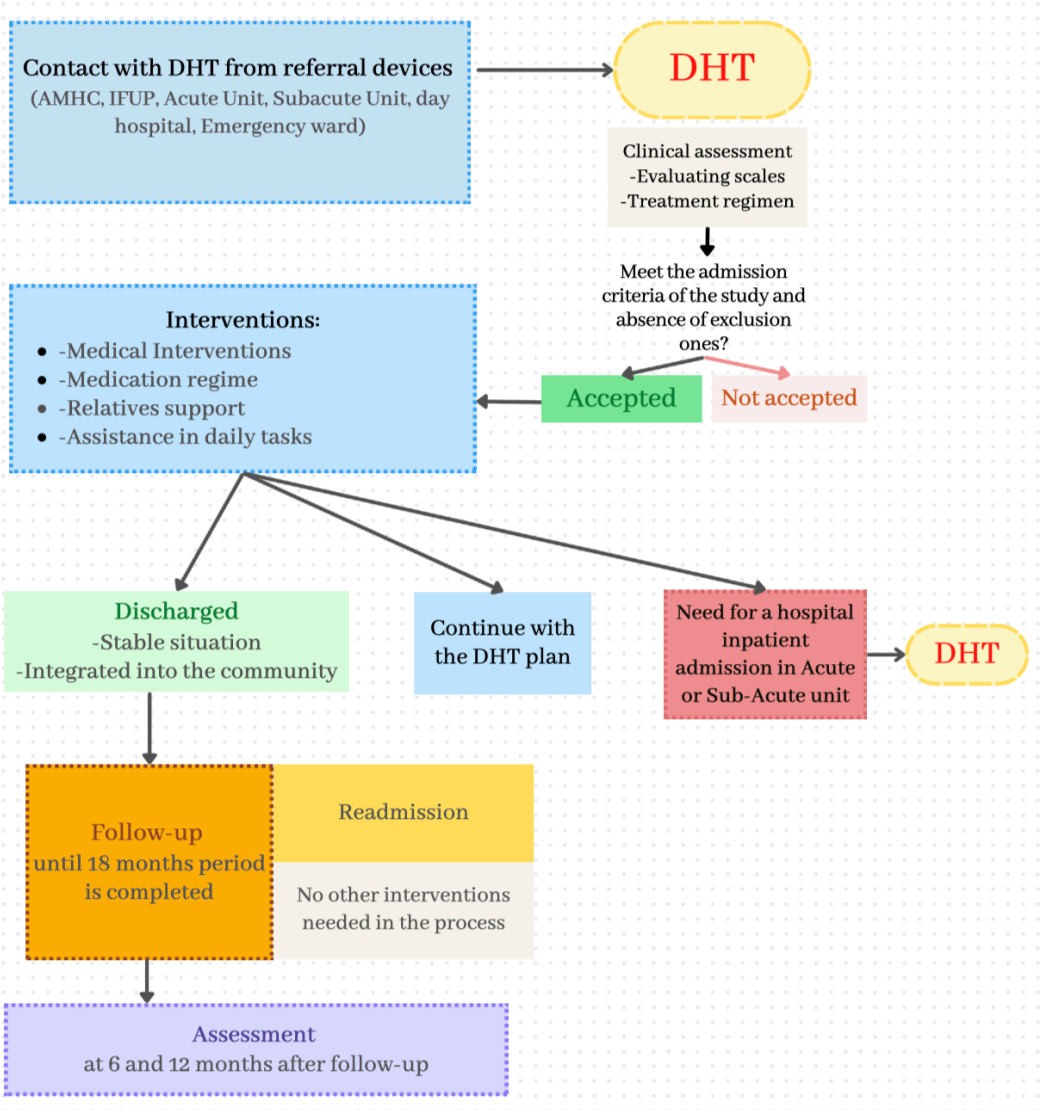

Figure 13: DHT Intervention process. DHT: Domiciliary intervention team. AMHC: Adult Mental Healthcare Centre, IFUP: Individualised Follow-up Program

Traditional Hospitalisation (TH)

This modality involves admission to the acute or subacute unit. Professionals in a psychiatric ward are psychiatrists, medical doctors, psychologists, nurses, and other mental health professionals (20). The Martí i Julià Parc Hospitalari has a capacity for 50 beds in the acute unit and 38 in the subacute unit (13,25). Mean stays in Acute Unit are 17,3 days, with 1.391 contacts established with the unit in 2021, and in Subacute Unit, with a mean stay of 42 days (13), with 397 assistance episodes during 2021 (12).

To provide crisis stabilisation, the facilities are a closed ward, firstly highly structured in the acute unit, with short and intense care; and later, when discharged, become less structured in the subacute unit. After all this process, a day treatment in an outpatient clinic may be indicated.

The profile of the patient who goes directly to the sub-acute unit is one in whom the onset of symptoms persists after several options of treatment, interfering with proper adaptability to the community.

The duration of the stages depends mainly on the severity of symptoms, the risk of self-harm, social factors such as housing, and the willingness of family and friends to provide support, amongst others (7, 6).

The content of treatment may be like the one provided by DHT professionals but in a different setting. The benefits to the patient of being inpatient may be (3): the feeling of being in a safe environment because professionals are close by, not relying on the help of family or friends, and freedom from the obligations present in the home environment.

Control group

In addition, as mentioned above, we have also established a control group, determined by its geographical location (see *figure 10*), receiving only the TH.

2- TYPE OF MENTAL DISORDER

As mentioned above, we have divided the groups according to the pathology; into psychotic or affective disorders (see *Table 1*).

DEPENDENT VARIABLES

1. Clinical and functional outcomes

The HoNOS (26,27) is a scale designed in 1993 by the UK Department of Health, a commission of the Royal College of Psychiatrist's Research Unit, to develop scales to measure health and social functioning in a physical, personal, and social dimensional way, of people with severe mental illness and in the general population (28). The instrument demonstrated good reliability and validity characteristics, and is generally acceptable to clinicians (29). The use of HoNOS is recommended by the English National Service Framework for Mental Health, and by the working group of the Department of Health on outcome indicators for severe mental illnesses (30), and it is the one used in Xarxa de Salut Mental from Girona.

It is a relatively simple scale, which consists of 12 items (see *Annex 6*) and should be scored in order from 1 to 12, without including information already scored in a previous item except item 10, which is an overall assessment. The most severe problem occurring during the period assessed should be scored, and all scales follow the 0-4 format, with 0 representing no problem and 4 representing a severe or very severe problem.

2. Hospital inpatients admissions in acute or subacute unit

It refers to the number of admissions in MiJMC Acute or Subacute unit (15). The period includes the whole duration of the intervention prior to discharge. After, the DHT will assess the case.

It is thanks to DH that these kinds of admissions are reduced, thus leaving room for the optimal development of these hospital units, since the number of available beds is increased and the workload is reduced, as well as decongesting the hospital emergency department. Likewise, the patient-professional bond takes on a different perspective, in which the therapeutic alliance is more intimate and accessible, as opposed to what could be a forced hospitalisation in a hostile environment for the patient.

3. Readmissions

It is expressed by the number of admissions, both in the DH or the TH modality, after discharge from the DH intervention, contemplated during the post-intervention follow-up period until the 18 months have been accomplished, and in the interviews at 6- and 12-months post follow-up.

4. Safety

To assess this item, we used the SDAS (Social Dysfunction and Aggression Scale), more precisely the SDAS-9 version (*Annex 7*). In this, the assessment of outward aggressiveness covers a minimum period of the preceding 3 days, and the information to be considered depends greatly on the observations made by the staff members or reports by primary care workers or family. However, interpersonal behaviour observed during the interview is also important. The items of the scale can be assessed both as the general level of outward aggression or hostility during the last 3 days and as the peak level (i.e., incidents or attacks of aggression). Within affective disorders, it is important to measure outward aggression in maniac states, where generalised levels of hostility are most often seen.

5. Acceptance, Satisfaction

To treat this topic, we have used the Client Satisfaction Questionnaire (CSQ) (31,32), (*Annex 8*). Our purpose is, with this 18-item version (CSQ-18), to see the effects of the intervention, as it has high internal consistency, and is a reliable tool for measuring patient-reported symptom changes. Furthermore, higher satisfaction is often associated with a decrease in symptoms, and those excellent results, together with their brevity, may be especially useful as a brief overall measure of the candidate's satisfaction (23).

