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TITLE OF THE DOCTORAL THESIS

Italian mental health services: critical issues and challenges in the management of psychosis. Patterns of care in Residential facilities and treatment of early psychosis: the two sides of the same coin?

S.S.D.

(Please complete this space with the S.S.D. of your thesis – mandatory information)*

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Abstract

In Italy, the law no.180/78 commanded the gradual closure of all Mental Health Hospitals with the development of a nation-wide network of Departments of Mental Health which actually deliver different types of services, among which Community Mental Health Services and Residential Facilities. The aim of this thesis is to touch on two of the main challenges that these two different types of services have to face. On one hand, in recent years some of the Italian Community Mental Health Services have attempted to provide innovative and youth-friendly services, such as early intervention for people at first episode psychosis. The GET-UP PIANO study was set up with the purpose of testing the effectiveness and the efficacy of a multidimensional early intervention for people at first episode psychosis. In the framework of this large trial, part of this thesis is aimed at identifying possible predictors and moderators of treatment outcomes for first episode psychosis patients. Analyses were performed on 444 patients. Education, duration of untreated psychosis, premorbid adjustment and insight predicted outcomes regardless of treatment. Only age at first contact with the services proved to be a moderator of treatment outcome (patients aged 53.5 years had greater improvement in psychopathology), thus suggesting that the intervention is beneficial to a broad array of patients with first episode psychosis. In conclusion, except for patients aged over 35 years, no specific subgroups benefit more from the multi-element psychosocial intervention, suggesting that this intervention should be recommended to all those with first episode psychosis seeking treatment in Community Mental Health Services.

Secondly, the problem of managing chronicity in Residential Facilities. The discharge from Residential Facilities remains a critical issue, often also for young patients who, frequently, have high care needs despite having high chances of benefiting from rehabilitative paths. In this context, the aim of the project VALERE was to assess whether specific facilities designed for different groups of patients, targeted their needs. Results showed that ‘Comunità Terapeutico-Riabilitative Protette’, ‘Comunità Alloggio’ and Group Homes, according with their specific mission hosted patients with different characteristics, above all with different clinical profiles. However, some problems still overlapped among the
three types of Residential Facilities: the mean length of stay for each group was longer than permitted; the number of people employed was still low also in Group Homes, where patients had a better level of functioning and less psychopathological symptoms. The number of unmet social need was still high for each group. In conclusion, though a big step forward has been taken in the creation of Residential Facilities with specific missions and maximum length of stay, the type of interventions delivered did not seem to fully target patients’ groups needs.
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<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>BPRS</td>
<td>Brief Psychiatric Rating Scale</td>
</tr>
<tr>
<td>CA</td>
<td>Comunità alloggio</td>
</tr>
<tr>
<td>CAN</td>
<td>Camberwell Assessment of Need</td>
</tr>
<tr>
<td>CBT</td>
<td>Cognitive Behavioural Therapy</td>
</tr>
<tr>
<td>CMHC</td>
<td>Community Mental Health Centre</td>
</tr>
<tr>
<td>CTRP</td>
<td>Comunità Terapeutico-Riabilitativa Protetta</td>
</tr>
<tr>
<td>DALYs</td>
<td>Disability Adjusted Life Years</td>
</tr>
<tr>
<td>DUP</td>
<td>Duration of Untreated Psychosis</td>
</tr>
<tr>
<td>ED</td>
<td>Early Detection</td>
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<tr>
<td>FEP</td>
<td>First-Episode Psychosis</td>
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<tr>
<td>GAF</td>
<td>Global Assessment of Functioning</td>
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<td>GAP</td>
<td>Group Homes</td>
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<td>GHPU</td>
<td>General Hospital Psychiatric Ward</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>HRSD</td>
<td>Hamilton Rating Scale for Depression</td>
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<tr>
<td>LHU</td>
<td>Local Health Unit</td>
</tr>
<tr>
<td>MANSA</td>
<td>Manchster Assessment of Quality of Life</td>
</tr>
<tr>
<td>MHD</td>
<td>Mental Health Department</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health System</td>
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<tr>
<td>NOS</td>
<td>Nottingham Onset Schedule</td>
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<tr>
<td>PCR</td>
<td>Psychiatric Case Register</td>
</tr>
<tr>
<td>PANSS</td>
<td>Positive an Negative Syndrome Scale</td>
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<tr>
<td>PSA</td>
<td>Premorbid Social Adjustment</td>
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<td>PSP</td>
<td>Personal and Social Performance</td>
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<td><strong>QoL</strong></td>
<td>Quality of Life</td>
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<td>---------</td>
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<tr>
<td><strong>RCT</strong></td>
<td>Randomized Controlled Trial</td>
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<tr>
<td><strong>RF</strong></td>
<td>Residential Facility</td>
</tr>
<tr>
<td><strong>SAI-E</strong></td>
<td>Schedule for Assessment of Insight</td>
</tr>
<tr>
<td><strong>SCAN</strong></td>
<td>Schedule for Clinical Assessment in Neuropsychiatry</td>
</tr>
<tr>
<td><strong>SOFAS</strong></td>
<td>Social and Occupational Functioning Assessment Scale</td>
</tr>
<tr>
<td><strong>TAU</strong></td>
<td>Treatment As Usual</td>
</tr>
<tr>
<td><strong>VADO</strong></td>
<td>Valutazione Attività a Definizione Obiettivi</td>
</tr>
<tr>
<td><strong>VSSS</strong></td>
<td>Verona Service Satisfaction Scale</td>
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Independent contribution to thesis

I was jointly responsible, along with Professor Mirella Ruggeri for the original study design, protocol, ethical applications and procedures.

Moreover, I was responsible for the development and administration of the assessment relating to a part of the data presented in this thesis (in particular data derived from the instruments used for the assessment). Following appropriate training, I collected, analysed and reported all of the data used.

The clinical data (diagnosis, comorbidity, services’ use, psychopathology and functioning) were extracted from the South-Verona Psychiatric Case Register by Professor Amaddeo, the data manager.
Acknowledgements

I would particularly like to thank my supervisors, Professor Mirella Ruggeri, for her confidence, insights, advice and continuous support over the three years.

There are a number of collaborators whose contributions to the study have been so important. I am very grateful to Dr Chiara Bovo, who was the Local Health Unit’s medical director on duty, for making the study possible, Dr. Marina Masetti and Dr Eva Baldassarri and all the administrative office of the Verona Department of Mental Health for the valuable help in monitoring the paths of residential treatment and collecting information about patients recruited; Professor Francesco Amaddeo for his contribution to extract data from the South-Verona Psychiatric Care Register (PCR).

The University of Verona not only for the funding that made the study possible, but also for the financial support to travel and present at conferences. Thank you also to the Residential Facilities’ consultants and staff (psychiatrists, psychologists and operators) whose contributions were instrumental, in various ways, to the recruitment and the assessment of patients. A huge thank you to all of our participants who kindly gave up their time to assist with our research.

I would also like to thank the research team (Dr Antonio Lasalvia, Dr.ssa Doriana Cristofalo, Dr.ssa Sarah Tosato) I have been part throughout the three years, who have undertaken proofreading duties, listened to presentations or generally endured endless discussions about the study, and, in particular Chiara Bonetto for her suggestions and help with the statistical analysis.

I am very grateful to Professor Helene Killaspy and Dr Giovanni de Girolamo for their reviews and suggestions which have been essential to enhance the quality and the scientific level of this work.

Finally, I cannot leave without mentioning my family, my husband and my lovely daughter. Thank you for your patience, willingness and support.
Overview of thesis and general aims

The European countries experienced the process of deinstitutionalization of psychiatric care in the second half of the 20th century, with various speed and methods due to differences in health care and social welfare system, as well as the specific features of national traditions, socio-cultural context and the level of available resources. In Italy, the legislative changes in 1978 commanded the gradual closure of all Mental Health Hospitals with the development of a nationwide network of Departments of Mental Health which, actually, deliver different types of services, among which Community Mental Health Services and Residential Facilities. In these two type of services still endure some problems.

Firstly, although is recommend as a priority the provision of innovative and properly assessed youth-friendly services, especially in urban areas (Lora et al., 2012; Rucci et al., 2012), a recent survey (Ghio et al., 2012) designed to evaluate the diffusion of early psychosis services in Italy showed that these services are very scarce (Ghio et al., 2012). Moreover, they do not have a homogeneous distribution among regions and provide a set of interventions that are far from the recommendations of the national guidelines (Sistema Nazionale Linee Guida, 2007). The GET-UP PIANO study was set up with the purpose of testing the effectiveness and the efficacy of a multidimensional early intervention for people at first episode psychosis. In the framework of this large trial, part of this thesis is aimed at identifying possible predictors and moderators of treatment outcomes for first episode psychosis patients.

Secondly, is the problem of managing chronicity in Residential Facilities. The discharge from Residential Facilities remains a critical issue, often also for young patients who, frequently, have high care needs even if they have an high potential to benefit from rehabilitative paths. In this context, the aim of the project VALERE was to assess if specific facilities designed for different groups of patients, really target their needs.
Structure of thesis

Chapter 1

This first introductory chapter illustrates the way in which the process of deinstitutionalisation of mental health care occurred in the world and the development and evolution of psychiatric care system, above all in Western Europe. The focus then restricts on the National Mental Health Plan and the origin of the community-based psychiatry in Italy, with the implementation of a network of mental health facilities (Community Mental Health Centres, Acute inpatients facilities, Day Centers, Residential Facilities). The chapter ends with the analysis of the concept of recovery which is strictly tied with the content of mental health reforms.

Chapter 2

This chapter introduces the first topic addressed by the thesis, looks specifically at schizophrenia. Conceptualisations of schizophrenia are considered as well as symptoms, presentation and patterns, epidemiology, course, recovery rate, predictors of outcomes, disability and costs of schizophrenia. It illustrates also the principal treatments used to treat and the strategies to manage the disease and, in particular, the worldwide development of early psychosis intervention services, the types of interventions available, their effectiveness and costs.

Chapter 3

Chapter 3 illustrates a sub-study of a pragmatic cluster randomized controlled trial (the GET-UP study) with the aim of identifying and assessing predictors and moderators of treatment outcome in patients receiving multi-element psychosocial intervention for early psychosis. The first part of the chapter explains in detail the framework of the project and the principal results attaining from the core project. The second one illustrates the methods (the trial, subjects, treatments and measures and the statistical analysis conducted). Finally the principal results are discussed both for predictors and moderators of treatment
outcome, highlighting the strengths and limitations of the study and the possible implication for further research.

Chapter 4

Chapter 4 focuses on the other topic addressed in this thesis that is the quality of care in RFs. In particular, the chapter explores the general concept of RFs, their costs, the characteristics of the residents living in these accommodations. It offers also a literature review on patients’ outcomes summarizing the most important results of the principal studies conducted in the area.

Chapter 5

Chapter 5 briefly describes the organization of Mental Health Services in Italy, focusing on the Veneto Region and explains the context in which the Valere Project arised. In this chapter is depicted, in detail, the main methodology of the study (aims, hypothesis, design and setting, facilities assessment, patients’ recruitment and assessment, statistical analysis) and results are discussed with in the light of the existing literature on outcomes’ evaluation.

Chapter 6

This chapter draws together the findings from the empirical chapters of this thesis, summarising the results and considering these both in relation to one another, and to previous literature. This chapter also considers a number of general methodological limitations, clinical relevance and observations relating to future research in the area.
Chapter 1. Deinstitutionalization of mental health care and the development of community based psychiatry

1.1 An international overview

The practice of psychiatry in the second half and particularly in the last decade of the 20th century has fundamentally changed (Mosher and Burti; 1989; Bhugra and Leff, 1993; Thornicroft and Szmukler, 2001; Levin et al., 2004). During the 19th and the first half of the twentieth centuries, more and more asylums for psychiatric patients were established in the industrialised or Western world (Talbott, 1992; Becker and Vazquez-Barquero, 2001; Rose, 2001). Patients were admitted to facilities far away from urban areas and, in many cases, stayed there for the rest of their lives (Talbott, 1992; Rose, 2001). The number of patients that lived in institutions increased in the first half of the 20th century: psychiatric asylums in Europe reached populations of up to 3.000 inmates in the middle of the 20th century (Bauer et al., 2001; Becker and Vazquez-Barquero, 2001; Burti, 2001; Johnson et al., 2001; Provost and Bauer, 2001; Stefansson and Hansson; 2001; Vazquez-Barquero et al., 2001). Anyway, state mental hospitals in the United States of America became villages with 3.000–10.000 inhabitants (Talbott, 1992; Rose, 2001). Independently of their diagnosis, patients were taken from their families, from the street, the prisons and poorhouses to the psychiatric asylums (Rose, 2001). One explanation for the enormous growth in psychiatric patients in asylums is partly the increasing incidence and prevalence of specific psychiatric disorders, such as neurosyphilis, epilepsy, partly the way in which society dealt with people with these disorders, the belief that people with severe mental disorders can neither manage their condition nor lead independent and self-determined lives in the community (Davidson et al., 2010) and, related to that, a therapeutic pessimism (Rose, 2001). Better therapies, particularly the introduction of chlorpromazine in 1954, the conviction that asylums created a high level of dependence, the need for a more humane attitude towards psychiatric patients, and the immense costs of maintaining the asylums, which were largely built in the 19th century, paved the way for changes in the second half of the 20th century (Goffman, 1977; Scull, 1984; Shorter, 1997; Rose, 2001). Moreover, in
the 1950s, concerns were being raised with increasing frequency about the inhumane conditions within which people with severe mental illness were treated (Geller et al., 2000). In Europe, the USA, Canada and Australia, rigorous changes started around 1950 (Talbott, 1992; Shorter, 1997; Bauer et al., 2001; Rose, 2001; Burti, 2001; Johnson et al., 2001; Provost and Bauer, 2001; Stefansson and Hansson, 2001; Vazquez-Barquero et al., 2001). In the last decennia of the twentieth century, the socio political strategy focused on non-institutional treatment of psychiatric patients: idealistic convictions, psychopharmacological drugs, General Practitioners (GPs), and medical and psychiatric social work made possible this move away from institutions. Clinical admissions became limited and, if still deemed necessary, their duration had to be as short as possible (Goodwin, 1997; Rose, 2001; Burti, 2001). Soon after this, a more systematic dehospitalisation policy was implemented in the USA, Canada, Australia and different regions of European countries. This led to community mental health care, supplied by community mental health teams, GP consultants and community-based living and day care facilities serving by and large as alternatives for in-patient treatment (Talbott, 1992; Shorter, 1997; Thornicroft and Transella, 1999; Henderson, 2000; Bauer et al., 2001; Burti, 2001; Johnson et al., 2001; Provost and Bauer, 2001; Stefansson and Hansson, 2001; Vazquez-Barquero et al., 2001). The most spectacular decline in beds in mental hospitals in the USA shows a decrease from 559,000 beds in 1955 to 138,000 in 1980, a decline of 75% (Thompson, 1982). Admissions increased from 150,000 in 1955 to 400,000 in 1970 (Mechanic, 1987). The mean length of stay decreased from 20 years in 1955 to 7 months in 1975 (Haveman, 1982).

1.2 The evolution of psychiatric care systems in western Europe

In the second half of the 20th century, the European countries experienced the process of deinstitutionalization of psychiatric care, even though the speed and methods by which it was implemented varied, notably due to differences in health care and social welfare system, as well as the specific features of national traditions, socio-cultural context and the level of available resources. The deinstitutionalisation process initiated in the 1970s followed a different timeline in
Europe, beginning much earlier in some countries such as in France and England. In these two countries, the first reforms were undertaken between the two World Wars, notably in England with the development of the first free outpatient services (Mental treatment Act de 1930), and shortly afterwards in France with the introduction of services for the treatment of mental prophylaxis (circular issued by Rucart in 1937).

In England, the creation of a National Health System (NHS) in 1948 and a favorable social and political climate will lead to the progressive closure of the old psychiatric hospitals. Contrary to France where the 1960 circular instituting sectorisation demonstrated a strong collaboration between decision makers and psychiatrists, reforms in England were more the result of reactions to emerging trends or broader political initiatives in the health and social domains (Glover, 2007). Thus, in the 1950’s, based on the observation that the number of long-stay patients suffering from schizophrenia or chronic disease was tending to decrease (Tooth and Brooke, 1961), the government progressively aimed at the closure of large psychiatric hospitals. It began with the Hospital Plan for England and Wales in 1962 planning the closure of half the psychiatric beds by 1975. Secondly, in 1971 a government paper proposed the complete abolition of the psychiatric hospital system with all services being delivered by general hospitals in close collaboration with primary care and social services (Killaspy, 2006). Nowadays the National Service Framework for mental Health (Department of Health, 1999) detailed the national implementation of specialist community teams (over 200 assertive community treatment teams, 50 early intervention services and 300 crisis resolution/home treatment teams) across England.