To assess these items, we will first administer the CSQ-18 questionnaires to the patient and family before starting the study, and we will conduct an interview with a professional to evaluate the subject's condition concerning the items assessed (T1). We will also carry it out during the follow-up period, and in the 6- and 12-month post-follow-up appointments (T3 and T4).

6. Linkage to the mental Health System

To determine the Mental Health System adherence of the patient, we have quantified the attendance to the medical appointments at the services of the CSMA, reporting them at the 6- and 12-month post-follow-up interview.

7. Burden

Epidemiological and economic estimates suggest that the global burden of mental disorders is considerable, both in its impact on human health and losses to societal welfare (33,34).

The MANSA is a brief instrument for assessing the quality of life, focusing on satisfaction with life as a whole and with life domains. Its psychometric properties appear satisfactory, and it has been

developed as a condensed and slightly modified instrument for assessing the quality of life, and its properties have been tested in a sample of community care patients (35,36). It is represented in *Annex 10*.

8. Mental Health Stigma

Mental Health stigma represents the identification of mental illness as a culturally situated and socially devalued identity. It is a major obstacle to well-being among people with mental illness (37).

Multiple studies provide evidence that discrimination due to mental stigma affects almost all aspects of life (25), including employment, housing, and medical care. Furthermore, experiences of stigma are associated with an increased symptom severity, decreased treatment seeking and non-adherence to treatment (26). It is due to these reasons that it is essential to address the stigma, to achieve the optimal intervention for the patient.

To assess it, the Internalised Stigma of Mental Illness Inventory (ISMI) scale is used, represented in *Annex 9*. This scale was validated in the USA for global punctuation (27). In rating this scale, we should note that it is a self-admissible scale, which assesses the subjective experience of stigma and correlates negatively with measures of self-esteem, empowerment, and recovery orientation.

It includes several sub-scales, measuring alienation, stereotype assumption or self-stigma, perceived discrimination or experience of discrimination, psychological isolation, and stigma resistance. It is scored, ranging from 1 (strongly disagree) to 4 (strongly agree). The first four scales indicate greater perceived stigma, in the higher the score. Then, the stigma resistance scale is to be scored inversely, by subtracting 5 from the score of each item.

CO-VARIATES

To establish a correct analysis, we consider that several co-variates must be analysed, to identify those factors able to affect the main outcomes.

- **Age**: divided into four groups: from 18 to 30 years, 31 to 45 years, 46 to 55 years, and over 55 years old– qualitative ordinal polytomous variable.
- **Sex**: Categorised in man or female – qualitative dichotomous variable.
- **Socioeconomic level** proxied by **employment status**, measured at t1, classified using: Yes, No, Pre-employment, Retirement, Disability – qualitative nominal polytomous variable-; and **educational level**, classified as the higher educational level reached by the patient, mainly divided into none, primary school, secondary school, university studies and others – qualitative ordinal polytomous variable.
- **Diagnosis**: classified following ICD-10 coding (See *Annex 2),* categorised into two groups: Psychosis (schizophrenia, schizotypal disorder, persistent delusional disorder, acute and transient psychotic disorder, schizoaffective disorder, other non-organic psychotic disorder, unspecified non-organic psychosis), and affective disorders (maniac, bipolar, depression, persistent affective disorder, others and non-specified)– qualitative nominal polytomous variable.
- **Patient area of reference**: The areas from Girona are divided into the following municipalities: Ripollès, Alt Empordà, Garrotxa, Selva Interior, Baix empordà i Selva Marítima, and the ones selected for the DH intervention; Gironès and Pla de L'Estany– qualitative nominal polytomous variable.
- **Previous inpatient's stay in psychiatric units**: obtained from the clinical history, recorded before the study - quantitative discrete variable.
- **Treatment state**: indicate whether the patient is going under treatment and indicate the nº of antipsychotic (separating 1st and 2nd generation), the nº of antidepressant (separating Dual vs ISRs), the nº of euthymic treatment, and the number of anxiolytics – qualitative nominal polytomous variable.
- **Domicile**: classified in house/flat, residence, pension, SOPA, or protected flat – qualitative nominal polytomous variable.
- **Toxic use**: Categorised in TH, Oh, Cocaine, Heroin, benzodiazepines, and others, the previous and current use – qualitative nominal polytomous variable.

DATA COLLECTION, HANDLING AND STORAGE

To proceed with the data collection, first, we must complete the recruitment period, and once this has been done, the admission date marks the start of data collection, and during the succeeding 18 months this information will be gathered. Preceding, the following year after intervention some parameters will also be recorded, at months 6 and 12.

Regarding data storage, a supervisor will make sure that all data is correctly classified following the right procedure. It will be a manual data extraction, codification and storage, in accordance with "*Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales*".

To continue with the data collection, we considered that the baseline information, consisting of the admission information and some selected data, should be recorded in the candidate's medical register. *Annex 12* reflects the complete form used in the DH unit (38). Additionally, the information about the study (*Annex 3)* and informed consent (*Annex 4)* will be handled (see more details in *informed consent,* in the sub-section).

Continuing, information containing clinical scales and questionnaires, as well as the medical interviews, will be recorded by a professional, a psychiatrist. We consider that information could be delicate and confidential, therefore a professional presence can be decisive, and moreover if a decompensation happens during the process, requiring an intervention. The information should be provided on the first treatment day (T1), and some other right before the clinical discharge (T2), and during a post-follow-up period, at 6 and 12 months in advance (T3, T4). This information will be stored in the Medical Register as well.

If in any of the periods a readmission or referral to the acute or subacute units occurs, information should be recorded as well in the Register, indicating the period, motive, interventions prosecuted and inpatient admission duration. Professionals from the AMHC or DH can be the ones assessing the case.

To continue, a pilot test will be performed before starting the recruitment, to do any further modifications and elaborate the final protocol. Then, once the study starts, a quality-control revision will take place at the beginning of the follow-up period just the ensure the correct protocol fulfilment and data collection procedure. At the end of the 6- and 12-month post-discharge interviews, before the statistical analysis, a new quality control will take place, just to

reassure that data is well determined, and check for any possible incidence, inadequacies, or missing data in the records.

It is important to point out that both, researchers and health professionals involved in the study, will receive formation regarding the data collection method before the recruitment period.

Table 4: Variables of the study

Dependent variables	Type	Measuring instrument	Assessor	Timetable				
				T0	T1	T2	T3	T4
Dependent variables								
Clinical and functional outcomes	ND	HoNOS	Psy, N		x	x	x	x
Hospital inpatients admissions	ND	Medical record	Psy, N			x		
Readmissions	ND	Medical record	RS				x	x
Safety	ND	SDAS	Psy, N		x	x		
Acceptance, Satisfaction	CO	CSQ-18	Psy, N			x	x	x
Adherence to mental Health System	ND	Medical record	RS				x	x
Burden	CO	MANSA	Psy, N		x	x	x	x
Mental Health Stigma	CO	ISMI	Psy, N		x	x	x	x
Co-variables								
Age	ND	Medical record	RS	x				
Sex	CN	Medical record	RS	x				
Employment status	CN	Clinical interview	RS	x				
Educational level	CN	Clinical Interview	RS	x				
Diagnosis	CN	ICD-10	Psy, N	x	x			
Patient area of reference	CN	Medical record	RS	x				
Previous inpatients stay in the psychiatric Unit	ND	Medical record	RS	x				
Treatment	CN	Medical record	RS	x	x	x	x	x
Domicile	CN	Clinical interview	Psy, N	x				
Toxic use: Oh, TH, cocaine, heroin, bzd, others.	CN, CO	Clinical interview	Psy, N	x	x	x	x	x

T0-Baseline, T1- First treatment day, T2- Previous to discharge, T3-6 months post-discharge, T4- 1 year after discharge, ND-Numeral discrete, NC-Numeral continuous, CO-Categorical ordinal, CN categorical nominal, RS-Researcher scientist, Psy-Psychiatrist, N-Nurse.

STATISTICAL ANALYSIS

Our study aims to compare DH with TH in those patients with a severe mental illness during the time of an acute crisis, conducting the study in MiJMC. To proceed, the analysis will be performed by the statistical analyst. It will be done using the Statistical Package for Social Sciences (SPSS) software version 28.1. We will set a p-value of $p<0.05$ as statistically significant, defining a 95% confidence interval for all analyses.