In France, on the contrary, the Second World War accelerated the mental health reform process. The abnormally high death rate among patients hospitalised in psychiatric institutions during the conflict (Lafont, 1987; von Bueltzingsloewen, 2007) revealed the dysfunctions of institutionalised psychiatric care (patients’ deplorable living conditions, stigmatisation and social exclusion) and contributed to raise awareness regarding the need for a radical change in the mental healthcare delivery system (Coldefy, 2011). The government circular of 1960 instituting the sectorisation of psychiatric services was the result of strong
collaboration between decision-makers and a minority of psychiatrists. In view of the limited awareness of disalienating practices among the majority of French psychiatrists, the text was considered revolutionary (George and Tourne, 1994). French sectorisation policy advocated the organization of public hospital services across a geographical network of sectors, the ‘psychiatric sector’. The sector became the basic unit for the provision of public sector psychiatric care, delivered and coordinated by multidisciplinary teams. It was to provide a comprehensive range of care and services covering all mental health care needs in a given geodemographic neighbourhood: prevention, care, post-cure and rehabilitation.

Anywhere, reforms were introduced much later for different reasons.

In Germany, for example, the effects of the Second World War contributed to retarding the reform process. The crimes perpetrated against the mentally ill during this period stirred up controversies and criticisms to such a point that fixing long-term mental health objectives using a conciliatory approach were impossible (Demailly, 2011). In this country, reform was undertaken following the Care Quality Commission report on mental health (Salize et al., 2007). The Commission denounced the ‘miserable and inhumane conditions’ in numerous psychiatric hospitals marked by inadequate care provision due to understaffing, the virtual absence of psychiatric services in general hospitals and within the community, and a segregated healthcare system in which mental health care was provided by a system separated from the general health system (Deutscher Bundestag, 1975). The Commission recommended a fundamental change of approach and notably, the restructuring of the majority of psychiatric hospitals (Demailly, 2011). So, the shift towards community-based care began in the mid 1970’s, a period of both political and social reform.

In Sweden up to the 80s, almost all resources were concentrated in a large psychiatric hospital and a psychiatric clinic in a general hospital. By the mid 90s significant advances had been made in shifting resources to community services in three catchment areas. The implementation of the Swedish Psychiatric Reform Bill passed in 1995 led to a structural change of the mental health care system and to the reallocation of financial resources from the counties to the municipalities (Caldas de Almeida and Killaspy, 2011).
In Italy where psychiatric care was regulated by the Giolitti Law of 1904 until the end of the 1960’s, reforms in all medical domains, including mental health, lagged seriously behind other European countries. Until the 1968 Mariotti Law introducing voluntary internment, admission into a psychiatric hospital was by compulsory commitment only and was entered in an individual’s criminal records. Several authors denounced this relationship with the law and the inhumane treatment of patients who were hospitalised in Italian psychiatric hospitals (de Girolamo, 1989). Chapireau (2008) evokes a ‘psychiatric prison’ in which surveillance and repression prevails over health and humanitarian aims (Maj, 1985). The 1968 Mariotti Law opened the way for the development of outpatient care and the opening of centres for mental hygiene (Chapireau, 2008). The slowness of reform and lack of progress in Italy gave rise to a militant movement, named ‘Psychiatria Democratica’, led by Franco Basaglia. It denounced the systematic violation of human rights in Italian psychiatric hospitals, demanded the radical transformation of mental health care, and finally resulted in Law 180 of 1978. Law no. 180 ratified the prohibition of all admissions to state mental hospitals, including readmissions (however, existing mental hospital patients were not forcefully discharged to the community), the implementation of community-based services responsible for the full range of psychiatric interventions and the prescription of voluntary and involuntary hospitalizations only in emergency situations (when community alternatives have already been tried and failed). Hospitalization takes place in small units (no more than 15 beds) located in general hospitals. The departmental organization of in- and out-patient services must ensure comprehensive interventions for the prevention and rehabilitation of psychiatric discomfort, besides the care of mental illness. Most importantly, the new services were designed to be alternative, rather than complementary or additional to mental hospitals. Although Italy was slower in initiating reform, it proved to be the most radical and it led to the closure of large scale psychiatric hospitals. On the contrary, in most European countries, deinstitutionalisation consisted more in restructuring and reducing psychiatric beds number rather than closing psychiatric hospitals (MHEEN, 2008).
Figure 1 illustrates the trends in bed numbers for western Europe Countries from 1970 until 2005.

Figure 1.1 Trends in availability of psychiatric beds in western Europe, 1970-2005.

As Figure 1.1 shows each country has seen bed number decrease markedly. In France, for instance, there were 81,225 beds in 1990, but this number had decreased to 44,311 by 2004. In Germany, the number fell from 45,000 to 33,033 beds between 1990 and 2000. In Iceland, Italy and Sweden in 2005, there were no longer psychiatric hospitals. There were also no psychiatric beds in Liechtenstein, but the situation there was different in that there never were psychiatric hospitals in the country and instead care had been provided in the psychiatric hospitals of neighbouring countries.

The picture is somewhat different for general hospitals. Some countries witnessed an increase, while in almost an equal number of countries the trend was in the opposite direction. Numbers have remained stable in Italy, Liechtenstein and Malta.

Social care facilities were not available in all countries (for example in Switzerland, Malta and Greece) and data on the provision of psychiatric beds in
social care homes in some countries were particularly difficult to obtain as these social care services are often under regional or municipal responsibilities and national statistics are not compiled. Nevertheless, it was more common to find that the numbers of social care home beds have increased rather than decreased. In line with these data, in most West European countries there has been a fall in the number of residents in psychiatric hospitals. Similarly, it was common to find a fall in the number of psychiatric residents in general hospitals. With respect to social care homes, in contrast, there was a strong tendency for an increase in residents with mental health problems. The patterns of admission and discharge bear some similarities to the patterns of resident numbers, but differ where countries have been trying to alter the typical length of stay. In eight West European countries there have been increases in admissions to psychiatric hospitals (France, Germany, Greece, Malta, Norway, Portugal, Switzerland and Scotland), and there have been decreases in another nine (Belgium, Cyprus, Finland, Ireland, Northern Ireland, the Netherlands, Spain, England, Wales) (Figure 1.1). Admissions of patients with mental health problems to general hospitals increased in Austria, Belgium, France, Germany, Greece, Norway, Portugal, Sweden, Switzerland and Scotland; fell in Cyprus, Malta, the Netherlands, England and Wales and remained stable Iceland and Italy. Admissions to social care homes were generally reported to have grown. The majority of West European countries reported an increase in discharges from psychiatric hospitals and only Ireland, Spain and Scotland reported a decrease. Similarly, in many countries there were increases in general hospital discharges, and a fall in Malta, England and Scotland. The data we obtained suggested that there were decreases in discharges from social care homes in Cyprus, Ireland and Northern Ireland; increases in Lichtenstein, the Netherlands and Norway, and no change in Greece, Iceland and Italy. The total number of psychiatric inpatients beds across Europe has still been declining slowly also over the past decade. In 2001, in the rest of Europe there were 73.6 psychiatric beds per 100,000 population and by 2010 this had fallen to 61.4 per 100,000 population (Eurostat, 2013). Figure 1.2 shows the total number of psychiatric beds per 100,000 population in 2010 (Eurostat, 2013).
Figure 1.2 Total number of psychiatric beds per 100,000 population for 2010
(includes psychiatric beds in psychiatric hospital and general hospital units.

In all countries, the deinstitutionalization process was pursued through actions aimed at improving patients care outside the hospital.

In England, a change in government in 1997 and considerable increases in health sector financing supported a series of initiatives: in 1995, an update of mental health legislation introduced the monitoring of patient follow-up care outside the hospital. In 1998, the National Service Framework for Mental Health addressing the mental health needs of adults aged from 18 to 65 years old, set out detailed national standards, service models and objectives. Local Implementation Teams associating local representatives, public and private care providers, and patient/family representatives were charged with its implementation. In 2003, England counted 174 Local Implementation Teams, each covering a median population of 230,000 habitants. The National Service Framework was further reinforced in 2000 with the NHS Plan favouring the recruitment and training of
mental health personnel. Community Mental Health Teams, 762 in 2008 but on the decrease since 2005 with the development of specialized teams, are made up of one or several doctors, nurses, social workers, psychologists and occupational therapists. Patients are referred to them directly by GPs. The bulk of their work consists in individual consultations, and occasionally home visits. In addition to the Community Mental Health Teams, three other teams constitute local mental health services: the Crisis Resolution Service charged with preventing hospitalizations through the provision of intensive home care (270 in 2008 available 24/7); the Assertive Outreach Teams, teams specialised in dealing with particularly difficult or desocialised patients or those not adhering to treatment (248 in 2008), and teams charged with the early identification and prevention of psychotic disorders (151 in 2008). Teams specialized in rehabilitation (52 in 2008) or the care of the homeless (32 teams in 2008) have also been created (Glover, 2007). It was within this framework that the ‘care programme’ approach emerged, setting out a clinical practice framework recommending care quality standards to minimise potential risks facing mentally ill individuals living in the community (Jones, 2002). Among the key care quality standards, one concerns primary care and the access to specialised services: identification and assessment of needs by a professional in the primary care sector, orientation toward effective treatment, including referral to a specialist, and continuity of care; the other concerns the care of severe disorders based on a coordinated care programme established between the user, the family, the main carer and the GP. This programme includes crisis prevention, risk reduction and discharge preparation in the case of hospitalisation, and an annual assessment of the care programme and carer needs (Boyle, 2011).

In Germany, the deinstitutionalization process was slowed by the restructuring of East Germany’s mental health system in 1990. Reforms had nevertheless been undertaken from the 1960’s with the opening of psychiatric units in general hospitals and the small-scale development of community-based services. Mental healthcare, however, remained dominated by the psychiatric hospital and, more especially, the lack of resources due to the weakness of the East German economy (Salize et al., 2007). As a result, an East-West divide in
Germany persists in the provision of community-based care. Numerous hospitals (general and psychiatric) thus supervise ambulatory psychiatric services (Institutsambulanz), particularly for patients suffering from serious disorders and patients requiring multidisciplinary care. In 2002, Germany counted 304 ambulatory care services. This was completed by the creation of 219 similar services (Ermächtigungsambulanz) whose aim is to treat patients with specific problems that are addressed by office-based psychiatrists. Home care is also delivered by teams comprising nursing staff, social workers and other professionals (such as ergotherapists) in addition to psychiatrists. These teams notably deal with prevention and carry out home visits (Salize et al., 2007). The second type of ambulatory care in Germany, the social-psychiatric services (Sozial-psychiatrische Dienste) address individuals suffering from chronic mental illness. Complementary to hospital and ambulatory services, they also include long-term rehabilitative care. In the majority of Länder, they are directed by psychiatrists and integrate social workers and/or psychiatric nurses. They deliver a broad range of care including prevention activities and day care. In 2000, Germany counted 586 socialpsychiatric services (Arbeitsgruppe Psychiatrie 2003) [Salize et al., 2007]. Despite these advances, access to rehabilitative care and the social integration of mental health patients is still considered insufficient (Busse and Riesberg, 2004).

In Sweden, in 1997, the three separated sectors were transformed in one unit with six sub-sectors, which allowed a more reduced and effective administration (Caldas de Almeida and Killaspy, 2011). At the same time, outpatient and inpatient facilities were further extended and decentralised. The current system provides integrated outpatient and inpatient care in community-based units that have a small number of beds. Services are organised in a way that reinforces accessibility to services, continuity of care, integrated care, and the involvement of families and key organisations in the community. There are no units directly connected with a psychiatric hospital and all of them are located in residential areas. There are a small number of in-patient care beds (75 beds for 270.000 inhabitants). Most of the efforts are concentrated on outpatient care and over 65% of the resources are directed towards outpatient care. Psychiatric health
care at home with home visits is the primary working method. Daytime activities, working in groups and family- and network-oriented working methods are an important part of outpatient care. The inpatient care facilities have an integrated responsibility for both in-patient and outpatient care of the long-term patients. The mental health teams have an extensive collaboration with the social services in each residential area. On-duty and open care centres have a long-term collaboration with primary health care centres in the residential areas. In order to provide care adapted to some specific needs, there are specialized units/programmes for forensic patients, people with eating disorders, geriatric patients and psychotherapy.

Mental health planning in Italy was made difficult by its political instability and economic problems and no plan was adopted before 1994 (Burti, 1997). In addition, Law no. 180 was essentially an indicative or a ‘guideline’ rather than a prescriptive law to which no budget was specifically allocated and which gave no indications regarding mental health care service requirements or professional training needs (de Girolamo et al., 2007). The national situation was so highly disparate and Italy’s 21 Regions were entrusted with the specific tasks of drafting and implementing detailed norms, methods and timetables for the organizational translation of the law’s general principles (de Girolamo, 1989; Piccinelli et al., 2002; Tognoni and Saraceno, 1989).

As a result, the transition from a hospital-based care system to a community-based model was neither linear nor uniform across the country, and the effective closure of all Italian mental hospitals was not successfully completed until the end of 1999 (Piccinelli et al., 2002). A review of all public psychiatric services, carried out 10 years after the reform (Frisanco, 1989), found that 31.8% were comprehensive and efficient, 23.4% were undersized but potentially efficient, 33.4% were recently established and with unsatisfactory organizational features compared with the national average, and 11.4% were deficient (Fioritti et al., 1997).

To reduce inequalities, the Ministry of Health launched multi-year plans (1994-1996 and 1998-2000) which are still operational.
1.3 The National Mental Health Plan and the origin of the community-based psychiatry in Italy

For the first time ever, in 1994, the Italian Parliament passed a National Mental Health plan. It had both the political effect of acknowledging the path indicated by the reform 16 years earlier, and the administrative one of providing the regions with common standards with which to operate and finance the services. The Plan prescribed the integration of all local mental health and human services under one administrative organization: the Mental Health Department (MHD), typically responsible for a population of 150,000, providing the following services:

- Community Mental Health Centre (CMHC): it offers out-patient care and emergency intervention, counselling and support to families, case management, welfare interventions, rehabilitation and vocational training, job finding, hospital gate-keeping, and resettlement of discharged mental hospital patients.
- General hospital psychiatric wards (GHPW) with one bed per 10,000 population.
- Semi-residential facilities, with one place per 10,000 population. They include day-hospitals and day-centres.
- Residential facilities (RFs) with at least one bed per 10,000 population: they offer long-term care in small (20 beds or fewer) home-like facilities to the chronically mentally disabled (including former mental hospital in-patients).

The national plan was applied minimally and had limited effectiveness for a variety of reasons such as lack of sanctions against noncompliant regions and lack of a monitoring system (de Girolamo and Cozza, 2000) to the point where, although the number of patients staying in mental hospitals continued to decline over time, most of the 76 psychiatric hospitals existing in 1980 were still active in 1996. For this reason, a second National Mental Health Plan was launched (Ministry of Health, 1998) to bring about definitive closure of psychiatric hospitals and better define the objectives to be achieved. It incorporated the system structure and quotas of the preceding plan, while stressing a number of goals in different directions, especially dealing with the integration of mental health services with other ones (for instance with university, local administrations, non-profit, user and family organizations) and quality assurance (information,
evaluation of efficacy and effectiveness of interventions, evidence-based medicine, standards for the certification of services, setting guidelines and reorganization of the service delivery system for children and adolescents).

Overall, the aim of the 1998 National plan was to underscore the role of the MHD in promoting and coordinating mental health prevention, care, and rehabilitation within a defined catchment area, through a multidisciplinary team (psychiatrists, psychologists, nurses, social workers, educators, occupational therapists, personnel with specific training in psychosocial rehabilitation, and secretarial staff). Although the second national plan was more effective than the first one, the establishment of new community-based services across Italy continued to be slow and uneven, and only the combined effects of strict legal pressure and financial sanctions forced through the definitive closure of all mental hospitals nationwide (Piccinelli et al., 2002). The situation depended on the fact that neither National plan was considered strictly mandatory, whereas variability was built into regional and local plans for mental health. Regional plans became necessary as of 1992, when the Italian regions acquired financial autonomy for health management and each Local Health Trust started to receive a budget for health care based on the size of the local population and other health-related indicators. A recent survey by the Italian Psychiatric Association (Angelozzi et al., 2012) showed that, even now, only half of Italian regions have a regional plan for mental health, and most of these plans lack local epidemiological data to support decisions and intervention planning. Over the years, differences in regional policies and the differing regional interpretation of national guidelines brought about a complex scenario in which, despite common development of the organizational model (the MHD), considerable regional variability in service provision emerged (Pycha et al., 2011). Over time, regional variability had diminished, but variability across various services remained, despite lack of any strict relationship with their geographical location (Piccinelli et al., 2002). To tackle this, a new policy document, the National Strategic Plan for Mental Health (Ministry of Health, 2008), was issued in March 2008, approved by the ‘Standing Conference on Relations Between the State, Regions and Autonomous Provinces’, updating priorities and underlining critical areas where intervention was required,
especially concerning the MHDs, and the need to standardize their services across the country.

Italy has, currently, a population of approximately 60 million. Health care is provided to the entire population by the NHS. All citizens have access to unlimited health care coverage through ‘Local Health Units’ (LHUs), each of which manages a geographically defined catchment area. While access to some services is partially paid for by the user, others are free of charge. As the administration of health services has gradually being transferred from the state to regional governments, psychiatric care may be totally free of charge in some regions, while other regions may request payment of a fee (‘ticket’) by citizens. Hospitalisation, day care, and psychiatric rehabilitation are free of charge throughout the whole nation. Psychiatric assistance is administered by a network of MHDs, each of which covers a geographically defined area, usually corresponding to that of a LHU.

The most recent survey on MHDs distribution which was carried out in 2009 by the Health Ministry showed that there were 208 MHDs (currently 211), including small psychiatric hospital units within general hospitals, to a total of 4,630 beds; 1,387 CMHCs; 1,679 nonhospital RFs, to a total of 19,299 beds; and 763 semi-residential facilities, totaling 12,835 beds (Ministry of Health, 2011). Furthermore there were 1,760 beds in private licensed facilities. This scenario is changing rapidly because of merging of MHDs and the reduction in hospital and RFs, mainly for cost containment reasons. However, at both local and national levels, there has long been a lack of monitoring of compliance with the standards of the national mental health plan, mostly resulting from insufficient attention to the development of systematic data collection (Munizza et al., 2011).

1.4 The network of mental health facilities

1.4.1 Community Mental Health Centres (CMHCs)

A national survey, named PROG-CSM (PROgetto Centri di Salute Mentale, i.e. community mental health center project) (Ministry of Health, 2008), was undertaken in 2005 with the aim of surveying all Italian CMHCs and examining the extent to which these facilities met defined quality standards
including continuity of care, coordination with other community-based services, accessibility, implementation of specific programs, and provision of care (Munizza et al., 2011). The 636 CMHCs surveyed were located in 195 out of 211 MHDs. They covered the full Italian territory, and about 60% were situated in small towns (40,000–300,000 inhabitants) or rural areas (<40,000 inhabitants). The CMHC/resident ratio was about one facility per 80,460 inhabitants. The overall 3-month treated prevalence was 86 cases per 10,000 inhabitants, and the overall one-year treated incidence was 46.6 cases per 10,000 inhabitants. Psychotic disorders accounted for more than one-third of the diagnoses of patients seen during the study index period and about one-sixth of the diagnoses of first-contact patients (Munizza et al., 2011).

An annual referral rate of 58.5 new episodes of care per 10,000 inhabitants was found in a study designed to describe the pathways followed by patients with new episodes of care in accessing a community-based mental health service in the South-Verona Area (Amaddeo et al., 2001). Most patients were referred by their GP (40%), 26% by a hospital doctor, while 23% were self-referred.

Reliable and accurate data on patients with specific severe mental disorders presenting for the first time to CMHCs were obtained between 2009 and 2010 through an information system based upon 22 selected CMHCs distributed across Italy and covering a total population of 1,941,853 inhabitants (Gigantesco et al., 2012). The project, named ‘SEME’ (Sorveglianza Epidemiologica in salute MEntale, i.e. mental health epidemiologic surveillance), was supported by the National Centre for Disease prevention and Control of the Italian Ministry of Health and aimed at identifying and characterizing all first-contact patients with a DSM-IV diagnosis of schizophrenia spectrum disorders, bipolar I disorder, major depressive disorder with psychotic symptoms or suicide attempt, and anorexia nervosa. In each CMHC the diagnoses were made by two trained psychiatrists using the Structured Clinical Interview for DSM-IV Disorders - Axis I (SCID-I) Research Version 2.0. A total of 343 first-contact patients met criteria for one of the mental disorders considered, with an annual treated incidence rate of 17.7 per 100,000 inhabitants over 14 years old (95% Poisson confidence intervals 15.8-19.6). Figure 3 reports the incidence rates for different diagnoses and different
Italian Macro Geographic Areas. It is necessary to consider that the reliability and validity of diagnoses in an administrative data set is always open to question, but such figures are a useful tool for a better understanding of the priorities in mental health systems. Furthermore, for severe mental disorders such as schizophrenia this is considered to be reasonably closer to the actual population incidence as it is unusual for a patient not to be referred to psychiatric services (Goldberg and Huxley, 1980).

Figure 1.3 Crude Treated Incidences of Disorders: Rates by Diagnostic Group and Macro Geographic Area (Rate Per 100.000)

<table>
<thead>
<tr>
<th></th>
<th>Rate/10^6/person-years (95% Poisson CI per 100 000)</th>
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<tbody>
<tr>
<td></td>
<td>Overall</td>
</tr>
<tr>
<td>Overall (22 centres) (n=343)</td>
<td>17.7 (15.8-19.6)</td>
</tr>
<tr>
<td>Psychotic disorders (n=143)</td>
<td>7.4 (6.2-8.7)</td>
</tr>
<tr>
<td>Bipolar disorders (n=104)</td>
<td>5.4 (4.4-6.5)</td>
</tr>
<tr>
<td>Major depressive disorder (n=65)</td>
<td>3.4 (2.6-4.3)</td>
</tr>
<tr>
<td>Anorexia nervosa (n=31)</td>
<td>1.6 (1.1-2.3)</td>
</tr>
</tbody>
</table>

Source: Gigantesco et al., 2012

Psychotic disorders accounted for 42% of identified cases, bipolar I disorder for 30%, psychotic or suicidal major depression for 19%, and anorexia nervosa for 9%. Most patients were referred to the participating CMHCs by their GP (31%) and many by hospital doctors, including those working in hospital emergency departments (21%). The SEME system found a median interval between the onset of psychiatric symptoms and the first contact with the CMHCs of 5 years for patients with psychotic disorders, bipolar I disorder, or anorexia nervosa, and 2 years for patients with psychotic or suicidal major depression (Gigantesco et al., 2012). These data are in line with additional local studies based on case registries found annual rates of first-contact patients which are comparable with those we observed (Bebbington and Tansella, 1989; Percudani et al., 2002; Lora et al., 2011) and the international literature (Norman et al., 2005; Brunet et al., 2007). The delay from symptom onset to contact with community
mental health services observed in severely mentally ill patients raises concern and may suggest the need to develop specific strategies to intercept severe cases at an earlier stage of the illness.

The incidence rate of a disorder is a crucial information for health policy makers. Since 1990, there has been considerable interest in early detection for instance, of schizophrenia and other psychotic disorders driven by the view that earlier treatment might favourably influence the course of illness (Lieberman and Fenton, 2000; Norman and Malla, 2001).

Within this framework, in 2009, 152 CMHCs were surveyed about the provision of early intervention in schizophrenia in Italy and the diffusion of early psychosis clinical services (Ghio et al., 2012). Forty-six of them (30.3%) reported the presence of an early psychosis service, although only 33 (21.7%) actually had a dedicated specialized team.

Among the existing early psychosis services, ‘Programma 2000’ is the best known of several programs designed to identify and treat individuals at high risk of psychosis or with a recent onset of psychotic symptoms (Cocchi et al., 2008). This program is a comprehensive multi-modal protocol of early intervention in psychosis, set up in Milan in 1999 in a dedicated CMHC created with the aim of treating young people (17-30 years). All patients referred for evaluation to this facility undergo a comprehensive, multidimensional evaluation with standardized assessment instruments, and receive an individual intervention package. Given that community-based mental health services aim to identify people suffering from psychiatric disorders and provide them with appropriate care for as long as required, the number of patients who do not return after first visit could be considered as a key outcome indicator in this setting. Studies performed at a local level on this topic reported that the percentage of patients who dropped out of treatment after the first visit ranged from 8% in the South Verona area (Rossi et al., 2008) to 9.7% in the Palestrina (Rome) CMHC (Palmieri et al., 2009), to 38.7% in four CMHCs located in the Campania region (Morlino et al., 2009).

1.4.2 Acute inpatients facilities
Within the MHD system, acute inpatient care is delivered in General Hospital Psychiatric Units (GHPUs). These inpatient facilities with a maximum of 15 beds are closely linked with the CMHCs to ensure continuity of care.

The PROgetto RESidenze (PROGRES-Acute) Project (de Girolamo et al., 2007) covered the network of acute inpatient facilities in 20 regions (except Sicily) during 2002-2003. Italy had a rate of 0.78 public acute-inpatient beds per 10,000 inhabitants, located in GHPUs (88%), University Psychiatric Clinics (10%) and 24-hour CMHCs (2%). The availability of public acute beds in Italy was approximately 20% less than the official national standard (1 bed per 10,000 inhabitants). The corresponding rate of private beds was 0.94 beds per 10,000 inhabitants. On the whole, in Italy, the rate of acute, short-term psychiatric beds (public and private) was 1.72 per 10,000 inhabitants. Not only did this rate (private plus public beds) present considerable variation across the different regions, the ratio being 8:1, but also the number of public beds varied greatly from the South to the North-East and Centre (by nearly a 1:2 ratio). Concerning staffing: all public and private facilities had 24 hours coverage, with staff on duty at night. The 301 public facilities employed 8,058 professionals, 86.5% of whom worked full-time. The number of staff in private facilities was much smaller (2,384 professionals, of whom 1918 were working fulltime). The staff quota per bed in private facilities is much smaller than in any type of public facility: in the public facilities the staff/patient ratio ranged from 1.44 to 5.17, showing that facilities for acute patients rely greatly on human resources; in contrast, ratios for private facilities were markedly smaller (0.45 staff/patient ratio). The mean length of stay varies between facilities, with a median number of days per admission of 11.4 in GHPUs, 17.8 in University Psychiatric Clinics, 21.1 in 24-hour CMHCs and 37.6 days in Private Facilities. There was a substantial variation in the length of stay across the different areas: the mean length of stay in the northeast region was almost twice that in the central and southern regions. Even the number of public beds differs greatly between the southern regions and the north-east and central regions. Indeed, the different bed availability could account for the much shorter average length of stay observed for the south. In 2001 the psychiatric admissions and the number of admitted patient-rates per 10,000 inhabitants in
public facilities were 19.8 and 13.4 respectively, whereas in private facilities these were 6.9 and 4.4 respectively. The percentage of ‘revolving-door’ patients (i.e. the patients who had had three or more admissions to the same facility) was similar in public and private facilities (8.7% versus 8.3%). The percentage of compulsory admissions was 12.9%, and it varies from region to region. As a temporal trend the percentage of compulsory admissions decreased from approximately 50% in 1975 (3 years before the Reform Law), to approximately 20% in 1984. Ten-years later, in 1994, this percentage had dropped to 11.8% of the total of public psychiatric admissions (Barbato, 1998). Within the context of PROGRES-acute, diagnoses in a sample of admissions were analyzed (Preti et al., 2009a). Patients with schizophrenia represented 37.9% of the total admissions to public inpatient units and 25.9% to private ones. Patients with bipolar affective disorders were 18.4% in public facilities and 19.6% in private; those with unipolar depressive disorders were 16.1% in public and 20% in private facilities. A second assessment was conducted specifically to address psychiatric inpatient characteristics on a given census day (Gaddini et al., 2008). The public and private facilities showed great differences in age and gender distribution: public facilities admitted mostly young men, whereas one third of the beds in private facilities were occupied by women aged 65 and older.

1.4.3 Day Centers

The creation of a community mental health system implied the opening of day centers for patients requiring a more intensive level of care than simple outpatient care. Maone and his colleagues (Maone et al., 2002) carried out a national survey of day centers: out of 481 facilities identified, 238 participated, yielding a response rate of 49.5%. The authors estimated an average of 1 place available in day centers per 10,000 population. Approximately one fourth of the 238 day centers surveyed were organized according to general principles of ‘milieu therapy’. In contrast with this, there were several day centers that selectively focused on facilitating acquisition of vocational skills; these facilities maintained strong ties with social cooperatives and assisted patients in finding a job. Overall, the duration of treatment was long, and about 39% of patients had been in
treatment for three or more years. Indeed, about 60% of the participating day centers regarded patient discharge as one of the most challenging problems (de Girolamo et al., 2007).

1.4.4 Community Residential Facilities (RFs)

Two Italian national surveys were carried out in 2000 and 2003 to provide a descriptive overview of the characteristics of inpatient and RFs (de Girolamo et al., 2007, 2002) as well as the patients admitted to and discharged from these facilities over an index period (Preti et al., 2009). The PROGRES study (de Girolamo et al., 2002), a wide national survey, monitored the network of community RF in Italy. In the year 2000, Italy had 1,370 RFs and a rate of 3.5 beds per 10,000 inhabitants over 14 years of age. There was marked variability (up to 10-fold) in the provision of residential places among the different regions: 73% of the RFs had 24-hour staffing and more than half were (and still are) managed directly by MHDs, and more than three quarters are funded by NHS. The mean number of full-time staff was 8.2 and the overall ratio of patients to full-time staff was 1.4:1. The results of the PROGRES survey also suggested that many RFs provide mostly long-term accommodation: three quarters of them have no formal limitation to the length of stay; resident turnover was low, there being few new admissions and few discharges, and discharge to independent accommodation is uncommon. For many chronic, disabled patients, RFs represent ‘a home for life’, rather than a transitional facility. The RFs had several external activities targeted at integrating patients within the local community, however 45% of the patients were completely inactive, not even assisting with their facility’s daily activities. Standardized assessment instruments and written treatment plans were rarely used. Leisure and socializing activities, psychomotor and creative interventions prevailed in the rehabilitative interventions (i.e. aimed at basic, interpersonal and social skills training); family addressed activities were not frequent (Santone et al., 2005).

Overall, the findings of the PROGRES study suggest that RFs were located at the convergence of three different needs: i) intensive rehabilitation for some patients, ii) care for patients who cannot live in the community due to illness severity.
and/or lack of family or service support, and iii) lodging for severely disabled patients. According to the authors of the project, one key future challenge for the Italian mental health system would be to design specific pathways, as well as specific facilities, for such different groups of patients (Santone et al., 2005).

1.5 ‘A life in the community’: mental health reforms and recovery

The implementation of deinstitutionalization process in the 1960s and 1970s, and the increasing ascendance of the community support system concept and the practice of psychiatric rehabilitation in the 1980s, have laid the foundation for a new 1990s vision of service delivery for people with severe mental disorders.

Recovery from mental illness was the standard that guided the organization of mental health systems in this decade. The concept of recovery is based on the awareness that people with severe mental illnesses may have multiple residential, vocational, educational, and social needs and wants (Anthony, 1993). Deinstitutionalization radically changed how the service system attempts to meet these wants and needs. The concept of recovery was introduced by the writings of consumers/survivors/clients (Anonymous, 1989; Deegan, 1988; Houghton, 1982; Leete, 1989; McDermott, 1990; Unzicker, 1989), and described as ‘[..] a complex, time-consuming process, […] a deeply personal, unique process of changing one's attitudes, values, feelings, goals, skills, and/or roles, […] a way of living a satisfying, hopeful, and contributing life even with limitations caused by illness that involves the development of new meaning and purpose in one's life as one grows beyond the catastrophic effects of mental illness’ (Anthony, 1993). This concept has been taking place also in light of evidence suggesting that recovery from mental illness, and, in particular, from schizophrenia can occur (Banham and Gilbody, 2010; Harrison et al., 2001; Jobe and Harrow, 2005). As a matter of fact since 1970s, long-term follow-up studies on schizophrenia have consistently indicated that approximately 25% of people with this diagnosis can be consider fully recovered during the follow-up period, with another 25-45% achieving significant improvement, including relatively independent role functioning (Ciompi, 1980; DeSisto et al., 1995a; 1995b; Huber et al., 1980). Concurrent with
the emergence of the concept of recovery in mental health care planning has been the widespread acknowledgement of the need for services delivery that was guided by evidence-based practices. Evidence-based care is an approach to classifying health care outcome research according to the quality and quantity of empirical evidence supporting a particular intervention. Recovery and evidence-based practices are strictly related each other. The purpose of the new mental health systems was to identify, provide and deliver evidence-based interventions or services promoting patients’ recovery.

As a result, there was a call for carrying research on outcomes with the aim of monitoring the quality of care and the efficacy of services provided. Given that recovery is a multi-dimensional concept, there is no single measure of recovery, but many different measures that estimate various aspects of it. The recovery vision expanded the concept of service outcome to include dimensions such as self-esteem, adjustment to disability, empowerment, and self-determination. In a recovery-oriented mental health system, each essential service should be analyzed with respect to its capacity to ameliorate people's impairment, dysfunction, disability, and disadvantage and not only the ‘clinical’ recovery. Major recovery may occur without complete symptom relief. That is, a person may still experience major episodes of symptom exacerbation, yet have significantly restored task and role performance and/or removed significant opportunity barriers. From a recovery perspective, those successful outcomes may have led to the growth of new meaning and purpose in the person's life.

1.6 Conclusion

Despite all the advances already made in Europe to improve mental health care for people with longer-term mental disorders, most European countries are still confronted with important challenges in order to complete this process of change. These challenges are closely related to a paradigm shift that involves the change from an approach focused on the exclusion of the mentally ill for an approach that focuses mainly on their inclusion in society. This paradigm shift, which results from an increasing recognition of the importance of the recovery
perspective, a perspective that emphasises self-determination and human rights of people with mental illness, also involves the evolution of a hospital-based model of care to a community-based integrated model of care.