Descriptive analysis

All the dependent variables, both, primary (HoNOS result), and secondary (number of admissions in the inpatient stay, number of readmissions, SDAS-9, CSQ-18, number of visits at 6- and 12-months post-discharge, MANSA, and ISMI), are quantitative discrete variables. We will summarize them using medians and the interquartile range (IQR).

We will stratify these variables in the groups defined by the independent variable (DH, TH, and control) and also psychosis and affective disorders.

Bivariate inference

The difference of medians of the dependent variables (all of them quantitative discrete) between the groups defined by DH, TH, and control; and psychosis and affective disorders, will be tested using the Mann-Whitney's U test.

Multivariate analysis

Finally, to assess the differences between DH and TH, and psychosis and affective disorders on the dependent variables, we will use Poisson regressions, controlling for the covariates, to avoid confounders and obtain interpretable results.

All analyses will be performed using Statistical information obtained from Xarxa de Salut Mental.

WORKPLAN

The study duration will last until its conclusion, 42 months, and it is organised as follows, with the activities and period realisation (M = month).

Team members

- *Main investigator* (MI): as the general coordinator, whose function is to supervise and coordinate the study, as well as provide the interviewers' formation.
- *Study coordinators* (SC): as researchers, corresponding to a multidisciplinary team, with professionals from each unit (acute and sub-acute unit, and the DH), responsible for assigned tasks and activities developed.
- *Services managers* (SM): from acute and subacute units, emergency department and every AMHC.
- Co-investigators: *Psychiatrist (P), nurses (N)* and *Statistician (S)*

PHASE 1: COORDINATION

This phase, with a 6-month duration, will include both investigators and collaborators, and will involve the following procedures:

1. *Protocol elaboration:* design of the study, establishment of methodology and definition of the variables to answer the research hypothesis. To do so, exhaustive research will be done to achieve it. Additionally. Ensure the funding and resources for it (M1-M3).
2. *Presentation:* as Final Degree Project to Universitat de Girona (M3).
3. *Committee's evaluation* of the protocol*:* the Clinical Research Ethical Committee (CEIC) from Insitut d'Assistència Sanitària de Girona for approval (see *Ethical Considerations*) (M4-M5).
4. *Professionals' recruitment:* selection of the personnel (M3-M5).
5. *Coordination and Formation*: the selected co-investigator candidates will receive an explanation of the study's procedure and working plan, and their functions will be disclosed. Additionally, those involved in the relevant areas will receive a formation course as well, on how to ask and fill in participants' data (M6).
6. *The realisation of a Pilot test:* It will consist of a medical visit with a study explanation, consent acceptance and data collection on T1, to detect management problems (M6).
7. *Modifications and elaboration* of the final protocol *(M6).*

PHASE 2: PARTICIPANTS' RECRUITMENT AND DATA COLLECTION

8. *Patient recruitment period*: to do so, some processes will take place:

-The referring services will inform about possible candidates to the DHT, and once the candidate fulfils the DH criteria, the investigator will evaluate whether they meet the inclusion criteria and do not meet any of the exclusion ones from the study, and the participant selection will take place. Since the average number of admissions per day is 3, being 60% of them voluntary, and 80% fulfilling the criteria, we estimate that this recruitment process will last 6 days approximately, so the process will finish once the desired sample size is achieved.

-To those selected candidates, the competence to give informed consent will be assessed (see *consent and mental competence*).

-Those participants able to give informed consent will be provided with the *information sheet* and a description of the study from one of the professionals. They will have time to read it and ask all pertinent questions. Then the *informed consent* form will be handed over to them.

-Those candidates that have decided to sign the consent will enrol in the study, and a clinical interview will take place, to obtain the baseline information.

-Finally, participants will be assigned to an intervention, either traditional inpatient treatment (acute/subacute unit) or DH. The control group will receive the TH only.

9. *Intervention:* This period will start simultaneously with the recruitment, and so the follow-up, with an 18-month duration for each participant since its recruitment (M7-M24), and inside of it the DH intervention, starting on M1, will last 3-6 weeks (depending on the patient's evolution). Some data will be collected during the intervention in certain timeframes:

- Data collection on T1 (first treatment days) (M7): Through a clinical interview, questionnaires and scales will be handed to the participants
- Mid-term analysis: to monitor correct data collection and protocol fulfilment.
- Data collection on T2 (before discharge) (M24): Again, participants will have a new interview, and variables will be assessed.

The Emergency Services, Acute, Sub-Acute Unit or DHT will manage any possible readmission along the process (M7-M36).

10. Post-follow-up *period*: during this time some data will be collected in a specific time of 6 (M30) and 12 months (M36) after the discharge. This approach will be through a clinical face-to-face interview, and variables will be assessed.

11. *Data compilation* of final participants: compilation and control of stored data, and the discussion of the missing information. All data will be registered in the study database and handed to the statistical expert to make the interpretation (M37).

PHASE 3: DATA PROCESSING AND INTERPRETATION

12. *Statistical analysis* (M37-38): Investigators and statisticians will intervene in this stage. 13. *Results obtention, interpretation and discussion:* within the research team, with the aim of defining the final discussion and conclusions of the study, and the final report elaboration will take place (M38).

PHASE 4: PUBLICATION AND RESULTS DISSEMINATION (M38 AND FORWARD)

14. *Article redaction and revision*: The results will be summarised in the format of scientific papers (M39-41).

15. *Disclosure*: Sending of the document to Journals for its publication, and other means of disclosure such as speeches and posters displayed in congresses. (M41 and further).

CHRONOGRAM

Table 3. Chronogram

Chronogram	Responsible	2024				2025				2026				2027								2028		
		S	O	N	D	J	F	M-D	J-M	M-A	A-D	J	F-M	A	S	O-N	D	J-M	A	M
PHASE 1: Coordination and redaction																				
1. Protocol elaboration	MI																			
2. Presentation of EDP	MI																			
3. Committee's evaluation	Committee																			
4. Professional's recruitment	MI, SM																			
5. Coordination and formation	MI, SC																			
6. Pilot Test	P, N																			
7. Elaborations of the final protocol	MI, SC, P, N																			
PHASE 2: Recruitment and follow-up																				
8. Recruitment	MI, SM, P, N																			
9. Intervention	P, N, SC																			
10. Post follow-up data collection	SC																			
11. Data compilation	S, MI																			
PHASE 3: Data processing and interpretation																				
12. Statistical analysis	S, MI																			
13. Result's interpretation	S, MI, SC																			
PHASE 4: Publication and results dissemination																				
14. Article's redaction	MI, SC																			
15. Disclosure	MI, SC																			

Chronogram describing in vertical shaft stages, activities, and responsible members. On the horizontal shaft, the year and month of activity realisation, abbreviated in their capital letter. MI-Main investigator, SM-Study coordinator, SM-Service managers, P-Psychiatrist, N-Nurse, S-Statiscian, EDP-End of degree project.

ETHICAL AND LEGAL CONSIDERATIONS

First, the study is conducted in accordance with the human rights and ethical principles, following the *64th Declaration of Helsinki* of the World Medical Association (39), last updated in October 2013, and in compliance with the principles stipulated in the *Belmont report* (40), concerning autonomy, justice, beneficence, and non-maleficence. Furthermore, our study protocol will be submitted to the "*Comitè Ètic d'Investigació Clínica"* (IdibGi's CEIC) from Hospital Josep Trueta, to appraise and, if convenient, give its approval, prior to the initiation of the investigation.

In a further step, participants who wish to participate in the study will be asked to read the *information sheet* (*Annex 3*), proceed to a debriefing interview, have their decision-making capacity evaluated by a professional and, once it is certain that all information is clearly understood and there is no room for doubt, then the *informed consent form* (*Annex 4*) will be provided (see *Consent and mental capaci*ty for more details of the process), according to "*Ley 41/2002, de 14 de Noviembre, Básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica".*

Once the consent is signed by a person capable to understand it, as described in *Oviedo Convention* from 1997, then the individual will proceed with the treatment plan.

A consent *withdrawal form (Annex 7*) is provided upon acceptance of informed consent, and will always be available by contacting the health care professionals. Patients' denial of or withdrawal from participation in the present trial will not be detrimental to future treatment.