From a scientific point of view, what is at stake is the replacement of the strict biomedical model by a more holistic and complex approach, which attempts to understand mental illness as a result of the complex interactions of biological, psychological and social factors; and combines a perspective of treatment with one of prevention and promotion. With respect to the organisation of services, the new paradigm is strongly influenced by new models of management of chronic diseases, which emphasise case management, collaborative models of care and participation of users and families in care delivery. It is also a paradigm that clearly implies a recognition of the importance of available scientific evidence on the costs and effectiveness of interventions and services to support the decision making process of clinicians and policy makers. It is important to safeguard and further expand the achievements that have been made in embedding long-term mental health care into societies, and in recognising it as part of local community development. The evolution to community-based and socially inclusive approaches to mental health needs to continue, and it should not be stopped or even reversed by the financial constraints which Member States have increasingly been facing in recent years.

In particular, in Italy, the main cultural merit of Law 180 is to have started a process of deinstitutionalizing psychiatric assistance and a process of destigmatizing people with severe mental disorders in favor of their social reintegration in the community (Bersani, 2009).

Thirty-eight years after the Italian psychiatric reform law, the process of deinstitutionalization has been achieved, and a community-based model of mental health care, based on nationwide development of MHDs, has been implemented. The MHD model is sufficiently developed throughout Italy from an organizational point of view (Munizza et al., 2011) because the network of community mental health facilities seems complete, especially as concerns CMHCs, RFs, and, partly, GHPUs, although considerable variability still remains among the regions (Lora, 2009). However, there are still many problems to be tackled, especially in relation
to the quality of interventions provided, their monitoring and evaluation, the treatment coverage, management of chronicity, and long-term RFs.

The mental health systems of these regions seem to work as expected, with a higher percentage of severe mental illness among prevalent cases and a higher percentage of common mental disorders among new cases. This trend is expected in a well-developed community mental health system, where prevalence is mostly influenced by patients with severe mental illness who are long-term users of services, whereas incidence depends mainly on the frequency of common mental disorders with shorter episodes of care. However, differences among the regions are still noteworthy, as highlighted by outpatient and inpatient rates. Differences in service use can be detected, such as accessibility for young patients with substance use disorders and elderly patients. As other Italian investigations have stated, the provision of innovative and properly assessed youth-friendly services, especially in urban areas is a priority indeed (Lora et al., 2012; Rucci et al., 2012).

In this regard, a recent survey (Ghio et al., 2012) designed to evaluate the diffusion of early psychosis services in Italy showed that this kind of service can be found only in 20% of CHMCs. Such services do not have a homogeneous distribution among regions and provide a set of interventions that are far from the recommendations of the national guidelines (Sistema Nazionale Linee Guida, 2007).

According to the second national plan for mental health (Ministry of Health, 1998), MHDs should also integrate the care of child/adolescent mental health into the infant neuropsychiatry services. However, neuropsychiatry services currently merge with MHDs only in four Regions, therefore, the provision of mental health services for the young population is often inadequate and fragmented among various health care settings, resulting in a long-term delay in recognizing and treating early-onset disorders. The National Health Plan 2011-2013 (Ministry of Health, 2011b), along with the most recent Italian Mental Health Action Plan (Ministry of Health, 2013), have highlighted the unsatisfactory state of child and adolescent mental health service provision in Italy and called for an integrated and coordinated response at national, regional, and local levels (OECD, 2013). In particular, the need to establish a comprehensive monitoring
system for child and adolescent mental health, which would entail: reorganize neuropsychiatric services in a homogeneous and efficient way throughout the Italian territory; encourage early intervention at the onset of the mental illness; and facilitate cooperation and coordination between mental health services and pediatric services, schools, community social services, and commissioned private health services (Ministry of Health, 2011b, 2013).

Besides the early interventions and child/adolescent mental health issue, there is another issue, which is the managing chronicity in RFs. Three major problems need to be tackled in this field: i) the provision of residential beds varies still greatly across the Regions; ii) analyses of the care process in residential facilities show large heterogeneity, and efforts should be made to improve the effectiveness, and coordination, of care within the MHDs; iii) in recent years the number of beds in residential facilities is still rapidly increasing (Report of Regione Emilia Romagna, 2006, Report of Regione Lombardia, 2008) and further RF expansion could hamper, in terms of competition for resources, the provision of intensive and innovative community care by CMHCs. This last is a crucial issue for the development of community care, not only in Italy but also throughout Europe (Priebe et al., 2005).

Unfortunately, although nearly 20 years have passed since the end of the PROGRES project, local data suggest that the target is yet to be achieved. Thus, in many RFs patients with different socio-demographic and clinical profiles, as well as needs for care, live together, making it difficult, and sometimes impossible, to suit individual rehabilitation plans to individual needs. RFs in Italy too often provide mental health assistance rather than therapeutic assistance, with a consequent risk for new forms of institutionalization (de Girolamo et al., 2002, 2005; OECD, 2013). Several studies (de Girolamo et al., 2005; Ghio et al., 2011) highlight the presence of critical issues in provision of care in RFs such as excessive length of stay, low turnover of residents, poor involvement in rehabilitation activities, great variety and scanty measurability of therapeutic interventions, and distinctly more psychotropic drug treatment than psychosocial or psycho-educational interventions. As has been observed (OECD, 2013), the
next step toward accomplishment of the deinstitutionalization process would be to improve and reorganize RFs.

The principal aims of this thesis are to address and add evidence about two of the major challenges that Italian MHDs have nowadays to face. Firstly the need to foster primary and secondary prevention strategies in schizophrenia in order to identify new cases at the very early phase of the illness to deliver evidence-based interventions in order to promote recovery or slow down unfavourable prognosis. Secondly, to evaluate clinical and functional profiles of patients living in RFs and monitor the quality and the adequacy of interventions delivered in these settings.
Chapter 2. Treatment and management of schizophrenia

2.1 Psychosis and schizophrenia

2.1.1 Symptoms, presentation and patterns

The term ‘psychosis’ is usually used to refer to a group of psychotic disorders that includes schizophrenia, schizoaffective, schizophreniform and delusional disorder. According to the tenth edition of the International Statistical Classification of Diseases and Related Health Problems (ICD–10; World Health Organization, 1992), psychosis and the specific diagnosis of schizophrenia represent a major psychiatric disorder (or cluster of disorders) in which the individual’s perception, thoughts, affect and behaviour are significantly altered. People who develop psychosis or schizophrenia will have their own unique combination of symptoms and experiences, the precise pattern of which will be influenced by their particular circumstances (such as the environment, the social context, and so on).

Generally, the onset of the disorder is preceded by a ‘prodromal’ period, often characterized by some deterioration in personal functioning. Difficulties may include memory and concentration problems, social withdrawal, unusual and uncharacteristic behaviour, disturbed communication and affect, bizarre ideas and perceptual experiences, poor personal hygiene, reduced interest in and motivation for day-to-day activities. During this period, individuals could feel that their world is changing, but their interpretation of this change may not be shared by others. These changes may well affect the person’s ability to hold down a job, study, or relate to family and friends.

The prodromal period is typically followed by an acute phase marked by characteristic positive symptoms of hallucinations, delusions and behavioural disturbances such as agitation and distress. Following resolution of the acute phase, usually treated by medications, positive symptoms diminish or disappear for many people, sometimes leaving a number of negative symptoms not unlike the early prodromal period. This third phase, which may last many years, is often
interrupted by acute exacerbations also called ‘relapses’, which may require hospitalisation and additional interventions.

Although this is a common pattern, the course of schizophrenia varies considerably. For example, some people could experience disturbing symptoms only briefly, others may live with them for months or years. A number of individuals experience no prodromal period, the disorder beginning with a sudden and often frightening acute episode. After an initial episode, between 14% to 20% of individuals will recover fully (NICE, 2014). Others will improve but have recurrences which could be drawn by stress, social adversity, and isolation. In the longer term (up to 15 years), over half of people with these diagnoses will have episodic rather than continuous difficulties (NICE, 2014). Some of these intervals of recovery will appear spontaneously and may be tied to individual patient factors such as resilience (Harrow et al., 2005).

2.1.2 Epidemiology

Schizophrenia is a relatively common illness, and it is certainly the most common form of psychotic disorder. Estimates of the incidence and prevalence of this disorder vary by geographic area and across time. It has been estimated that approximately twenty-four million people suffer from schizophrenia worldwide, with annual incidence rates of 1–4 per 10,000 adults aged 15–54 years (Goldner et al., 2002; Bresnahan et al., 2003) and an average lifetime prevalence of between 0.5–1% (Goldner et al., 2002; Saha et al., 2005). Average rates for men and women are similar, although the mean age of onset is about five years greater in women (hence a lower female rate in adolescence), with a second smaller peak after the menopause.

2.1.3 Disability and costs of schizophrenia

Although the problems and experiences associated with psychosis and schizophrenia are often distressing, the effects of the disorder can be pervasive. A significant number of people continue to experience long-term impairments, and as a result psychosis and schizophrenia can have a considerable effect on people’s personal, social and occupational lives. A European study of six countries found
that over 80% of adults with this diagnosis had some persistent problems with social functioning, though not all of them were severe. The best predictor of poorer functioning in the long term was poor functioning in the first 3 years post-diagnosis (Wiersma et al., 2000), particularly for unemployment, which was linked to duration of untreated psychosis and increased negative symptoms (Turner et al., 2009). Current estimates of employment for people with schizophrenia are 5 to 15% with an average of 8% (Schizophrenia Commission, 2012), which is significantly less than the general population (of which 71 % are currently employed).

The disabilities experienced by people with psychosis and schizophrenia are not solely the result of recurrent episodes or continuing symptoms. Unpleasant side effects of treatment, social adversity and isolation, poverty and homelessness also play a part. These difficulties are not made any easier by the continuing prejudice, stigma and social exclusion associated with the diagnosis (Sartorius, 2002; Thornicroft, 2006). As stated Norman Sartorius in an editorial for the British Medical Journal ‘stigma remains the main obstacle to a better life for the many hundreds of millions of people suffering from mental disorders’ (Sartorius, 2002). Different factors may contribute to maintain the stigma such as the mental health legislations (the use of compulsory treatment in the community), the side effect of medications (hyper-salivation, involuntary movements, sedation and severe weight gain) and the use of diagnostic labels by mental health workers.

Worldwide, it has been estimated that schizophrenia falls into the top fifteen medical disorders causing disability (WHO, 1990; Tandon et al., 2008; Murray et al., 2013). When the burden of premature mortality and non-fatal health outcomes are combined and expressed in disability adjusted life years (DALYs), schizophrenia is the 26th leading cause of worldwide burden among all diseases and the ninth leading cause of DALYs at ages 15–44 years (Murray and Lopez, 1996). Mortality among people with schizophrenia is approximately 50% above that of the general population. This is partly as a result of an increased incidence of suicide and violent death. The lifetime risk of suicide in the general population is approximately 0.5–1% (Roy, 1986; Caldwell and Gottesman, 1992), compared
to persons with schizophrenia which is approximately 15–25 times higher (Caldwell and Gottesman, 1992; Addington and Addington, 1992, WHO, 2005).

More recently Hor and Taylor, (2010) found an approximate lifetime suicide risk of 5% among patients with a diagnosis of schizophrenia. The high rate of mortality can also being explained by an increased risk of a wide range of physical health problems. Cardiovascular events have been found to be the largest single contributor (Lawrence et al., 2003; Hennekens et al, 2005; Osborn et al., 2007), with illnesses associated with obesity, metabolic aberrations, smoking, alcohol, lack of exercise, poor diet and diabetes, making significant contributions (Holt and Peveler, 2009; Dickerson et al., 2006; Homel et al., 2002; Pearsall et al., 2016; Sokal et al., 2004; Dembling et al., 1999; von Hausswolff- Juhlin et al., 2009). The precise extent to which high mortality and disability rates are, at least in part, a result of some of the medications prescribed for schizophrenia is still not clear (Weinmann et al., 2009). Difficulties experienced by people with mental health problems in accessing general medical services in both primary and secondary care continue to contribute to reduced life expectancy (Lawrence and Kisely, 2010).

Despite affecting only up to 1% of the population, schizophrenia is one of the main contributors to global disease burden (Collins et al., 2011), having a significant impact on patients, family members, friends and placing heavy responsibility on their carers, as well as potentially large demands on the healthcare system. The direct and indirect costs associated with schizophrenia has been estimated for a number of countries including Australia (Andrews, 1991; Carr et al, 2002; 2003), Belgium (De Hert et al., 1998), Canada (Goeree et al., 1999; 2004), Denmark (Knapp et al., 2002), France (Rouillon, 1997), Germany (Kissling et al., 1999; Salize and Rossler 1996), Hungary (Rupp et al., 1999), Italy (Moscarelli et al., 1991; Amaddeo et al., 1997), The Netherlands (Evers and Ament, 1995; Meerdink et al., 1998), Norway (Rund, 1995; Rund and Ruut, 1999), Spain (Knapp et al., 2002), Sweden (Hertzman, 1983), the United Kingdom (Rupp and Keith, 1993; Knapp et al., 2002; Mangalore and Knapp, 2007; Guest and Cookson, 1999) and the United States (Rice and Miller, 1998).
Figure 2.1 National total, direct and indirect, costs of schizophrenia.

<table>
<thead>
<tr>
<th>Country</th>
<th>Source</th>
<th>Year of costing</th>
<th>Total National currency units</th>
<th>National currency units</th>
<th>Costs Direct</th>
<th>As percent of national health expenditure</th>
<th>Indirect National currency units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Hall et al. 1985</td>
<td>1976&lt;sup&gt;2&lt;/sup&gt;</td>
<td>$139 million</td>
<td>$24.6 million</td>
<td>-</td>
<td>$114.3 million</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Andrews 1991</td>
<td>1990&lt;sup&gt;2&lt;/sup&gt;</td>
<td>$69.5 million</td>
<td>$12.8 million</td>
<td>-</td>
<td>$56.7 million</td>
<td>-</td>
</tr>
<tr>
<td>Belgium</td>
<td>De Hert et al. 1998&lt;sup&gt;6&lt;/sup&gt;</td>
<td>1994</td>
<td>-</td>
<td>$304.0 million</td>
<td>1.9</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Canada</td>
<td>Goeree et al. 1999</td>
<td>1996</td>
<td>$2.35 billion</td>
<td>$1.12 billion&lt;sup&gt;4&lt;/sup&gt;</td>
<td>-</td>
<td>$1.23 billion</td>
<td>-</td>
</tr>
<tr>
<td>Danmark</td>
<td>Lund 1994</td>
<td>1992</td>
<td>$562 million</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>France</td>
<td>Roulton et al. 1997</td>
<td>1992</td>
<td>Fr17.6 billion</td>
<td>Fr12.4 billion</td>
<td>2.0</td>
<td>Fr5.2 billion</td>
<td>-</td>
</tr>
<tr>
<td>Germany</td>
<td>Ptaszker 1987</td>
<td>1993</td>
<td>DM8 billion</td>
<td>DM4.1–8.7 billion</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Osterheider et al. 1998</td>
<td>1993</td>
<td>DM12.3–26 billion</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td></td>
<td>Klasing et al. 1999</td>
<td>1995</td>
<td>DM3.5–10 billion</td>
<td>DM1.1–2.4 billion</td>
<td>-</td>
<td>DM7.4–15.7 billion</td>
<td>-</td>
</tr>
<tr>
<td>Hungary</td>
<td>Rupp et al. 1999</td>
<td>NA</td>
<td>P25.63 billion</td>
<td>E18.81 billion</td>
<td>-</td>
<td>F115.82 billion</td>
<td>-</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Evers and Ameti 1995</td>
<td>1999</td>
<td>843.7 million</td>
<td>776.0 million</td>
<td>2.0</td>
<td>65.6 million</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Meerting et al. 1998</td>
<td>1994</td>
<td>-</td>
<td>800.0 million</td>
<td>1.4</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Norway</td>
<td>Rund 1996</td>
<td>1994</td>
<td>NOK1.35 billion</td>
<td>NOK1.18 billion</td>
<td>-</td>
<td>NOK1.7 billion</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Rund and Ruid 1999</td>
<td>1994</td>
<td>-</td>
<td>NOK1.2 billion</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>Rubio-Stipec 1994</td>
<td>1994</td>
<td>$265.1 million</td>
<td>$36.1 million&lt;sup&gt;5&lt;/sup&gt;</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$350 million&lt;sup&gt;3&lt;/sup&gt;</td>
<td>$19.56 million&lt;sup&gt;6&lt;/sup&gt;</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sweden</td>
<td>Jönnson and Wallinder 1994</td>
<td>1990</td>
<td>SEK12 billion</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>U.K.</td>
<td>Davies and Drummond 1994</td>
<td>1990/91</td>
<td>£2.1 billion</td>
<td>£366.0 million</td>
<td>1.6</td>
<td>£1.7 billion</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Knapp 1997</td>
<td>1992/93</td>
<td>£2.4 billion</td>
<td>£80.0 million&lt;sup&gt;7&lt;/sup&gt;</td>
<td>2.8</td>
<td>£1.8 billion</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Guest and Cockson 1999&lt;sup&gt;8&lt;/sup&gt;</td>
<td>1997</td>
<td>£17.5 million</td>
<td>£86.2 million</td>
<td>-</td>
<td>£84.3 million</td>
<td>-</td>
</tr>
<tr>
<td>U.S.</td>
<td>Gunderson and Mosher 1975</td>
<td>1975</td>
<td>$111.6–195 billion</td>
<td>$2–4 billion</td>
<td>-</td>
<td>$8.5–11.4 billion</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Rice and Miller 1996</td>
<td>1985</td>
<td>$220.0 billion</td>
<td>$111.1 billion</td>
<td>3.0</td>
<td>$11.6 billion&lt;sup&gt;9&lt;/sup&gt;</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Rice and Miller 1996</td>
<td>1990</td>
<td>$325.0 billion</td>
<td>$17.3 billion</td>
<td>2.5</td>
<td>$15.2 billion&lt;sup&gt;9&lt;/sup&gt;</td>
<td>-</td>
</tr>
</tbody>
</table>

Source: Knapp et al., 2004

Comparing the direct and indirect (or productivity) cost estimates for schizophrenia across countries can be difficult because of the differences in incidence and prevalence rates, the availability of programs and services, the organization of the delivery systems, relative prices, physician and clinic practice patterns, the range of costs included in the analysis, and costing methodologies (Chong et al., 2016). Despite differences in data sources and costing methodology, the direct cost estimates of schizophrenia have been relatively
similar across the countries, ranging from 1.5% to 3% of national healthcare expenditures (Rupp and Keith, 1993; Rice and Miller, 1996; De Hert et al., 1998; Rouillon et al., 1997; Evers and Ament, 1995; Meerding et al., 1998; Knapp, 1997; Davis and Drummond, 1994). Direct costs usually cover expenditures for hospital and nursing home care, physician and other professional services, drugs and appliances and are generally estimated as the product of the number or amount of services used and the unit price or charge. In 2004, Knapp and colleagues systematically reviewed the existing international literature about costs of schizophrenia worldwide (Figure 2.1). Authors concluded that despite the large heterogeneity of estimates, inpatients admission resulted to be the largest contributor to the direct costs of treating schizophrenia, sometimes accounting for over the 50% of mental health costs (Davis and Drummond, 1994; Kavanagh et al., 1995; Guest and Cookson, 1999; De Hert, 1998, Carr et al., 2003). Different results were found in an Italian study (Garattini et al., 2004) which separately analyzed the direct costs of schizophrenia and related disorders in 14 CMHCs (7 in from the north of Italy and 7 from the South; total sample= 643 patients). The authors interestingly found that, despite the large heterogeneity of estimates, inpatients admission resulted to be the largest contributor to the direct costs of treating patients with related psychotic disorders than schizophrenia, accounting for over the 30% of mental health costs (Garattini et al., 2004). In contrast, patients with schizophrenia resulted to receive more care in community RFs (they represented the 13.7% of the schizophrenic sample compared to the 8.9% of patients with related psychotic disorders). For patients with a diagnosis of schizophrenia, the main component of the total direct costs was residential treatment (47.7%), followed by inpatient admissions (19.9%). Similar results were showed by Lora and colleagues (2009) who found that residential care in 2001 accounted for 42% of total costs of schizophrenia, despite involving only 7% of these patients. These findings replicated and showed a substantial increase compared with the results of Tarricone and colleagues (2000) who demonstrated that patients suffering from schizophrenia and living in RFs represented almost the 20% of the total direct costs of schizophrenia in 10 Italian CMHCs.
On the contrary, indirect costs are associated with the lost productivity due to morbidity and premature mortality, pension and other income support payment and the family impact costs. In a five country European study, Magliano and colleagues (1998), reported that family caregivers for adults with schizophrenia spent on average from six to nine hours per day providing support (Magliano et al., 1998). Relatives reported mainly constraints on social activities, negative effects on family life and feeling of loss. Taking care for people with schizophrenia impose additional costs through household expenditure, travel costs or lost earnings for those who care for them. In spite of these costs constitute a small proportion of the total costs of schizophrenia, their impact on some families can be large.

From a government and societal perspective, schizophrenia is also associated with high non-healthcare costs which are represented by the criminal justice system costs. The association between violence and schizophrenia and other psychoses has been extensively examined in literature. There are wide variations in risk ratios reported from different studies, with estimates ranging from seven-fold increases in violent offending in schizophrenia compared with general population controls (Tiihonen et al., 1997; Mullen et al., 2000) to no association in a highly influential prospective investigation (Steadman et al., 1998). In a recent systematic review and meta-analysis by Fazel et al. (2009), schizophrenia and other psychoses have been found to be associated with violence and violent offending, particularly homicide. The costs of policing, investigations, legal defense, prosecution and incarceration, as well as victim costs (damages, lost property, time away from work because of emotional and physical injury) have therefore to be included in estimates of societal costs of schizophrenia.

2.1.4 Course, recovery rate and predictors of outcomes in schizophrenia

In the last quarter of the 20th century, evidence for a more promising long-term course of schizophrenia accumulated across studies (Ciompi, 1980; Shepherd et al., 1989; Jaaskelainen et al., 2013). Different long-term follow-up studies were commissioned by the World Health Organization (WHO) in order to examine clinical and social outcomes of schizophrenia in wide incidence and prevalence
cohorts of patients (Jablensky et al., 1992; Wiersma, 1996; Sartorius et al., 1996). Findings from these studies suggested that, over periods of 20 to 40 years, there is a moderately good long-term global outcome in over half of people with schizophrenia, with a smaller proportion (between 18% and 22%) having extended periods of remission of symptoms without further relapses (Hegarty et al., 1994; Gaebel & Frommann 2000; Harrison et al., 2001; Jobe & Harrow, 2005). It should also be noted that some people who never experience complete recovery from their experiences nonetheless manage to sustain an acceptable QoL if given adequate support and help. An ICD-10 diagnosis of schizophrenia resulted to be consistently associated with poorer outcomes in symptoms, social disability and resources utilization compared to people diagnosed with other psychotic disorders (Harrison et al., 2001; Lang et al., 2013). The risk of rehospitalisation and relapses is high during the first five years of illness onset and is generally followed by a plateau (Mason et al., 1996).

Furthermore, accordingly to McGlashan (1988), also these studies found that functional deterioration after five-ten years relented somewhat. Short-term course of illness strongly predicted long-term outcome, even if local environment played a significant role in determining both symptoms and social disabilities. Particularly, the percentage of time experiencing psychotic symptoms in the first two years of illness onset was the strongest predictor of both symptoms and disability. A number of social and economic factors also appear to affect the course of schizophrenia. For example, in developed countries it is well established that schizophrenia is more common in lower socio-economic groups. However, this appears to be partly reversed in some developing countries (Jablensky et al., 1992), suggesting that the relationship between incidence, recovery rates and cultural and economic factors is more complex than a simple correspondence with socio-economic deprivation (Warner, 1994).

Overall, data showed that early poor outcome, symptoms and deficits predict unfavorable long-term outcomes (Harrison et al., 2001). A more recent review and meta-analysis from literature based on fifty naturalistic studies (Jaaskelainen et al., 2013) found that the proportion of individuals with
schizophrenia who met recovery criteria was 13.5%. This proportion is very small compare to those found in long-term follow-up studies. The great variance observed could be due to different factors such as diagnostic inclusion criteria, length of follow-up periods and criteria used to define ‘recovery’.

Irrespective of the agreement on recovery rate, all these studies showed that in schizophrenia the disease process seemed to be most active at onset and early in its manifest course, suggesting the existence of a ‘critical window’ in the early period of syndromal differentiation. Thus, the provision of early intervention programmes and intensive engagement strategies in this ‘window of opportunity’ may have favorable impact upon the evolution of symptoms over the years, at least, for some patients (Harrison et al., 2001).

If accomplishing symptomatic and functional remission is one of the major objectives of treating individuals with a first episode of schizophrenia (Andreasen et al., 2005; Harvey and Bellack, 2009) with a final objective of functional recovery, recognizing and amending socio-demographic, premorbid and clinical factors associated with the likelihood of achieving remission would be of great value in order to improve the outcome of the illness. In this regard, the identification of modifiable predictors may allow designing appropriate interventions to improve the outcome and likelihood of remission. Likewise, the recognition of predictors of non-remission may help to identify non-remitter subjects in which the intervention should be intensified. Different factors have been identified as predictors of worse treatment outcomes in literature. These include: male gender (Simonsen et al., 2007; Albert et al., 2011; Chang et al., 2012), low level of education (Whitty et al., 2008; Allot et al., 2011; Ayesa-Arriola et al., 2013), early age at illness onset (Malla et al., 2006; Crespo-Facorro et al., 2007; Tandon et al., 2009; Albert et al., 2011), a family history of psychosis (Fanous and Kendler, 2005; Crespo-Facorro et al., 2013), poor insight (Schennach-Wolff et al., 2011), a diagnosis of schizophrenia (Crespo-Facorro et al., 2007; Ayesa-Arriola et al., 2013), poor adherence to medication (Malla et al., 2006), poor premorbid functioning (Crespo-Facorro et al., 2007; Jeppesen et al., 2008; Allot et al., 2011; Albert et al., 2011; Ayesa-Arriola et al., 2013), the
presence of neurocognitive deficits such as memory, attention and processing speed impairments (Allot et al., 2011; Neuetherlein et al., 2011; Peña et al., 2012) and a long duration of untreated psychosis (DUP) (Addington and Addington, 2008; Schimmelmann et al., 2008; Jeppesen et al., 2008; Whitty et al., 2008; Chang et al., 2012; Crespo-Facorro et al., 2013). As regard to psychopathology, some studies have demonstrated an association between the severity of psychopathology at baseline and illness outcomes, in sense that higher symptoms at baseline predict worse outcomes (Hatta et al., 2003; ten Velden Hegelstad et al., 2013).

2.2 Treatment and management of schizophrenia in the NHS

Until the 1950s, the treatment and management of schizophrenia generally took place in large asylums, where people remained confined for much of their lives. Although government policy initiated a programme of gradual closure of these large hospitals and the rehousing of the residents in the community, this process was greatly assisted by the introduction of antipsychotic drugs, such as chlorpromazine, thioridazine, and haloperidol. Antipsychotic medication would become the mainstay of treatment for the rest of the twentieth century.

2.2.1 Pharmacological treatment

Today, within both hospital and community settings, antipsychotic medicines remain the primary treatment for schizophrenia. There is well-established evidence for their efficacy in both the treatment of acute psychotic episodes and relapse prevention over time (Janicak et al., 1993). However, despite this, considerable problems remain. Up to 40% of service users have a poor response to conventional antipsychotic drugs, and continue to show moderate to severe positive and negative psychotic symptoms (Klein and Davis, 1969; Kane et al., 1996). In addition, conventional or typical antipsychotic agents (more recently called first-generation antipsychotics) are associated with a high incidence and broad range of side effects, including lethargy, sedation, weight gain and sexual dysfunction. Movement disorders, such as parkinsonism, akathisia, dystonia, often referred to as acute extrapyramidal side effects, are common and can be disabling.
and distressing. A serious long-term side effect is tardive dyskinesia, which develops in around 20% of people receiving first-generation antipsychotic drugs (Kane et al, 1985). Although a person who develops tardive dyskinesia is usually unaware of the movements, they are clearly noticed by others, and the condition has long been recognised as a severe social handicap (Barnes & Kidger, 1978). In response to the limited effectiveness and extensive side effects of first-generation antipsychotics, considerable effort has gone into developing pharmacological treatments for schizophrenia that are more effective and produce fewer or less disabling side effects. The main advantage of these second-generation (‘atypical’) antipsychotics appears to be that they have a lower liability for acute extrapyramidal side effects and tardive dyskinesia. However, in practice this must be balanced against other side effects, such as weight gain and other metabolic problems that may increase the risk of type-2 diabetes and cardiovascular disease (American Diabetes Association, 2004; Lindenmayer et al., 2003; Mackin et al., 2007; Nasrallah, 2003, 2008; Suvisaari, 2007).

2.2.2 Psychological and psychosocial interventions

The use of specific psychological and psychosocial methods to helping people with schizophrenia is relatively recent. Some of the earliest attempts included psychoanalysis (Fromm-Reichman, 1950), and a modification of psychoanalysis designed to enhance better integration into a hospital environment (Stack-Sullivan, 1947). These pioneering efforts increased awareness of the psychological processes and personal impact of schizophrenia. Since then a number of other psychological approaches have been introduced. For example, social skills training, developed in the 1970s, was derived from the recognition of the social difficulties that many people with schizophrenia face, especially those in institutions, and used methods popular at the time, based on learning theory and behaviourism (Shepherd, 1978). As deinstitutionalisation gained ground in the 1970s, psychological and social research into factors that might contribute to relapse in people living in community settings, such as stressful life events and communication difficulties in families (high expressed emotion), stimulated the development of family interventions to prevent relapse (Leff et al., 1982). Family
interventions often included education for family members about schizophrenia (sometimes called ‘psychoeducation’), and in time, research was conducted on the benefits of ‘psychoeducation’ alone. By 1980s, cognitive behavioural therapy (CBT) approaches, originally developed in the 1970s for depression, were first applied to helping to reduce distressing psychotic symptoms and then broadened to work with emotional problems and functioning (Garety et al., 2000). Cognitive remediation therapy, was also developed between 1980 and 1990, and differs from CBT in that it is not directed at distressing symptoms but is instead focused on training in cognitive functions such as learning, planning, attention or memory (Green, 1993). A specific cognitive behavioural approach that aims to enhance compliance with medication was also developed towards the mid 1990s, and is commonly known as ‘adherence therapy’ (Kemp et al., 1996). Counselling and supportive psychotherapy as well as various forms of group therapy and ‘milieu’ therapy have long been practised with this client group. Finally, the four arts therapies that emerged as organised professions in the middle of last century, have in recent years begun to be evaluated formally in trials (Crawford and Patterson, 2007).

2.2.3 Service-level interventions and models

Service-level interventions for people with schizophrenia include both ‘inpatient’ services and a variety of community team models. According to recent figures, services for people with schizophrenia account for 24% of the NHS spend on mental health in United Kingdom (MIND, 2005). Two-thirds of that spend is on inpatient care where people with schizophrenia use over 60% of the provision (Knapp, 1997). Inpatient services comprise a range of statutory, independent and third sector provision ranging in degree of restriction and cost from high-secure hospitals, medium-secure and low-secure units for mentally disordered offenders, through to intensive care, acute beds and rehabilitation units. The rates of use, care models and outcomes vary widely in these settings and there is no substantial evidence base for the optimal model, although a range of national regulators and peer review networks describe architectural ‘healing’ designs, standards and care pathways (Waller and Finn, 2004). Service-level interventions in the community
include, most commonly, psychiatric outpatient clinics, generic locality Community Mental Health Teams, case management, acute day hospital care and non-acute day centre care.

Accordingly to Singh and Fisher (2005), there are three basic models whereby early intervention can be provided in the community: by enhancing existing community mental health teams; using a ‘hub and spoke’ model; and by a stand-alone early intervention service. The first model involves generic services adopting the principles of early intervention for the treatment of patients with first-episode psychosis either through education of the whole team or by employing a specialist worker. Although this can be an inexpensive option (Whitwell, 2001), particularly in rural areas (Craig 2003), it does not necessarily ensure specific and optimal treatment for this client group. The second model consists of a central specialist service (the ‘hub’) that supports existing generic teams by providing specialist input (the ‘spokes’) for individual patients. This requires fewer resources than a stand-alone team and could be a useful stepping-stone for fledgling services. However, there is potential for uncertainty and confusion regarding each service’s responsibility for these patients, together with a disruption of continuity of care. The stand-alone early intervention service is advocated as the gold standard for the United kingdom (Department of Health, 2001). This ensures provision of a comprehensive early intervention package delivered by dedicated and trained staff. However, it is resource intensive, may result in the loss of a single point of entry into mental health services and has implications for continuity of care when its time-limited intervention has expired.

2.3 The development of early psychosis intervention services

In the 1990s, three emerging and interwoven strands of evidence supported the case for specialized early intervention services. The early stages of schizophrenia are often characterized by repeated exacerbation of symptoms such as hallucinations and delusions and disturbed behaviour. While a high proportion respond to initial treatment with antipsychotic medication, around 80% will
relapse within 5 years of a treated first episode, which is partly explained by discontinuation of medication (Robinson et al., 1999, 2002; Nadeem et al., 2004).