Additionally, regarding the patients' data confidentiality, it will be collected according to "*Ley Orgánica 15/1999, de 13 de Diciembre, de protección de Datos de Carácter Personal*" and under the recent *Regulation (EU) 2016/679* of the European Parliament and of the Council of *27 April 2016.* Additionally, protecting their personal data, as *"Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales (LOGP-GDD)".*

Competing interest

The authors, accepting the research ethics after having read and approved the final protocol, declare that there was no conflict of interest regarding the study. Additionally, no monetary interest in the study or funding is involved in the development of the research.

BUDGET

In order to create the final budget for the project, we then set out the fractional and total costs (*Table 5*). In addition, other factors must be considered, such as the fact that the main investigator and researchers do not get any economic profit from this study, since their labour concurs during their research hours scheduled in their working time. It is so that the bibliography's search and protocol elaboration will be carried out without any compensation. Moreover, the formation course destined for the personnel will take place in their working place by the Main researcher, without any further cost.

Other elements to consider are the transport expenses, both for meetings held in MiJMC and other settings, and the domiciliary visits covered by the Catalan Health Plan presuppose. As the coordinating meetings between the researchers, personnel, and referral devices will take place in each centre, in their workplace, not causing any other additional cost, only the transport's.

Professionals' collaboration is performed in visits planned as normal treatment practice; therefore, no costs are added for the study.

In the following table, we will expose the costs:

Table 5: Study expenses and costs

	Expenses	Costs
Personnel costs		
Statistician	35€/h x 100h of work	3500€
First coordination meeting	10 € per travel (10 people)	100 €
Further researchers' meetings	10 € per travel (10 meetings) per researcher (main investigator and 5 more)	600 €
Total		*4200€*
Material costs		
Information sheet	0.05 € per sheet (3) per 96 participants	14,4 €
Informed consent printing	0.05 € per sheet (2) per 96 participants	9,6 €
Withdrawal form	0.05 € per sheet (4) per 96 participants	4,8 €
Questionnaires and scales printing	0.05 € per sheet (6) per 96 participants	28,8 €
Total		*57,6 €*

Publication and dissemination cost	
- Revision - Edition - Digital data preparation cost - Assistance of the team to conferences and congresses (registration, transport and accommodation included)	*3000€*
Global cost of the study is of	7257,6 €

STUDY STRENGTHS AND LIMITATIONS

LIMITATIONS

Internal validity

In the context of the study design, we have finally agreed to carry out a cohort study, acknowledging that it has less scientific evidence, since randomisation during the participant's severe crisis would not correspond to the ethical standards of the study, due to the situation and the geographical disparity, as other elements come into play, that are beyond the scope of control of the study.

Next, analysing the selection bias, we are faced with the following problems: on the one hand, the representativeness of the sample, which, for ethical reasons, we accept is limited to those persons with the capacity to give informed consent. For these reasons, professionals are responsible for carrying out detailed and precise verification to measure the capacity.

Another limitation of the study will be a possible problem of the recruitment derived from the novelty and unfamiliarity of the DH intervention, given the fact that it is of a recent application, and that DH admission is voluntary, whereas admission to acute or subacute care is not always voluntary and has a long implementation path, thus influencing the patient's perception and the effectiveness. Additionally, professionals may be biased toward one of the methods. To avoid this situation, frequent meetings are organised with the professional to discuss and analyse any issues, and the patient will receive all information.

Concerning the population-based study, we must consider that the candidates create a heterogeneous sample, which generates certain limitations concerning the detection and control

of a greater number of co-variables. However, these undescribed co-variates are expected to be distributed between the DH and TH groups, thus levelling out the results. To mitigate the co-variates confounding bias, the results' multivariate analysis is stratified according to possible influential variables (see co-*variates section*).

To continue, we must also consider withdrawal and loss bias. To prevent it, because is a long-time duration study, we will have to focus our efforts on accompanying patients along the process, considering satisfaction and acceptance as the main values. Despite the fact that DH has been shown to have low drop-out rates, we will have to abide by an overall loss of the study when less than half of the participants have the necessary data at the time of analysis.

Next, addressing information bias, we must consider the risk of not recording all data accurately, as might happen in substance use or social issues. To mitigate this, we rely on professionals who receive thorough training, and family integrity in the process.

In addition, when administering scales and questionnaires, we may also encounter such bias. To reduce it, several measures will be applied, such as keeping the same professional assessor by decreasing variation in judgment, and choosing those recording scales that have been validated and tested. Although some of them indeed provide data considered subjective, these are the ones compiled by the Department of Health of Catalonia, and they are the ones used in the clinical setting. This gives us an advantage, and that is that many of our professionals are already familiar with their use, making the process easier. Moreover, they are more intelligible to the patient and provide a comprehensive approach to the situation (scales in *Annex 6, 7, 8, 9, 10, 11*).

External validity

There is significant variation in the availability and care capacity of DH services in the different areas. This is a piece of important information for understanding the implementation process of this methodology, and seeing that there is a global problem in generalising the results of DH efficacy studies, since depending on the area in which it is developed, this implementation is affected by the resources.

Taking the *REFINEMENT* study in Europe as a reference (see *Experience of the Research Team* section), it revealed different types of delivery systems: some were more community-oriented, such as England and southern European countries (including Girona), while others, such as Sør-Trøndelag in Norway, are identified as community-oriented systems with a higher proportion of

hospital care. Finally, in Loiret (France) a predominantly hospital-based system was considered (17,18).

In summary, from all the information discussed above, we can say that it is possible to extrapolate information, only when the countries or areas compared share similarities in their availability and capacity for care (18).

STRENGTHS

One of the main strengths would be that DH has proven to be a safe intervention, providing multiple benefits, not only on the clinical outcomes but also on the functional ones, improving patients' daily life. Additionally, the family benefits from the intervention.

Regarding the methodology, our professionals have been properly trained in this modality of treatment, and they upgrade steadily as they gain more experience in the field. In addition, as mentioned before, some of the scales used are the ones used in their daily practice.

Regarding the population-based study, candidates create a heterogeneous sample, which increases the reliability of the intervention, by being able to extrapolate the data to the general population. Other strengths to mention would be that group variances are levelled.

Another interesting phenomenon is that the study has areas covered and not covered by the DH intervention (see *Figure 10),* which allows an ethical and reliable control group to be obtained. What is more, by proving its effectiveness, the promotion of DH expansion will be strengthened, benefiting users in the control group. This will promote equally accessible mental healthcare.

FEASIBILITY

We must ensure that our study is doable, and to do so, resources have been optimized in order to achieve the highest feasibility possible. As evidence, we can verify that it has an achievable budget, adjusted as much as possible, and that the necessary resources are within our reach, with a domiciliary hospitalisation team at our disposal. Furthermore, it is a unicentric study, developed only in MiJMC, an available center, with professionals involved in this project.

EXPERIENCE OF THE RESEARCH TEAM

To get a broad overview of the mental health scenario in Girona, we can trace it back to its historical roots, when the current unit was built under the foundations of the old asylum of Salt. Over time, this was sealed, and with it, an enormous step was taken in order to benefit mental health care, by breaking down, little by little, the boundaries that had been established around it. From this spirit of striving for transformation, the current MiJMC was born, which, with its drive for improvement, tries, step by step, to break through the previously established barriers, providing the best resources and outcomes for its patients, and trying to create a society free of prejudice and stigma towards mental health.

This reform began around 1970, with the creation of the mental health network, and since then it has not ceased to innovate, driven by this social concern, with community interventions taking precedence. An example of these would be the creation of the following devices: the teams of early intervention for psychosis, the PSI case management, the DH unit, and the youth centre. All of them are designed to break down the walls and beliefs established about mental health (35).

Although it is, indeed, only five years since the first home mental health care program of DH was set up in the Girona area, it is bearing great fruit. Proof of that are the results obtained in the European *REFINEMENT* study (Research on Financing systems' Effect on the quality of Mental health care), a collaborative project between different countries including Norway, Finland, Sweden, England, Italy, etc, comparing different items to assess the quality of mental health care on the continent. It shows that Girona, despite having fewer resources, has the highest proportion of community versus hospital resources in Europe (70/30). It also has one of the best accessibilities to its centres, the highest continuity of care rate in Europe (90%, versus 57% for the European average) (*Figure 15*), and the lowest percentage of readmissions in Europe (18% versus 40% for Europe (*Figure 14*)) (36, 10).