The existence of an early window of opportunity, ‘the critical period’, was postulated on the basis of strong evidence that early trajectory and disability were strongly predictive of long-term course and outcome (Wiersma et al., 1998; Harrison et al., 2001) and the greatest impact on the illness might be made during this period of neuronal and psychosocial plasticity (Birchwood et al., 1998). Evidence from literature showed that an early involvement in a progressive therapeutic programme incorporating social and psychological interventions as well as medication might be an important factor in realising long-term gains (Harrison et al., 2001; Linszen et al., 2001; de Haan et al., 2003). Research has also suggested that delayed access to mental health services in early schizophrenia (DUP) is associated with slower or less complete recovery, and increased risk of relapse and poorer outcome in subsequent years (Harrigan et al., 2003; Bottlender et al., 2003). It became also clear that even well-resourced community services were not meeting the needs of young people in their first psychotic episode and had not improved their outcomes (Singh et al., 2003). Politically, an important lever for change was pressure from service users and their carers determined to tackle the ‘scandal of delays in care’ for young people with emerging psychosis (RETHINK, 2002). The policy for developing early intervention services was therefore mainly based not on the ‘best possible’ evidence for their effectiveness but the ‘best available’ evidence that early psychosis was being inadequately treated by generic teams.

‘Early intervention’ is primarily concerned with two types of strategies of identification and initial treatment of people with psychotic illnesses such as schizophrenia. Early interventions may be directed either at people in the prodromal phase of the illness (‘primary prevention’) or at those who have already developed psychosis (‘secondary prevention’).

Primary prevention aims at ameliorating patients risk symptoms, reducing the duration of untreated psychosis if psychosis develops, when possible
preventing the transition to psychosis or at postponing at all the onset of the illness (Yung et al., 1996). Prevention strategies include information campaigns, pharmacological treatment; psycho-educational interventions and individual cognitive behavioral therapy (CBT). Usually information campaigns aim to teach the public about the recognition of early signs of severe mental illness and the importance of getting help early, to provide targeted educational programs for teacher and general practitioner’s about prodromal signs, and provide targeted educational programs in specialized mental health services to learn then to recognize possible prodromal individuals. Psycho-educational interventions inform patients and families about current problems, how to understand and cope with them, and finally individual cognitive behavioral therapy (CBT) allows to deal with social/cognitive distortions and deficits in order to maintain real world investment. Results from studies suggested that receiving treatment in the phase ‘at risk’ was associated with a lower risk of developing psychosis at six, twelve and eighteen months. Similar conclusion are sustained by two more recent reviews which however questioned the long-term effectiveness of such strategies (Preti and Cella, 2010; NICE, 2009). Hence, further evidence is needed before recommendations could be given.

From an economical point of view, cost-effectiveness studies are still missing. In the past years Valmaggia et al. (2009) compared the costs of the Outreach And Support In South London, a clinical service for ‘at risk psychosis people’, with the costs of treatment for people who experience a first episode psychosis without having had prior contact with specialized mental health services. Data showed that during the first year the per-person costs were higher for early detection services (£2.596 vs £724). However, over the period of two years the costs of early detection progressively decreased due to the reduced number of hospitalization and increased time spent working of people at risk (£4.396 vs £5.357).

Secondary prevention refers to early interventions provided soon after the onset of psychosis. Onset could be defined as related not only to positive or negative symptoms, but also to the onset of a syndrome with specific criteria of
symptom combinations and duration (Larsen et al., 2001). The onset of positive symptoms has been reported to be more reliable than negative symptoms (Beiser et al., 1993), but thorough studies of the early course of illness have shown that about 70% of the patients with schizophrenia develop negative symptoms before positive symptoms (Hafner et al., 1992). Central to the rationale for this type of early identification is the concept of DUP. A number of researchers have reported that the longer the psychosis goes untreated, the poorer the prognosis becomes (for example, Loebel et al., 1992). This finding has led them to argue that new services are required to reduce the length of time people with psychosis remain undiagnosed and untreated. Moreover, these researchers have argued that such services should offer specialised, phase-specific treatment to their users, to maximise their chances of recovery. Finally, tertiary prevention refers to the possibility to provide effective treatments for a long enough period of time after the onset of psychosis (Birchwood, 1992, Herz and Lamberti, 1995) in order to prevent relapses (Herz and Lamberti, 1995). In this sense tertiary prevention is not a real early intervention strategy but has more to do with the need to guarantee an adequate treatment to people suffering of psychosis (Figure 2.2).

Figure 2.2 The early course of schizophrenia

![Figure 2.2 The early course of schizophrenia](source: Larsen et al., 2001)
2.4 Early interventions in first episode psychosis and their effectiveness

Pharmacological interventions have been the mainstay of treatment of schizophrenia since their introduction in the 1950s, bringing important improvements in the care and management of individuals suffering schizophrenia. Despite the significant advances made, there is a growing awareness that medication alone is not sufficient for the treatment of schizophrenia in many cases. Some limitations concerning pharmacological interventions include limited response of some people to antipsychotic medication, high incidence of disabling side-effects (such as weight gain, mellitus, an atherogenic lipid profile) and poor adherence to treatment. Furthermore, many patients continue to experience persistent and distressing psychotic symptoms despite appropriate doses of medication. Psychosis is also associated with an increased risk of associated emotional disturbance and this is reflected in the prevalence of comorbid depression, anxiety and elevated risk of suicide which characterized lots of patients diagnosed with schizophrenia in comparison to the general population (Henry et al., 2007). In addition there is a significant degree of social disability associated with this disorder that is not (and cannot) be addressed by use of medication alone. This includes the disability associated with persistent symptoms and associated emotional disturbances, but also reflects problems such as isolation, difficulties in finding suitable accommodations and work.

Over the past three decades there has been also a growing recognition of the importance of psychological processes in psychosis, both as contributors to onset and persistence, and in terms of the negative psychological impact of a diagnosis of schizophrenia on the individual’s well-being, psychosocial functioning and life opportunities. These factors have contributed to the develop of psychological therapies and psychosocial interventions as additional treatment of schizophrenia (generally in combination with antipsychotic medication).

Recently, emphasis has also been placed on the value of multi-disciplinary formulation and reflective practice, particularly where psychologists and allied
mental health professionals operate within multidisciplinary teams (BPS, 2007). The ‘New Ways of Working’ report (BPS, 2007) also details the increasing demand by both service users and carers to gain access to psychological interventions, and the increasing recognition of these interventions in the treatment and management of serious mental illnesses including schizophrenia.

Although the rationales for medical, psychological and psychosocial interventions are derived from a variety of different biological, psychological and social theories, the development of the stress-vulnerability model (Zubin & Spring, 1977; Nuechterlein, 1987) has undoubtedly facilitated the theoretical and practical integration of disparate treatment approaches. In this model, individuals develop vulnerability to psychosis attributable to biological psychological and/or social factors; treatments, whether pharmacological or psychological treatments then aim to protect a vulnerable individual and reduce the likelihood of relapse, reduce the severity of the psychotic episode and treat the problems associated with persisting symptoms. Psychological interventions may, in addition, aim to improve specific psychological or social aspects of functioning and to have a longer-term effect upon an individual’s vulnerability. Particularly these treatments are tailored to improve one or more of the following outcomes: to decrease the person’s vulnerability; reduce the impact of stressful events and situations; decrease distress and disability; minimize symptoms; improve the QoL; reduce risk; improve communication and coping skills; and/or enhance treatment adherence. Research into psychological interventions needs to address a wide range of outcomes, as far as possible.

Clinical guidelines recommended to use an early and integrated approach based on combining two or more psychological and/or psychosocial interventions in order to increase the effectiveness of the intervention (APA, 2004; OYH, 2008; NICE, 2009). The combinations are various and thus these ‘multi-modal’ or ‘multi-element’ interventions do not form a homogenous group of interventions. Different types of psychological interventions are available.
2.4.1 Adherence therapy

Pharmacological interventions are the primary treatment for schizophrenia. Nevertheless, about 50% of people with schizophrenia and schizophrenic-form disorder resulted to be non-adherent (or non-compliant) to their medication (Nosè et al., 2003) and this expose them to a higher relapse risk and repeated hospital admissions increasing the economic and social burden for the service users themselves as well as for the mental health services (Gray et al., 2006; Robinson et al., 1999). ‘Compliance therapy’ was first developed by Kemp and colleagues targeting service users with schizophrenia and psychosis with the aims to improve service users’ attitude to medication and treatment adherence, enhance their clinical outcomes and prevent potential and future relapse (Kemp et al., 1996; 1998). Recently, the terms ‘adherence’ and ‘concordance’ have been used synonymously to denote ‘compliance therapy’ and its major aim, that is, adherence to medication (McIntosh et al., 2006). Overall, ‘adherence therapy’ is the commonly accepted term used. It is a brief intervention borrowing techniques and principles from motivational interviewing (Miller & Rollnick, 1991), psychoeducation and cognitive therapy (Kemp et al., 1996). A typical adherence therapy course usually comprises four to eight sessions, each lasting roughly from thirty minutes to an hour (Kemp et al., 1996; Gray et al., 2006). The intervention uses a phased approach in order to i) assess and review the service user’s illness and medication history; ii) explore his or her ambivalence to treatment, maintenance medication and stigma; iii) conduct a medication problem-solving exercise to establish the service user’s attitude to future medication use. Evidence of adherence therapy’s effectiveness is limited and mainly come from the work of Kemp and colleagues (1996). The improvements in measures of compliance and insight they found, has not been supported by other studies including those with follow-up measures. Actually, adherence therapy seemed to not have an effect on symptoms, QoL, relapse or rehospitalisation.

2.4.2 Art therapies

Arts therapies are complex interventions which combine psychotherapeutic techniques with activities aimed at promoting creative
expression. The arts therapy professions in the US and Europe have their roots in late nineteenth and early twentieth century hospitals where involvement in the arts was used by patients and interested clinicians as a potential aid to recovery. Art therapy, music therapy, drama therapy and dance movement therapy, all, focus on the creation of a working therapeutic relationship in which strong emotions can be expressed and processed. The art form is also seen as a safe way to experiment with relating to others in a meaningful way when words can be difficult. A variety of psychotherapeutic theories are used to understand the interactions between patient and therapist but psychodynamic models tend to predominate (Crawford and Patterson, 2007). More recently, arts therapy approaches to working with people with psychosis have begun to be more clearly defined, taking into consideration the phase and symptomatology of the illness (Gilroy and McNeilly, 2000; Jones, 1996). Results from some RCTs studies (Green et al., 1987; Talwar et al., 2006; Richardson, 2007; ) found that, compare to ‘treatment as usual’, arts therapies are effective in reducing negative symptoms and these medium to large effects are sustained at up to six months follow-up. Additionally, there is consistent evidence to indicate that their effectiveness is unconnected to the modality used within the intervention (music, movement or art), and that arts therapies are equally as effective in reducing negative symptoms in both inpatient and outpatient populations.

2.4.3 Cognitive-behavioural therapy (CBT)

CBT is based on the assumption that there is a relationship between thoughts, feelings and behaviour. Most Cognitive Therapy (CT) has its origins in the work of Aaron T Beck who, in the 1970s, developed CBT for the treatment of depression (Beck., 1979). CBT has been found to be an effective treatment in a wide range of mental health problems including anxiety, obsessive compulsive, post-traumatic stress disorder and bulimia nervosa. In the early 1990s, on the back of an increased understanding of the cognitive psychology of psychotic symptoms (Slade and Bentall, 1988; Frith, 1992; Garety and Hemsley, 1994), interest grew in the application of CBT for people with psychotic disorders. Early CBT trials were particularly symptom focused, helping service users develop coping
strategies to manage hallucinations (Tarrier et al., 1993). CBT for psychosis (CBTp) has evolved and now tends to be formulation-based. The general aim is to help the individual normalise and make sense of their psychotic experiences and to reduce the associated distress and impact on personal and social functioning. CBTp trials have investigated a range of outcomes over the years; these include symptom reduction (positive, negative and general symptoms) (Rector et al., 2003), relapse reduction (Garety et al., 2008), social functioning (Startup et al., 2004), and insight (Turkington et al., 2002). More recently researchers have shown an interest in the impact of CBTp on changes in distress and problematic behaviour associated with these experiences (Trower et al., 2004). Furthermore, the populations targeted have expanded, with recent developments in CBTp focusing on the treatment of first-episode psychosis (Jackson et al. 2008; 2009) and people with schizophrenia and co-morbid substance use disorders (Barrowclough et al. 1997). Evidence from a recent review on 31 CBTp trials (NICE, 2009) showed that CBT is effective in reducing: rehospitalisation rates (up to 18 months following the end of treatment), the duration of hospitalisation (of 8.26 days on average), symptom severity (both at the end of the treatment and also overtime). Robust small to medium effects has been also demonstrated for reductions in depression when comparing CBT to both standard care and other active treatments (NICE, 2009). Furthermore, when compared to any control, there is some evidence for improvements in social functioning up to 12 months.

Evidence for positive symptoms is however more limited; data demonstrate some consistent effect for symptom specific measures including voice compliance, frequency of voices and believability. On the contrary, the evidence on the efficacy on delusions is still inconsistent (NICE, 2009).

Given the interest that this type of intervention has raised, some studies have tried to assess cost-effectiveness of CBT for people with schizophrenia (Kuipers et al., 1998; Startup et al., 2005). Kuipers and colleagues (1998) evaluated the cost-effectiveness of CBT added to standard care compared to standard care alone in 60 people with medication-resistant psychosis participating in a RCT conducted in the UK (Kuipers et al., 1998). The time horizon of the
analysis was 18 months (RCT period plus naturalistic follow-up). The study estimated NHS costs (inpatient, outpatient and day-hospital care, primary and community services) and costs associated with specialist, non-domestic accommodation. Medication costs were not considered. The primary outcome of the analysis was the mean change in BPRS score. CBT was shown to be significantly more effective than its comparator in this aspect, with the treatment effect lasting 18 months after the start of the trial.

The costs between the two treatment groups were similar: the mean monthly cost per person over 18 months was £1,220 and £1,403 for CBT added to standard care and standard care alone, respectively ($p=0.416$, 1996 prices). The study had insufficient power to detect significant differences in costs. The authors suggested that CBT might be a cost-effective intervention in medication-resistant psychosis, as the clinical benefits gained during the nine months of CBT were maintained and even augmented 9 months later, while the extra intervention costs seemed to be offset by reduced utilisation of health and social care services. More recently, Startup and colleagues (2004) conducted a cost-consequence analysis to measure the cost-effectiveness of CBT on top of Treatment As Usual (TAU) versus TAU alone in 90 people hospitalised for an acute psychotic episode participating in a RCT in North Wales (Startup et al., 2004). The time horizon of the analysis was 2 years; the perspective was that of the NHS and Personal Social Services. Costs included hospital care, primary and community care, medication and residential care. Health outcomes were measured using the Scale for the Assessment of Positive Symptoms, the Scale for the Assessment of Negative Symptoms, the Social Functioning Scale and the GAF scale. CBT showed a significant effect over control in Scale for the Assessment of Negative Symptoms and Social Functioning Scale scores, at no additional cost: the mean cost per person over 24 months was £27,535 for the CBT group and £27,956 for the control group. The study had insufficient power for economic analysis. These results indicate that CBT could be potentially a cost-effective intervention for people with acute psychosis or medication-resistant schizophrenia. However, the study samples were very small and insufficient to establish such a hypothesis with certainty. The guideline meta-analysis of CBT data on hospitalisation rates
showed that providing CBT in addition to standard care to people with schizophrenia significantly reduces the rate of future hospitalisations compared to people receiving standard care alone.

Figure 2.3 Studies considered in the economic analysis of CBT in addition to standard care versus standard care alone and results of meta-analysis.

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Country</th>
<th>Total events (n) in each treatment arm (N)</th>
<th>CBT plus standard care (n/N)</th>
<th>Standard care alone (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TARRIERI998</td>
<td>UK</td>
<td>16/33</td>
<td></td>
<td>9/28</td>
</tr>
<tr>
<td>BACH2002</td>
<td>non-UK</td>
<td>12/40</td>
<td></td>
<td>19/40</td>
</tr>
<tr>
<td>LEWIS2002</td>
<td>UK</td>
<td>33/101</td>
<td></td>
<td>37/102</td>
</tr>
<tr>
<td>TURKINGTON2002</td>
<td>UK</td>
<td>36/257</td>
<td></td>
<td>38/165</td>
</tr>
<tr>
<td>GUMLEY2003</td>
<td>UK</td>
<td>11/72</td>
<td></td>
<td>19/72</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td>108/503 (21.47%)</td>
<td></td>
<td>122/407 (29.98%)</td>
</tr>
</tbody>
</table>

Table 2.4 Results of cost analysis comparing CBT in addition to standard care versus standard care alone per person with schizophrenia.