All these data corroborate the following fact: the Xarxa de Salut mental of Girona has high technical efficiency, thanks to the intense face-to-face coordination with hospital resources, the involvement of stakeholders, the clinical management units, the high integration of health and social resources, and the flows between them, the flexible management of resources, and finally the integrity of the professionals of the community resources in welfare, teaching, justice, and work structures.

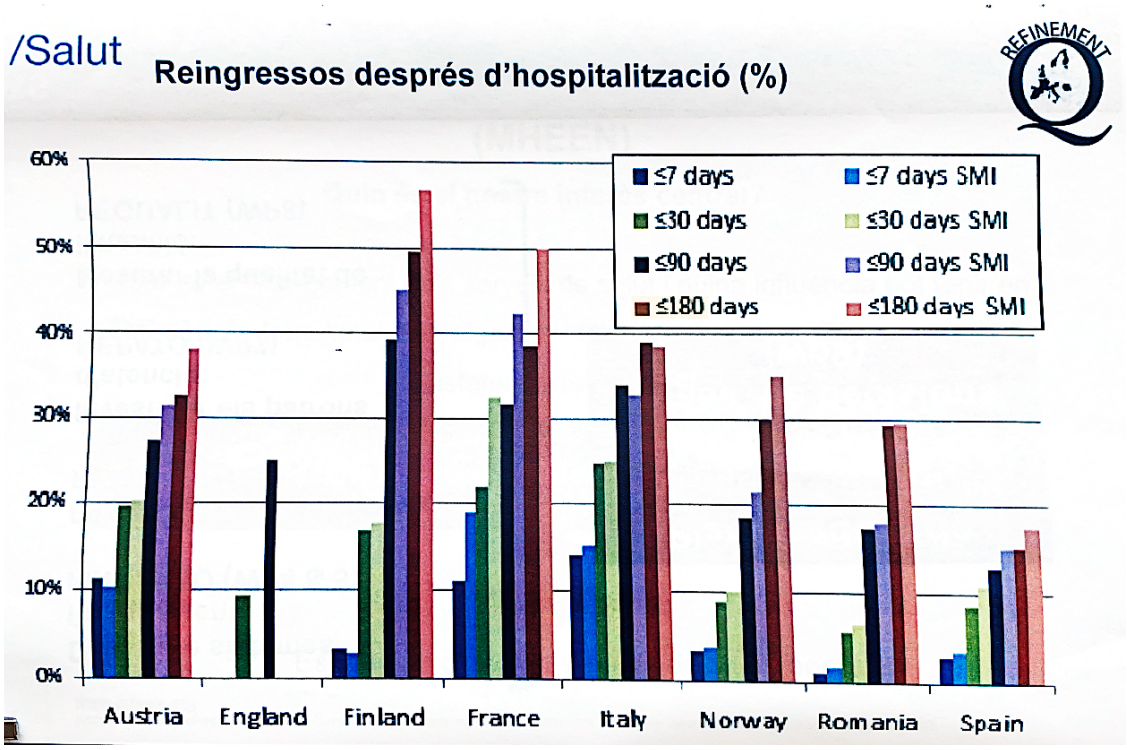

Figure 14: percentage of readmissions after hospitalisation. Source: Refinement study (10)

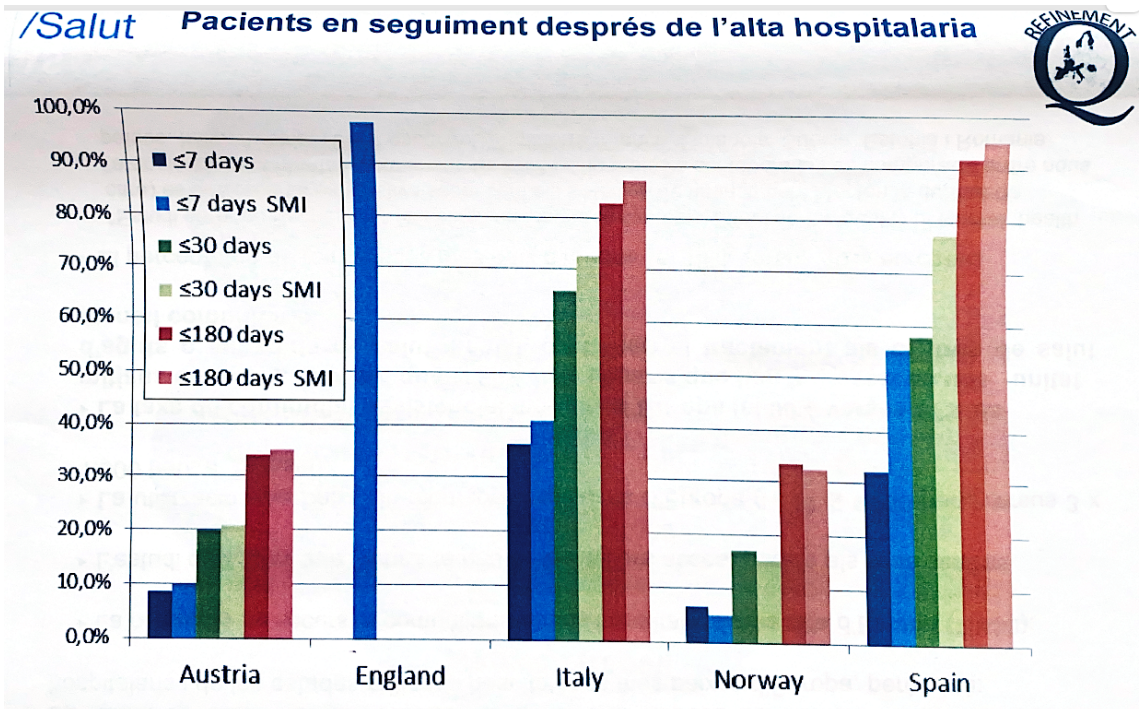

Figure 15: Patients in post-discharge follow-up. Source: Refinement study (10)

FURTHER STUDIES

Further studies can be done to assess the cost-effectiveness of the treatment. Mental disorders are commonly occurring and often seriously impairing in many countries throughout the world. As a group, they have a high prevalence, in general, compared with many other health conditions. The estimates reveal considerable variation across disorders, from $11 billion per year for a simple phobia to more than $200 billion per year for alcohol use disorders or drug use disorders. These estimates are composed of direct and indirect costs (41). Expansion of treatment could be cost-effective from both employer and societal perspectives (33).

Additionally, other studies can be done to assess DH modality, including other kinds of mental health disorders under the scrutiny of it, not only focusing on the psychosis group and the affective disorder one. What is more, as mentioned previously, further studies can be made comparing the community-oriented systems and hospital-oriented systems of the different regions more in deep.

ANNEX

ANNEX 1. INPATIENT ADMISSION CRITERIA FOR DH TREATMENT

The diagnostic profile of the candidates for DH treatment would fulfil the following criteria:

Table 6: Study inclusion and exclusion criteria for DH treatment. Source: Adapted from the document kindly provided by Ramón Rovira, from *Xarxa Salut Mental.*

INCLUSION CRITERIA	EXCLUSION CRITERIA
-Acute psychotic disorders or re-exacerbation of chronic disorders. -Affective disorders -Acute adaptive disorders	-Patients under 18 years of age -Domicile outside the area of coverage -Non-acceptance of consent by the person assisted/family. -Lack of a family environment suitable for this model of care. -High risk of suicide. -Intoxication and withdrawal syndrome. -Active toxic use. -Comorbidity with a serious organic disorder. -Requirement of the use of nursing techniques or a complex medical utilisation. -Absence of an acute psychiatric disorder. -Only and exclusively terminal care. -A solution to social problems or situations of hospital blockage.

ANNEX 2. DIAGNOSTIC GROUPS

Following the Catalonian guidelines, they are classified using the ICD-10 (*Diagnosis of mental disorders from International Classification of Diseases 10th edition*), grouped in categories from the WHO. It is based on codification, and it is the system required to notify the Administration of the activity carried out by primary care centres and primary care emergency centres that use this classification. It is also used for the coding of causes of death and occupational health problems, among others. All ICD-10 codes are included in the CatSalut's Catalogue of diagnoses and procedures, which is used to validate the activity data submitted to the Administration by health centres that code with this classification (42).