<table>
<thead>
<tr>
<th>Costs</th>
<th>CBT plus standard care</th>
<th>Standard care alone</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBT cost</td>
<td>£1.072</td>
<td>0</td>
<td>£1.072</td>
</tr>
<tr>
<td>Hospitalisation cost</td>
<td>£6.526</td>
<td>£8.587</td>
<td>-£2.061</td>
</tr>
<tr>
<td>Total cost</td>
<td>£7.598</td>
<td>£8.587</td>
<td>-£989</td>
</tr>
</tbody>
</table>

Source: NICE, 2013.
The economic analysis (Figure 2.4) showed that CBT is likely to be an overall cost-saving intervention for people with schizophrenia as the intervention costs are offset by savings resulting from a reduction in the number of future hospitalisations associated with this therapy. The net cost of providing CBT was found to lie between −£2.277 (overall net saving) and £557 per person with schizophrenia (for a mean duration of hospitalisation of 110.6 days) or −£1.017 to £751 per person (for a mean duration of hospitalisation of 69 days), using the 95% Confidence Intervals of Risk Ratios of hospitalisation, as estimated in the guideline meta-analysis. It must be noted that possible reduction in other types of health and social care resource use and subsequent cost-savings to the NHS and social services, respectively, as well as broader financial implications to the society (for example, potential increased productivity) associated with provision of CBT to people with schizophrenia, have not been estimated in this analysis. In addition, clinical benefits associated with CBT, affecting both people with schizophrenia and their families/carers, such as symptom improvement and enhanced health-related QoL following reduction in future inpatient stays, should also be considered when the cost-effectiveness of CBT is assessed. Taking into account such benefits, even a (conservative) net cost of £751 per person can be probably justified.

2.4.4 Cognitive remediation

The presence of cognitive impairment in a proportion of people with schizophrenia has been recognised since the term was first coined (Bleuler, 1911).

The precise cause of these deficits (such as structural brain changes, disruptions in neuro-chemical functions or the cognitive impact of the illness and/or of medication) remains contentious, whereas progress on characterising the cognitive problems that arise in schizophrenia has been substantial. Major domains identified include memory problems (Brenner, 1986), attention deficits (Oltmanns and Neale, 1975) and problems in executive function, such as organisation and planning (Weinberger et al., 1988). An initiative to promote standardisation of methods for evaluating research on cognitive outcomes (the Measurement and Treatment Research to Improve Cognition in Schizophrenia
consensus panel (MATRICS; Neuchterlein et al., 2004) has identified eight more specific domains: attention/vigilance, speed of processing, working memory, verbal learning and memory, visual learning and memory, reasoning and problem solving, verbal comprehension and social cognition. Few studies as yet examine changes in all these domains. Cognitive impairment is strongly related to functioning in areas such as work, social relationships and independent living (McGurk et al., 2007). Because of the importance of cognitive impairment in terms of functioning, it has been identified as an appropriate target for interventions. Cognitive remediation programmes have therefore been developed over the past 40 years with the goal of testing whether direct attempts to improve cognitive performance might be more effective (McGurk et al., 2007). The primary rationale for cognitive remediation is to improve cognitive functioning, with some papers also stated improved functioning as an additional aim (Wykes and Reeder, 2005). Approaches adopted have ranged from narrowly defined interventions, which involve teaching service users to improve their performance on a single neuropsychological test, to the provision of comprehensive remediation programmes, increasingly using computerised learning (Galletly et al., 2000). The programmes employ a variety of methods, such as drill and practice exercises, teaching strategies to improve cognition, suggesting compensatory strategies to reduce the effects of persistent impairments and group discussions (McGurk et al., 2007). Early studies had mixed results (Pilling et al., 2002) there remains uncertainty as to which techniques should be used (Wykes and van der Gaag, 2001) and whether the outcomes are beneficial, both in terms of sustained effects on cognition and for improving functioning.

There was limited evidence suggesting that cognitive remediation when compared to standard care may improve social functioning. However, this effect was driven by a range of studies conducted by Velligan and colleagues (Velligan et al., 2000; Velligan et al., 2002; Velligan, 2008a, 2008b), in which the intervention was more comprehensive than typical cognitive remediation programmes in the UK, and included the use of individually tailored environmental supports to ameliorate areas in addition to basic cognitive functions. Other UK studies (Wykes et al., 1999; 2007a; 2007b), though well-
conducted, did not report evidence of improvement in social or vocational functioning or symptoms at either end of treatment or follow-up. Overall, there was no consistent evidence that cognitive remediation alone is effective in improving the critical outcomes, including relapse rates, rehospitalisation, mental state, and QoL. Recently reports of combinations of cognitive remediation with other psychosocial interventions such as social skills training or vocational interventions such as supported employment programmes have been increasing in the literature.

2.4.5 Counselling and supportive therapy

Supportive therapy has been cited as the individual psychotherapy of choice for most patients with schizophrenia (Lamberti and Hertz, 1995). It is notable that most trials involving this intervention have used it as a comparison treatment for other more targeted psychological approaches, rather than investigating it as a primary intervention. This may be because supportive therapy is not a well-defined unique intervention, has no overall unifying theory and is commonly used as an umbrella term describing a range of interventions from ‘befriending’ to a kind of formal psychotherapy (Buckley, et al. 2007). More formal supportive therapy approaches tend to be flexible in terms of frequency and regularity of sessions and borrow some components from Rogerian counselling, namely an emphasis on empathic listening and ‘non-possessive warmth’. These may be called ‘supportive psychotherapy’ and also tend to rely on an active therapist who may offer advice, support and reassurance with the aim of helping the patient adapt to present circumstances (Crown, 1988). This differs from the dynamic psychotherapist who waits for material to emerge and retains a degree of opacity to assist in the development of a transference relationship.

Undoubtedly there are overlaps between counselling, supportive therapy and the other psychotherapies; known as ‘non-specific factors’ these are necessary for the development of a positive treatment alliance and are a prerequisite for any psychological intervention to stand a chance of success (Roth et al., 1996). Many of these factors are also part of high-quality ‘standard care’, as well as forming the key elements of counselling and supportive therapy. Fenton and McGlashan
(1997) report that a patient’s feeling of being listened to and understood is a strong predictor of medication compliance for example. Also, according to McCabe and Priebe (2004) the therapeutic relationship is a reliable predictor of patient outcome in mainstream psychiatric care. A remarkable number of RCTs studies, including over 1,586 participants, suggest that counselling and supportive psychotherapy does not improve outcomes in schizophrenia, when compared with standard care and other active treatments, most notably CBT (Falloon et al., 1981; Eckman et al., 1992; Haddock et al., 1999; Valmaggia et al., 2005; Röhricht and Priebe, 2006).

2.4.6 Family intervention

Family intervention in the treatment of schizophrenia has evolved from studies of the family environment and its possible role in affecting the course of schizophrenia (Vaughn and Leff, 1976), after an initial episode. In this context, ‘family’ includes people who have a significant emotional connection to the service user, such as parents, siblings and partners. Brown and others (Brown et al., 1962; Brown and Rutter, 1966) developed a measure for the level of ‘expressed emotion’ within families and were able to show that the emotional environment within a family was an effective predictor of relapse in schizophrenia (Bebbington and Kuipers, 1994; Butzlaff and Hooley, 1998). The importance of this work lay in the realisation that it was possible to design psychological methods (in this case family intervention) that could change the management of the illness by service users and their families, and influence the course of schizophrenia. Family intervention in schizophrenia derives from behavioural and systemic ideas, adapted to the needs of families of those with psychosis. More recently, cognitive appraisals of the difficulties have been emphasised. Models that developed aim to help families cope with their relatives’ problems more effectively, provide support and education for the family, reduce levels of distress, improve the ways in which the family communicates and negotiates problems and try to prevent relapse by the service user. Family intervention is normally complex and lengthy (usually more than ten sessions) but delivered in a structured format with the individual family, and tends to include the service user as much as
possible. Some RCTs reported robust and consistent evidence for the efficacy of family intervention, above all in reducing the risk of relapse at the end of treatment and up to 12 months following treatment (Herz et al., 2000; Magliano et al., 2006; Carrà et al., 2007; Bressi et al., 2008). In addition, family intervention seem also to reduce hospital admission during treatment and the severity of symptoms both during and up to 24 months following the intervention. Family intervention may also be effective in improving additional critical outcomes such as social functioning and patient’s knowledge of the disorder. Nevertheless evidence for the latter is more limited and comes from individual studies reporting multiple outcomes across a range of scale based measures.

2.4.7 Psychodynamic and psychoanalytic therapies

Psychoanalysis, psychoanalytic and psychodynamic psychotherapies, originate from the work of Freud at the first quarter of the 20th Century. These approaches assume that humans have an unconscious mind where feelings that are too painful to face are often held. A number of psychological processes known as defences are used to keep these feelings out of everyday consciousness.

Psychoanalysis and psychodynamic psychotherapy aim to bring unconscious mental material and processes into full consciousness so that the individual can gain more control over his or her life (Freud, 1914). These approaches were originally regarded as unsuitable for the treatment of the psychoses (Freud, 1914; 1933). However, a number of psychoanalysts have treated people with schizophrenia and other psychoses, using modified versions of psychoanalysis (Fromm-Reichmann, 1950; Stack-Sullivan, 1974).

Psychoanalytically-informed approaches to psychotherapy continue to be accessed by people with schizophrenia today, though the actual psychoanalytic technique is rarely used (Alanen, 1997). Approaches tend to be modified to favour relative openness on the part of the therapist, flexibility in terms of content and mode of sessions, holding off from making interpretations until the therapeutic alliance is solid, and the building of a relationship based on genuineness and warmth whilst maintaining optimal distance (Gabbard, 1994). Randomised
controlled trials were undertaken in the 1970s and 1980s to investigate the use of psychoanalytically oriented psychotherapy. Research into the effects of psychoanalytic approaches in the treatment of schizophrenia has been repeated more recently, with mixed results (Fenton and McGlashan, 1995; Jones et al., 1999; Mari and Streiner, 1999), leading to the publication of a Cochrane Review of the subject (Malmberg and Fenton, 2001). Only one new RCT was identified for the update (Durham et al., 2003), which used a psychodynamic based intervention as a comparator for CBT. The new paper did not provide any evidence for the effectiveness of psychodynamic approaches in terms of symptoms, functioning or QoL.

2.4.8 Psychoeducation

Psychoeducation implies provision of information and education to a patients about the diagnosis, its treatment, appropriate resources, prognosis, common coping strategies and rights (Pekkala and Merinder, 2002). In his review of the NHS, Darzi (2008) emphasised the importance of ‘empowering patients with better information to enable a different quality of conversation between professionals and patients’. Precisely what and how much information a person requires, and the degree to which the information provided is understood, remembered or acted upon, will vary from person to person. Frequently, information giving has to be ongoing. As a result, psychoeducation has now been developed as an aspect of treatment in schizophrenia with a variety of goals over and above the provision of accurate information. Some ‘psychoeducation’ involves quite lengthy treatment and runs into management strategies, coping techniques and role-playing skills. It is commonly offered in a group format. The diversity of content and information covered, as well as the formats of delivery vary considerably, so that ‘psychoeducation’ as a discrete treatment, can overlap with ‘family intervention’, especially when families and carers are involved in both. Desired outcomes in studies have included improvements in insight, treatment adherence, symptoms, relapse rates, and family knowledge and understanding (Pekkala and Merinder, 2002). There is no new robust evidence for the effectiveness of psychoeducation on any of the critical outcomes.
2.4.9 Social skills training

An early psychological approach to the treatment of schizophrenia involved the application of behavioural theory and methods with the aim of normalising behaviour (Ayllon and Azrin, 1965), improving communication or modifying speech (Lindsley, 1963). Given the complex and often debilitating behavioural and social effects of schizophrenia, social skills training was developed as a more sophisticated treatment strategy derived from behavioural and social learning traditions (see Wallace et al., 1980, for a review). It was designed to help people with schizophrenia regain their social skills and confidence, improve their ability to cope in social situations, reduce social distress, improve their QoL, and, sometimes also, to aid symptom reduction and relapse prevention. Social skills training programmes begin with a detailed assessment and behavioural analysis of individual social skills, followed by individual and/or group interventions using positive reinforcement, goal setting, modelling and shaping. Initially, smaller social tasks (such as responses to non-verbal social cues) are worked on, and gradually new behaviours are built up into more complex social skills such as conducting a meaningful conversation.

There is a strong emphasis on homework assignments intended to help generalise newly learned behaviour away from the treatment setting. Although this psychosocial treatment approach became very popular in the USA and has remained so (for example, Bellack, 2004), since the 1980s it has had much less support in the UK, at least in part as a result of doubts in the UK about the evidence of the capacity of social skills training to generalise from the treatment situation to real social settings (Hersen and Bellack, 1976; Shepherd, 1978).

Evidence do not suggest that social skills training is effective in improving the critical outcomes. There is also limited evidence for the effectiveness of social skills training on negative symptoms. However this evidence is is largely driven by one small study (Roncone et al., 2004) with multiple methodological problems.
2.5 Effectiveness and economic impact of early interventions in FEP

In the current economical downturn policy makers are under increasing pressure to make substantial cuts to healthcare budgets. Resources are scarce and the demand is largely unlimited, so governments have to distribute their budget wisely in the face of increasing costs associated with factors such as ageing population and expensive technological advances. In view of these financial constrains, it is vital for mental health providers to be transparent about the costs involved with providing services. Furthermore, new services innovations need to demonstrate their cost-effectiveness. Prevention, early detection and intervention in psychosis have the potential to be cost saving in the long term however they do require an initial investment. It is therefore essential to examine the evidence for these type of interventions to inform service commissioners and policymakers (Jones et al., 2010).

2.5.1 The EPPIC study

The Early Psychosis Prevention and Intervention Centre (EPPIC) Long-term Follow-up Study represent the first attempt, in Australia, to implement a service of early detection and intensive phase-appropriate intervention as a large-scale ‘real-world’ service (McGorry, 1993; Edwards et al., 1994). The EPPIC centre provided a comprehensive, integrated, community-based treatment programme to first episode patients (FEP) aged 14–30 years, drawn from a catchment area of approximately 850,000 inhabitants and included a set of interventions as the Early Psychosis Assessment Team (EPAT), in-patient units, case management services, therapeutic programmes, and family interventions. The study purposes were to compare the course of the illness, the predictors of clinical and functional outcomes several years after initial diagnosis and the costs of treatment in a cohort of 51 EPPIC patients matched by 51 historical patients cared for prior to the establishment of the EPPIC. The two cohort were followed-up for 1 year and 8 years. Results showed that at 8 years follow-up outcomes were significantly better for the EPPIC group. Almost 8 years after initial treatment, EPPIC subjects displayed lower levels of positive psychotic symptoms were more
likely to be in remission and had a more favorable course of illness than controls. Fifty-six percent of the EPPIC cohort were in paid employment over the last 2 years compared with the thirty-three percent of controls (p=.083). As concern the economic impact, each EPPIC patient costs on average A$3.445 per annum compared with controls, who each costs A$9.503 per annum. Hence, the total mean mental health service costs, per patient, of the EPPIC group were approximately $48,000 (discounted) and were significantly lower than the control group. The average yearly cost of the EPPIC group was about one-third of the control group and these differences remained stable over the follow-up period. In particular the variance was due to the inpatients (residential and rehabilitation units) and community mental health services which were significantly more used by the control group (Mihalopoulos et al., 2009).

2.5.2 The TIPS Study

The early Treatment and Intervention in Psychosis study (TIPS) (Johannessen et al., 2005) used a quasi-experimental design to assess the effectiveness of an early detection and intervention systems compare to TAU in four specialized psychiatric healthcare services in Norway and Denmark, covering a global area of 295,000 inhabitants. A comprehensive Early Detection system (ED) based on low-threshold psychosis-detecting teams and public information campaigns was set up in two of the four areas. Information campaigns aimed at disseminating information about psychosis in the general population through newspapers, radio and cinema advertisement, simultaneously raising information in primary care professionals through targeted educational sessions. ED treatments included antipsychotic medication, assertively oriented individual outpatients treatment and psycho-educational family work. The purposes of the study were to test if i) ED programmes could reduce the DUP; ii) reducing DUP will be related to a comparative reduction in positive and negative symptoms displayed at the beginning of the treatment; iii) the initial differences between ED and no-ED areas will be maintained over the 2 years of treatment. A Total of 281 patients were followed-up for 1, 5 and 10 years. After the first 2 years, ED strategies resulted to be successful in reducing the DUP of people referred to the clinical
service and in bringing people with less severe symptom levels into treatment (Melle et al., 2004; Larsen et al., 2006). No differences in the reduction positive psychotic symptoms were found in the two groups. However, when the information campaign stopped, the benefits faded away quickly suggesting that this ED strategy could be successful but need recurrent funding to have long lasting effects (Joa et al., 2008). At 5 years, the ED group continued to show less severe psychopathological and depressive symptoms, less cognitive impairment and a better social functioning (more contacts with friends). All these differences were not found at 10 years. Nevertheless, a significantly higher number of ED patients recovered over the long follow-up period (30.7% ED patients vs 15.1% no-ED patients). ED patients who did not recover presented a significantly higher excitative symptoms level. The yearly costs of the information campaign were estimated to be 1.3 million Norwegian Kroner per year (in 1997-98 this was equal to USD 195.000), which was equivalent to the costs associated with running the clinical team (Johannessen et al., 2001). These high costs prevented other mental health services from embarking in large information campaigns (Valmaggia et al., 2012).