The following table will expose more specific content regarding the classification (43):

Table 7: Classification of the psychiatric disorders

Diagnosis	Earliest possible age at onset, y	ICD-10-DCR Codes	Equivalent ICD8-Codes
Any psychiatric disorder	1	F00-F99	290–315
Organic, including symptomatic, mental disorder (including dementia)	35	F00-F09	290.09, 290.10, 290.11, 290.18, 290.1[illegible] 292.x9, 293.x9, 294.x9, 309.x9
Mental and behavioral disorders due to psychoactive substance abuse	10	F10-F19	291.x9, 294.39, 303.x9, 303.20, 303.2[illegible] 303.90, 304.x9
Schizophrenia and related disorders (including schizophrenia, schizoaffective disorder)	10	F20-F29	295.x9, 296.89, 297.x9, 298.29–298.9[illegible] 299.04, 299.05, 299.09, 301.83
Mood disorders (including bipolar, single and recurrent depressive disorder)	10	F30-F39	296.x9 (excluding 296.89), 298.09, 298.19, 300.49, 301.19
Neurotic, stress-related, and somatoform disorders (including obsessive-compulsive disorder)	5	F40-F48	300.x9 (excluding 300.49) 305.x9, 305.68, 307.99
Eating disorders	1	F50	305.60, 306.50, 306.58, 306.59
Specific personality disorders (including borderline)	10	F60	301.x9 (excluding 301.19), 301.80, 301.81, 301.82, 301.84
Mental retardation (Intellectual disability)	1	F70-F79	311.xx, 312.xx, 313.xx, 314.xx, 315.x[illegible]
Pervasive developmental disorders (Autism spectrum disorder)	1	F84	299.00, 299.01, 299.02, 299.03
Behavioral and emotional disorders with onset usually occurring in childhood and adolescence (including hyperkinetic disorder)	1	F90-F98	306.x9, 308.0x

Classification of the psychiatric disorders according to ICD-10-DCR and equivalent ICD-8 diagnoses. Source: Creative *Commons Attribution 4.0 international* (44)

The pathologies included in our study are divided into the 2 following groups:

- Group 1 (Psychosis): schizophrenia, schizotypal disorder, persistent delusional disorder, acute and transient psychotic disorder, induced delusional disorder, schizoaffective disorders, other non-organic psychotic disorder, non-organic psychosis, and unspecified
- Group 2 (Affective disorders): maniac episode, bipolar affective disorder, depressive episode, recurrent depressive disorder, persistent affective disorder, other and unspecified disorder

ANNEX 3. INFORMATION SHEET

INFORMATION SHEET

Title of Research: *Testing the effectiveness of Domiciliary Hospitalisation when treating patients with an acute psychiatric crisis*.

Principal Investigators: Dr Isabel Mitjà, Dr Nayef Fadel, Mr Ramon Rovira and Miss Miriam Costa

Institutional Contact: Xarxa de Salut Mental d'Adults, Albareda street, 3-5 2a floor of the Fòrum building (Girona), phone number: 972 212 266 fax: 972 212 308, mail: csma.girones@ias.cat

1. Introduction

From the Xarxa de Salut Mental adults, we would like to invite you to be part of our present study, since your collaboration would be of great help to carry out the project. This is part of the end-of-term project of the medical student Miriam Costa, tutored by Dr Isabel Mitjà, and will be carried out through the Xarxa de Salut mental from Girona's municipality, based at the Parc Hospitalari Martí i Julià in Salt.

Continuing, we would like to briefly explain the reasons why we want to develop such a study; although until now hospitalisation in institutions has indeed been the standard intervention when dealing with patients in a serious crisis, home hospitalisation appears as a new methodology, in which instead of institutionalising patients, we choose to move to the patient's home and carry out the therapeutic intervention there, without the need for any medical admission. We aim to evaluate the effectiveness of this treatment.

2. Description of the Research

When you will enter the program, you will be asked to attend a clinical interview with a professional, who will explain to you everything you need to know about the intervention: the team, modality types of interventions, confidentiality, etc. Subsequentially, informed consent will be given to you, and, with all information, you must decide if you want to enrol in the study or not. Note that it is a completely voluntary decision.

In the affirmative case, you will then be placed in one of the groups, in which you will receive domiciliary hospitalisation treatment or the traditional hospitalisation method. As the study proceeds, clinical interviews, questionnaires, and medical assessments will be performed, and after the discharge period, 6 and 12 months after.

3. Subject Participation

We estimate that 96 participants will enrol in this study. Participants must have had a psychiatrist stating that admission to a clinical crisis care unit (acute or subacute ward) is indicated, based on clinical outcomes, judgments of other professionals, and information from informal caregivers, a diagnosis of an onset, acute or exacerbation of mental health crisis, and environmental factors that allow the patient to be contained in the home environment. Additionally, your residency will have to be in Girona province or surroundings, and your age should be around 18 and 65 years old. Finally, you should have the ability to read and understand Spanish or Catalan language.

4. Potential Risks and Discomforts

Regarding the risks, home hospitalisation has been shown in several studies with other settings to be an alternative without major risks. However, if you have any doubts, we are available to you 24 hours a day, by telephone. You can also visit our Acute and Sub-Acute home hospitalisation centres.

5. Potential Benefits

People who participate in this study may have a better understanding of additional treatment methods that enable individuals to experience and increase their overall sense of well-being. Additionally, several studies indicate that it may help reduce hospital admission days, and higher the satisfaction of patients and their relatives. Another important fact to mention is that social and environmental triggers can contribute to a crisis, and by visiting the patient's they can be better assessed, by learning coping skills.

Finally, it may foster the widespread implementation of DH internationally.

6. Confidentiality

All information taken from the study will be coded to protect each subject's name. No names or other identifying information will be used when discussing or reporting data. The investigator(s) will safely keep all files and data collected in a secured locked cabinet in the principal investigator's office. Once the data has been fully analysed it will be destroyed.

No personal identifying information or IP addresses will be collected. Data will be aggregated into the medical record.

8. Voluntary Participation and Authorisation

Your decision to participate in this study is completely voluntary. If you decide to not participate in this study, it will not affect the care, services, or benefits to which you are entitled.

9. Withdrawal from the Study and/or Withdrawal of Authorisation

If you decide to participate in this study, you may withdraw from your participation at any time without penalty.

10. Cost/Reimbursements

There is no cost for participating in this study. Any medical expenses resulting from participation in this study will not be reimbursed by the investigators.

Please do not hesitate to contact us with any queries you may have.

Sincerely,

The Research Team

ANNEX 4: INFORMED CONSENT

INFORMED CONSENT

Title of Research: *Testing the effectiveness of Domiciliary Hospitalisation when treating patients with an acute psychiatric crisis.*

Principal Investigators: Dr Isabel Mitjà, Dr Nayef Fadel, Mr Ramon Rovira and Miss Miriam Costa

Institutional Contact: Xarxa de Salut Mental d'Adults, Albareda street, 3-5 2a floor of the Fòrum building (Girona), phone number: 972 212 266, fax: 972 212 308, mail: csma.girones@ias.cat

Authorisation

I (name and surname), _____

- I have received all the necessary information about the study, I have read it in detail, and understood all the information provided about my participation in the study, and the role I will assume.

-I authorize the use of my medical records, any observations, and findings found during the course of this study for education, publication, and/or presentation, knowing that all my data will be kept confidential.

-I understand that after they have been checked, all information that could identify me will be removed from the record.

-I have understood the voluntary nature of my participation, being able to withdraw from the present study at any time, and independently receiving the necessary treatment.

-I accept that there will be further contact 6 months and 12 months after the follow-up, so a new assessment will be made.

If so, we would be grateful if you could provide your e-mail address, your telephone number and one of your relative's telephones numbers:

I voluntarily agree to participate in this research program

□ Yes

□ No

I understand that I will be given a copy of this signed Consent Form.

Note: A copy of the signed, dated consent form must be kept by the Principal Investigator(s) and a copy must be given to the participant

ANNEX 5: CONSENT WITHDRAWAL FORM

CONSENT WITHDRAWAL FORM

I (Name and surname), _____ revoke my consent to participate in the study previously indicated.

Signature:

Date:_____/_____/ _____

ANNEX 6. THE HEALTH OF THE NATION OUTCOME SCALE (HONOS)

To rate it, the summary of rating instructions is the following:

a) Rate each scale in order from 1-12
b) Do not include information rated in any earlier item, except for item 10 which is an overall rating.
c) Rate the MOST SEVERE problem that occurred during the period rated.
d) All scales follow the format:
   0= No problem
   1= Minor problem requiring no action
   2= Mild problem but definitely present
   3= Moderately severe problem
   4= Severe to very severe problem

Source: *Servicio Andaluz de Salud* (45), adapted from the *Royal College of Psychiatrists from the UK* (22).

Nombre: Historia:

Evaluador/a: Fecha:

ESCALA HoNOS: PERFIL DE RESPUESTAS

A. Problemas conductuales	**0**	**1**	**2**	**3**	**4**	
1. Conducta hiperactiva, agresiva, disruptiva o agitada						
2. Autolesiones no accidentales						
3. Consumo problemático de actitud o drogas						
Puntuación (rango 0-12)						**TOTAL A:**
B. Deterioro	**0**	**1**	**2**	**3**	**4**	
4. Problemas cognitivos						
5. Problemas con enfermedad física o discapacidad						
Puntuación (rango 0-8)						**TOTAL B:**
C. Problemas clínicos	**0**	**1**	**2**	**3**	**4**	
6. Problemas asociados a la presencia de ideas delirantes y alucinaciones						
7. Problemas en relación con el humor depresivo						
8. Otros problemas mentales o conductuales.						
Especificar el tipo de trastorno: A-Fóbico; B-Ansiedad; C- Obsesivo compulsivo; D- Sobrecarga mental y tensión; E-Disociativo; F-Somatoforme; G-Alimentación; H-sueño; I-sexual; J-Otros.						
Puntuación (rango 0-12)						**TOTAL C:**
D. Problemas sociales	**0**	**1**	**2**	**3**	**4**	
9. Problemas con las relaciones						
10. Problemas en relación con las actividades de la vida cotidiana						
11. Problemas con las condiciones de vida						
12. Problemas en relación con la ocupación y las actividades						
Puntuación (rango 0-16)						**TOTAL D:**
Puntuación Total (rango 0-48)						

0=sin problema; 1=problema menor que no requiere intervención; 2=problema leve pero claramente presente; 3= problema de moderada gravedad; 4= problema grave o muy grave; 9=sin valor o desconocido **(no sumar en totales)**.

ANNEX 7: SOCIAL DYSFUNCTION AND AGGRESSION SCALE (SDAS)

Source: *The Bech, Hamilton and Zung Scales for Mood Disorders* (46).

4.1 Scoring Sheet with Standardizations

No.	Item	Score
1	Irritability	
2	Negativism/uncooperative behaviour	
3	Dysphoric mood	
4	Socially disturbing/provocative behaviour	
5	Non-directed verbal aggression	
6	Directed verbal aggression	
7	Physical violence towards things	
8	Physical violence towards staff members	
9	Physical violence towards non-staff	
	Total score	

The SDAS criteria (standardization) for total score:

0–5: No aggression
6–10: Passive aggression
11–17: Verbal acts of aggression
18–36: Physical acts of aggression

ANNEX 8: CLIENT SATISFACTION QUESTIONNAIRE (CSQ-8)

Source: *NHS questionnaire, Department of Health Science from Leicester University* (47), https://www.nhs.uk

This form contains a list of questions that ask you what you think of your visit to the doctor today. Your answers will be kept entirely confidential and will not be shown to the doctor so feel free to say what you wish.

- Please answer all the questions by placing a tick in the answer box that is closest to what you think. "Neutral" means you have no feelings either way.
- Please do not write your name on the form and be sure to place this form in the box provided before you leave today.
- If you prefer, you can complete this form online at www.csq.org.uk. You will need to enter the number that is printed at the bottom of this page.

		STRONGLY AGREE	AGREE	NEUTRAL	DISAGREE	STRONGLY DISAGREE
	For example: This surgery is too big	☐	☑	☐	☐	☐
1	I am totally satisfied with my visit to this doctor	☐	☐	☐	☐	☐
2	This doctor was very careful to check everything when examining me	☐	☐	☐	☐	☐
3	I will follow this doctor's advice because I think he/she is absolutely right	☐	☐	☐	☐	☐
4	I felt able to tell this doctor about very personal things	☐	☐	☐	☐	☐
5	The time I was able to spend with the doctor was a bit too short	☐	☐	☐	☐	☐
6	This doctor told me everything about my treatment	☐	☐	☐	☐	☐
7	Some things about my consultation with the doctor could have been better	☐	☐	☐	☐	☐
8	There are some things this doctor does not know about me	☐	☐	☐	☐	☐

		STRONGLY AGREE	AGREE	NEUTRAL	DISAGREE	STRONGLY DISAGREE
9	This doctor examined me very thoroughly	☐	☐	☐	☐	☐
10	I thought this doctor took notice of me as a person	☐	☐	☐	☐	☐
11	The time I was allowed to spend with the doctor was not long enough to deal with everything I wanted	☐	☐	☐	☐	☐
12	I understand my illness much better after seeing this doctor.	☐	☐	☐	☐	☐
13	This doctor was interested in me as a person not just my illness	☐	☐	☐	☐	☐
14	This doctor knows all about me	☐	☐	☐	☐	☐
15	I felt this doctor really knew what I was thinking	☐	☐	☐	☐	☐
16	I wish it had been possible to spend a little longer with the doctor	☐	☐	☐	☐	☐
17	I am not completely satisfied with my visit to the doctor	☐	☐	☐	☐	☐
18	I would find it difficult to tell this doctor about some private things	☐	☐	☐	☐	☐
19	How old are you?	☐ years				
20	Are you male or female? Tick which applies	☐ male		☐ female		

Do you have any other comments about the consultation?

ANNEX 9: ISMI SCALE

Source: *Servicio andaluz de Salud, Junta de Andalucia* (48).

En este cuestionario se utiliza de forma repetida la palabra "enfermedad mental", por favor, piense cómo aplicar esta palabra a su caso. Para cada afirmación marque si está 1. muy en desacuerdo, 2. en desacuerdo, 3. de acuerdo, 4. muy de acuerdo.

	Muy en desacuerdo	En desacuerdo	De acuerdo	Muy de acuerdo
1. Me siento fuera de lugar porque tengo una enfermedad mental	1	2	3	4
2. Tener una enfermedad mental ha destrozado mi vida	1	2	3	4
3. Siento que las personas sin enfermedad mental no pueden entenderme	1	2	3	4
4. Me da vergüenza tener una enfermedad mental	1	2	3	4
5. Me siento culpable por tener una enfermedad mental	1	2	3	4
6. Me siento inferior a las personas que no tienen enfermedad mental	1	2	3	4
7. Respondo a la imagen o estereotipo que se tiene de las personas con enfermedad mental.	1	2	3	4
8. Por mi apariencia la gente puede decir que tengo una enfermedad mental.	1	2	3	4
9. Las personas con enfermedad mental tienden a ser violentas	1	2	3	4
10. La mayoría de la veces, otras personas deben decidir por mí a consecuencia de mi enfermedad mental	1	2	3	4
11. Las personas con enfermedad mental no pueden vivir una vida satisfactoria y gratificante	1	2	3	4
12. Las personas con enfermedad mental no deberían casarse.	1	2	3	4
13. No puedo aportar nada a la sociedad porque tengo una enfermedad mental.	1	2	3	4
14. La gente me discrimina porque tengo una enfermedad mental	1	2	3	4
15. Algunas personas piensan que no puedo conseguir mucho en la vida porque tengo una enfermedad mental	1	2	3	4
16. La gente me ignora o me toma menos en serio porque tengo una enfermedad mental	1	2	3	4
17. A menudo la gente me trata con condescendencia o me tratan como a un niño/a, porque tengo una enfermedad mental.	1	2	3	4
18. Nadie se interesaría en acercarse a mí porque tengo una enfermedad mental.	1	2	3	4
19. No hablo mucho sobre mí porque no quiero cansar a los demás con mi enfermedad mental.	1	2	3	4
20. No me relaciono con otras personas tanto como solía porque podría comportarme de forma extraña a causa de mi enfermedad mental.	1	2	3	4
21. Los estereotipos o creencias negativas sobre las enfermedades mentales me aíslan del mundo "normal."	1	2	3	4
22. No me relaciono con otras personas para no avergonzar a mi familia y mis amistades.	1	2	3	4
23. Cuando estoy con personas sin enfermedad mental siento que no estoy a la altura o que estoy fuera de lugar.	1	2	3	4
24. Evito acercarme con personas sin enfermedad mental para evitar el rechazo.	1	2	3	4
25. No me importa e incluso me apetece que la gente sepa que tengo enfermedad mental.	1	2	3	4
26. En general, soy capaz de vivir mi vida como quiero.	1	2	3	4
27. Puedo tener una vida satisfactoria y plena, a pesar de mi enfermedad mental.	1	2	3	4
28. Las personas con enfermedad mental hacen importantes contribuciones a la sociedad	1	2	3	4
29. Vivir con una enfermedad mental me ha convertido en un/a superviviente nato.	1	2	3	4

ANNEX 10: MANSA SCALE

Source: *International Journal of Social Psychiatry (35,36)*

MANSA ITEMS	DISSATISFIED (LOWER THAN 4) %	NEUTRAL MIDDLE POINT (4) %	SATISFIED (HIGHER THAN 4) %
How satisfied are you with your life as a whole today?	24.30	23.36	52.34
How satisfied are you with your job (or sheltered employment, or training/education as your main occupation)?	37.38	11.21	51.41
How satisfied are you with your financial situation?	38.64	21.11	40.25
How satisfied are you with the number and quality of your friendships?	12.15	14.02	73.83
How satisfied are you with your leisure activities?	26.17	28.04	45.79
How satisfied are you with your accommodation?	40.19	17.76	42.06
How satisfied are you with your personal safety?	15.89	19.63	65.09
How satisfied are you with the people that you live with?	11.21	6.54	82.24
How satisfied are you with your relationship with your family?	11.21	12.15	76.64
How satisfied are you with your health?	23.36	16.82	59.81

ANNEX 11: STATISTICS VARIABLES FORM

Based on the one used in DH Unit (38). Courtesy of R. Rovira.

General information	
1. Patient's name 2. Patient CH number. 3. Origin 0 CSMA-Girona 1 TAC 2 EIPP 3Emergency Room 4 Acute Unit 5 Subacute Unit 4. CSMA Sub-Team 1 Vilagran / Baron 2 Ferrer / Baone 3 García / Martínez 4 Ferrés / Anido 5. Patient's age. 6. Age group. 1 18-25 2 26-35 3 36-45 4 46-55 5 over 55 7. Sex. 0 Man 1 Female	8. Domicile. 1. House/Flat 2. Residence. 3. Pension. 4. SOPA. 5. Protected flat. 9. Principal caregiver 1 1st degree parentage (parents, children, parents-in-law, stepdaughters, husband). 2 2nd-degree parentage (grandparents, grandchildren, siblings, brothers, sisters-in-law, brothers) 3 3rd-degree parentage (uncles, aunts) 4 4th Degree parentage (Cousins) 5 Friends 6 Lives alone 7 FTCG 8 Caregiver 10. Nº of persons living in the family nucleus. 11. Working 1 Yes 2 No 3 Pre-employment 4 Retirement- 5 Disability

Toxic use		
12. THC before. 1 Yes 2 No 13. Current THC. 1 Yes 2 No	14. Oh before. 1 Yes 2 No 15. Current Oh 1 Yes 2 No	16. Cocaine before. 1 Yes 2 No 17. Current cocaine use. 1 Yes 2 No
18. Heroin in the past. 1 Yes 2 No 19. Current heroin. 1 Yes 2 No	20. Bzd before. 1 Yes 2 No 21. Current Bzd. 1 Yes 2 No	22. Other before. 1 Yes 2 No 23. Current other kind of substance. 1 Yes 2 No
CSMA data		
24. Visits in the ER in the previous year from DH. 25. Inpatient admissions previous year DH. 26. Total days of hospital admission in the previous year. 27 treatment abandonment previous to DH. 1 Yes 2 No		

<table>
<tr><td>28. Injectable medication.</td><td colspan="4">29. Oral medication</td></tr>
<tr><td>1 Paliperidone palmidad (Xeplion)
2 Fluphenazine + Ak
3 Fluphenazine + Haloperidol
4 Fluphenazine
5 Risperdal Consta
6 Zuclopenthixol (Cisordinol)
7 Aripripazole (Abilify Maitena)
8 Trevicta
9 None</td><td>0 None
1 Invega
2 Lithium
3 Clonazepam
4 Solian
5 Clozapine
6 Venlafaxine
7 Mirtazapine
8 Olanzapine
9 Depakine
10 Fluoxetine</td><td>11 Lamictal
12 Aripripazol
13 Anafranil
14 Risperidone
15 Quetiapine
16 diazepam
17 Zeldox
18 Depprax
20 Citalopram
21 Trileptal</td><td>22 Sycrest
23 Paroxetine
24 Haloperidol
25Escitalopram
26Daparox Drops (Paroxetine)
27Lorazepam
28Tranxilium
29 Etumine
30Duloxetine
31 Lormetazepam</td><td>32 Topiramate
33 Sertraline
34 Alprazolam
35 Brintellix (vortioxetine)
36 Gabapentin
37Prisqiq (Desvenlafaxine)
38 Tofranil (Imipramine)
39 Reagila</td></tr>
<tr><td colspan="2">30. Are you currently in treatment?
0 No
1 Yes</td><td colspan="3">31. Nº of Antipsychotic treatment (separate 1st generation vs. 2nd generation)
32. Nº of antidepressant trtt (separate Duals vs. ISRs)
33. Nº of euthymotic trtt.
34. Nº of anxiolytic trtt.</td></tr>
<tr><td colspan="2">35. Reason for referral.
1 Change of trtt.
2 Decompensation of underlying disease.
3 Lack of response to trtt or no improvement.
4 Diagnostic orientation.
5 Other</td><td colspan="3">36. Linkage to CSMA.
0 Good linkage
1 Partial
2 No linkage
3 No initial linkage</td></tr>
<tr><td colspan="2">37. Diagnosis (ICD-10).
1 Psychosis</td><td colspan="3">41. Compliance with criteria.
1 Yes</td></tr>
</table>

2 Affective disorders. 3 Other	0 No

38. Current Suicidal Ideation. 1 Yes 2 No	39. Current suicide attempt. 1 Yes 2 No	40. Previous suicide attempt. 1 Yes 2 No

Follow-up 6 months and 1 year after DH.

42. ER visit 6 months after DH:

43. Inpatient admissions 6 months post-DH:

44. Days in Hospital 6 months after DH:

45. CSMA linkage 6 months after DH:

46. ER visits 1 year after DH:

47. Inpatient admissions one year after discharge from DH:

48. Total days of admission to hospitalisation year of discharge:

49. CSMA linkage after 1 year of discharge DH:

Domiciliary Hospitalisation

50. Month of admission to DH. 51. Date of admission to DH. 52. Date of DH discharge. 53. Days of admission to DH. 54. DH Days Statistics. 1 1-10 2 11-20 3 21-30 4 31-50 5 + 50	55. DH home visits. 56. Reason for DH discharge. 1 Success 2 Hospital admission 3 Voluntary discharge or at own request. 4 Discharge due to improvement or achievement of objectives. 5 Loss of criteria for home admission.

DH referrals	DH pre-activities.	Activities initiated DH.
57. Chief/Nobody. 58. Day hospital. 59. Day consult. 60. CSM TS. 61. CSM Psychology. 62. 1st visit CSMA. 63. SAD. 64. SOPA. 65. PSI.	66. None/None. 67. Circle. 68. Astres. 69. Group of Voices. 70. CAP Medication/ CSMA Medication. 71. Other.	72. None/ None. 73. Circle. 74. Astres. 75. Group of Voices. 76. CAP Medication/ CSMA Medication. 77. Other.

DH Interventions	Other
78. Family interview. 79. Pharmacological. 80. Laboratory care and procedures. 81. Psychotherapeutic. 82. Family interventions. 83. Social and recreational activities. 84. Coordination. 85. ER Visit during admission to DH 86. Admissions Hospitalisation during admission to DH. 87. Re-admission to DH in more than 6 months. 0 No 1 Yes	89. Do you have animals at home? 0 No 1 Yes 90. Type of animal 0 None. 1 Cat. 2 Dog. 3 Bird. 4 Miscellaneous. 91. Nº of animals. 92. Type of lift. 0 Does not have. 1. Old. 2. New or in good condition.

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