2.5.3 The OPUS Study

The Danish OPUS study (Petersen et al., 2005) compared the clinical outcome of 547 patients with first episode of schizophrenia spectrum disorder randomized to integrated treatment or standard treatment. The integrated treatments lasted two years and consisted of assertive community treatment with programmes for family involvement and social skills training, whereas standard treatment offered contact with a CMHC (physician, nurse, social worker). Follow-up were set at 1 and 2 years. Overall patients who received the integrated treatment showed a less number of psychotic and negative symptoms both after 1 and 2 years. They also presented less comorbid substance misuse, better adherence and more satisfaction with treatment (Petersen et al., 2005). A five years follow-up of the OPUS study was performed by Bertelsen et al. (2008) who found no differences in favour of early intervention for psychotic symptoms and
functioning and the use of inpatients services (hospitalisation and residential services).

2.5.4 The LEO Study

The Lambeth Early Onset (LEO) team is a London community team comprising ten staff members (team leader, consultant psychiatrist, trainee psychiatrist, clinical psychologist, occupational therapist, four community psychiatric nurses, and two healthcare assistants). It was established on the principles of assertive outreach: evidence based interventions are adapted to the needs of people with early psychosis and include low dose atypical antipsychotic regimens, cognitive behaviour therapy based on manualised protocols (Jolley et al., 2003; Jackson et al, 1998), family counselling and vocational strategies (McGorry and Edwards, 2002). The LEO study was a randomised controlled clinical trial aimed at evaluating the effectiveness of the assertive outreach vs standard care delivered by community mental health teams. A total of 144 people presented to mental health services were randomized to specialised care group or control group and were followed-up at 18 months. Compared with patients in the standard care group, those in the specialised care group were less likely to relapse (odds ratio 0.46, 95% confidence interval 0.22 to 0.97), were readmitted to hospital fewer times (0.39, 0.10 to 0.68), and were less likely to drop out of the study (odds ratio 0.35, 0.15 to 0.81). The economic impact of LEO services was measured by McCrone and colleagues (2009) using a decision model approach.

The authors found that over one year the cost associated to the early intervention were £11.685 vs £14.062 for the standard care group, with the difference not being significant (95% CI –£8.128 to £3.326). However, when costs were combined with improved vocational and QoL outcomes it was shown that early intervention would have a very high likelihood of being cost-effective.

In a follow-up of the LEO study, Gafoor and others (2010) examined admissions in the period 3.5-5 years after entry in the study. They found that the 33% of the patients in the specialised group and 39% of those randomised to the standard care group had a several number of admission, and on average, the mean length of stay in hospital for the sperimental group was higher than the control group. This study
suggests that early intervention does not have a long-term effect, because when patients were discharged back to standard care, they had similar outcomes to others.

2.5.5 The COAST study

In another RCT study of early intervention, Kuipers et al. (2004) evaluated the effectiveness of a new service in South London, the Croydon Outreach and Assertive Support Team (COAST). 59 patients were randomized to COAST (which offered medication, psychological interventions, behavioural therapy and family interventions) or to TAU. Outcomes were evaluated at baseline, 6 and 9 months. Results showed that the patients of both the groups improved over time with no significantly differences except for a better QoL reported by COAST patients (Kuipers et al., 2004).

2.5.6 The Programma 2000

Programma 2000 (Cocchi et al., 2008) was established in 1999 in a catchment area of inner Milan (Italy), which serves approximately 200,000 inhabitants with the purpose of treating young people aged 17-30 years at their first episode of psychosis, or showing prodromal signs of it. All patients enrolled in the programme received an individual intervention package that takes into account their wishes and needs. Proposed interventions include individual informative and motivational sessions, medication, CBT, individual and family psychoeducation and support, therapeutic group activities (e.g. anxiety management, social problem solving, assertive training, substance abuse prevention etc.), social group activities (e.g. musical group, multimedia group, computer training sessions, language courses, empowerment group), individual employment support, intensive and personalized school support, medication group support, and planning of recreational activities and so on. Part of the patients enrolled in Programma 2000 (N=23) were followed-up by authors for five years and their outcomes were compared to 23 patients who received standard care. Significant changes were found, with respect to initial outcomes with larger effect sizes in the early intervention programme than in the standard care group.
Average costs per patient over 5 years were quite similar, being €39.671 for the index and €42.810 for the contrast group. The average cost per day of treatment was €22.6 and €23.0, respectively. In Programma 2000, allocation of costs was: outpatient care = 77.4%, inpatient care = 9.9%, residential facilities care= 12.7%. The corresponding figures in standard care were: 59.1%, 25.6% and 15.3%, respectively. Patients in Programma 2000 were marginally less likely to be treated in day hospital and, on average, had been hospitalised for shorter periods. Therefore their hospital costs were far lower than the standard care group (€3.928 vs. €10.969; respectively). Patients in Programma 2000 were also marginally less likely to have been admitted to semi-residential facilities, so costs for semi-residential facilities care, too, were also lower in Programma 2000 in comparison to the standard care group, though this did not reach statistical significance. In contrast, outpatient treatment was more intensive in Programma 2000 than in standard care, which is reflected in the higher costs for outpatient interventions: (€30.701 vs. €25.292). Average costs were higher in the first 2 years of treatment for patients in Programma 2000, after which they decreased, whereas they increased smoothly over time among patients in standard care, concurrently to a higher chance of hospitalization. Overall the cost-effectiveness ratio was still favour the Programma 2000 group (Cocchi et al., 2011).

2.5.7 The ‘Parachute Project’

The Parachute project (Cullberg et al., 2006) aim was to compare patients with schizophrenia receiving early intervention (N=61) with those receiving standard care (from a historical cohort) (N=41) and another group receiving current social psychiatric care (N=25). The early intervention service focused on crisis intervention, family support, continued engagement over a five-years period, non-hospital based residential care and low dose medication. The follow-up at three years revealed better symptomatic and functional outcomes for the early intervention group compared to the TAU group but similar to the third group. Compared to the latter, early intervention resulted in inpatients costs that were 94% lower in the first year of follow-up, 57% in year two and 55% in year three. Outpatients costs were though 255%, 15% and 11% higher for these three
years. Total costs for early intervention were therefore lower by 29% in year one, 55% in year two and 61% in year three (Cullberg et al., 2006).

2.5.8 The Canadian experience

This study was conducted in London and Middlesex, Ontario, Canada, with a catchment area population of 390,000 people in 1996. In 1997, a specialized early intervention service, called ‘PEPP’, was introduced to serve the entire catchment area. PEPP was established to provide assessment and treatment to individuals, in an outpatient setting, diagnosed with a non-affective, first-episode psychosis. The treatment program in PEPP incorporates an assertive case management model modified to address the special needs of a younger, treatment-naive patient population. In a study from Goldberg et al. (2006) 159 patients receiving an early intervention were compared to 146 receiving standard care in a period before the service was established. Outcomes were assessed after 2 years.

Even if the number of readmission to hospital was not significantly different between groups, the mean length of stay in hospital was smaller for early intervention patients (43.7 vs 60.2 days). Early intervention patients had also fewer involuntary admissions and emergency room visits. Total mean costs were respectively $2,371 for early intervention and $2,125 for standard care patients.

However, there was a significant mean reduction in costs per case of regular hospital bed use: $1028.49 (SD 528.02) compared with $792.28 (SD 528.02) ($p < 0.01) and emergency visits $519.18 (SD 353.79) compared with $353.79 (SD 345.0), ($p < 0.01).

2.5.9 Report from ORYGEN and UK

The ORYGEN research centre commissioned a cost-effectiveness report reviewing the cost-effectiveness of a number of services across the world and calculated that if specialised early intervention services were to be available to all new patients in Australia, it would lead to a projected saving of AUD 212.5 million (AUD 82.5 million in financial savings and AUD 130 million in reduced burden of disease) over a period of five years (Access Economics, 2008).
A report commissioned by the Department of Health in the UK showed that comparable savings could be made in the UK where it was calculated that savings at six and ten years could be as high as £17.9 million (McCrone et al., 2009)

2.5.10 The GET-UP study

The GET-UP (Genetics, Endophenotypes, Treatment: Understanding early Psychosis) PIANO (Psychosis: early Intervention and Assessment of Needs and Outcome) trial was designed to assess early multi-element psychosocial interventions in an Italian epidemiologically representative sample of patients treated in routine generic mental health settings (Ruggeri et al., 2015). 444 first episode patients were randomized to multi-element psychosocial interventions or to TAU and were assessed at baseline and 9 months. Based on the retention rates of patients (and families) in the experimental arm, multi-element psychosocial interventions can be implemented in routine mental health services. Patients in the experimental arm showed greater reductions in overall symptom severity, while no difference could be found for days of hospitalization. Greater improvements were detected in the experimental arm also for global functioning, emotional well-being, and subjective burden of delusions. No difference could be found for service disengagement and subjective burden of auditory hallucinations. Overall, these findings support feasibility and effectiveness of early interventions for psychosis in generalist mental health services.
Chapter 3. Predictors and moderators of treatment outcome in patients receiving multi-element psychosocial intervention for early psychosis. Results from the GET-UP pragmatic cluster randomized controlled trial

3.1 Introduction

Consistent evidence has been accumulated over the past years showing that early interventions facilitate recovery and reduce long-term disability in patients with psychosis (Penn et al., 2005; Haddock and Lewis, 2005). Literature has also shown that early interventions should be provided on an integrated basis (i.e., multi-element) and be grounded on evidence-based psychosocial treatments (IEPA, 2005; OYH, 2008; NICE, 2009). However, there is as yet no consensus on a service model for the provision of early interventions for first-episode psychosis (FEP) patients, nor do we know to which extent early intervention services are generalizable (Singh and Fisher, 2005; Friis, 2010; Castle, 2011). The GET-UP (Genetics, Endophenotypes, Treatment: Understanding early Psychosis) PIANO (Psychosis: early Intervention and Assessment of Needs and Outcome) trial (Ruggeri et al., 2012) was set up to fill this gap. It was designed to assess early multi-element psychosocial interventions in epidemiologically representative samples of patients treated in routine generic mental health settings. A previous paper reported the feasibility and effectiveness of adding a multi-element psychosocial intervention to the standard treatment of FEP patients. At 9 month follow-up it was clear, based on the retention rates of patients and families in the experimental arm, that early multi-element interventions could be delivered effectively in routine mental health services. Moreover, compared with patients receiving ‘routine care’, those treated with the early multi-element interventions displayed greater reductions in overall symptom severity, and greater improvements in global functioning, emotional well-being, and the subjective burden of delusions (Ruggeri et al., 2015). In the present study we sought to identify, among baseline demographic and clinical characteristics, predictors and moderators of treatment outcomes at 9 months. Existing literature provides some
information on predictors of treatment outcome in FEP patients (Crespo-Facorro et al., 2013; Harrington et al., 2013; Bergè et al., 2016; Albert et al., 2011; Allott et al., 2011; Schimmelmann et al., 2013). Available data, however, are rarely based on epidemiological samples compared with controls and this increases the risk of underestimating the complexities of treating FEP in real-world services (Ruggeri et al., 2013). The present study attempted to deal with this gap, and, in particular, aimed to understand: i) which patients’ characteristics are associated with a better treatment response, regardless of treatment type (non-specific predictors); and ii) which characteristics are associated with a better response to the specific FEP treatment provided in the GET-UP trial (moderators). Predictors of outcome across treatment groups provide prognostic information by clarifying which patients will respond more favourably to treatment in general, whereas treatment moderators provide prescriptive information about optimal treatment selection (Wolitzky-Taylor et al., 2012), which treatment may have more important clinical and cost effectiveness implications. Despite the value of identifying the subgroups of patients and the circumstances associated with the effectiveness of early multi-element psychosocial interventions for psychosis, there is as yet little information about moderators of outcome. These findings would be extremely relevant in order to clarify generalizability issues of the experimental intervention effectiveness. The present study aim is to fill this knowledge gap. Based on the existing literature, we hypothesized that, regardless of treatment, symptomatic improvement at 9 months would be poorer in males (Crespo-Facorro et al., 2013), and in people with an early age of onset (Harrington et al., 2013), lower levels of education (Allott et al., 2011), a longer DUP (Crespo-Facorro et al., 2013; Schimmelmann et al., 2013), poor pre-morbid functioning (Crespo-Facorro et al., 2013; Albert et al., 2011; Allott et al., 2011), poor insight (Bergè et al., 2016), lower adherence to medication (Malla et al., 2006), diagnosis of non-affective psychosis (Ayesa-Arriola et al., 2013), and higher baseline symptom severity (Crespo-Facorro et al., 2013; Albert et al., 2011; Allott et al., 2011). Given the lack of available information, no specific a priori hypotheses could be made about moderators; thus moderator analyses will be exploratory, and will use the same set of variables analyzed as predictors.
3.2 Methods

3.2.1 The GET-UP PIANO trial

The GET-UP PIANO trial is a large multicenter randomized controlled trial comparing an add-on multi-element psychosocial early intervention with ‘routine care’ for patients with FEP and their relatives provided within Italian public general mental health services. Of the 126 CMHCs located in two northern Italian regions (Veneto and Emilia- Romagna) and the urban areas of Florence, Milan, and Bolzano, 117 (92.8%) participated, covering an area of 9,304,093 inhabitants. The assignment units (clusters) were the CMHCs, and the units of observation and analysis were patients and their families. The trial received approval by the ethics committees of the coordinating center (Azienda Ospedaliera Universitaria Integrata di Verona) and each participating unit and was registered with ClinicalTrials.gov (NCT01436331). Full details on the protocol of the GET-UP study and on the main findings of the GET-UP PIANO trial are given elsewhere (Ruggeri et al., 2012; 2015).

3.2.2 Subjects

During the index period all CMHCs participating in the GET-UP PIANO trial were asked to refer potential cases of psychosis at first contact to the study team. The inclusion criteria were: (a) age 18–54 years; (b) residence within the catchment areas of the CMHCs; (c) presence of at least one of the following symptoms: hallucinations, delusions, qualitative speech disorder, qualitative psychomotor disorder, bizarre, or grossly inappropriate behaviour; or 2 of the following symptoms: loss of interest, initiative, and drive; social withdrawal; episodic severe excitement; purposeless destructiveness; overwhelming fear; or marked self-neglect; (d) first lifetime contact with CMHCs, prompted by these symptoms. Exclusion criteria were: (a) prescribed anti-psychotic medication in the last 3 months, for an identical or similar mental disorder; (b) mental disorders due to a general medical condition; (c) moderate-severe mental retardation diagnosis assessed by a clinical functional assessment; and (d) psychiatric diagnosis other
than ICD-10 for psychosis. All eligible patients who achieved clinical stabilization were invited to provide written informed consent for assessment.

They were told of the nature, scope, and possible consequences of the trial and that they could withdraw consent at any time. They were also asked to give consent for family member assessments; family members who agreed to participate provided written informed consent. The best-estimate ICD-10 diagnosis (F1x.4; F1x.5; F1x.7; F20–29; F30.2, F31.2, F31.5, F31.6, F32.3, F33.3) was made at 9 months by consensus of a panel of clinicians taking into account all available information by completing the Item Group Checklist of the Schedule for Clinical Assessment in Neuropsychiatry-SCAN (WHO, 1992).

3.2.3 Treatments

The experimental treatment consisted of a multi-element psychosocial intervention, adjunctive to routine care. It included the delivery of Cognitive Behavioural Therapy for psychosis to patients (Kuipers et al., 1998; Garety et al., 2008), and of psychosis-focused Family Intervention (Kuipers et al., 2002) to families, together with Case Management (Burns and Firn, 2002) involving both patients and their families. It was provided by CMHC staff, trained in the previous 6 months and supervised by experts. The intervention began as soon as patients achieved clinical stabilization (i.e., a condition in which they could collaborate in a brief clinical examination). Core baseline measures were taken. Control arm CMHCs provided only TAU, which, in Italy, comprises personalized outpatient psychopharmacological treatment and non-specific supportive clinical management by the CMHC (Ferrannini et al., 2014). Family interventions in TAU consisted of non-specific informal support sessions.

3.2.4 Measures

A set of core outcome instruments, and, in particular the Positive and Negative Syndrome Scale-PANSS (Kay et al., 1987), the Global Assessment of Functioning-GAF (APA, 1994) and the Hamilton Rating Scale for Depression-HRSD (Hamilton, 1960) were administered by a panel of independent researchers at baseline (after clinical stabilization and before treatment was initiated) and at 9-
month follow-up. For the PANSS the three traditional sub-scales were considered (positive symptoms, negative symptoms, and general psychopathology). An extensive set of standardized instruments was also administered at baseline, including the Premorbid Social Adjustment scale-PSA (Foerster et al., 1991) for pre-morbid functioning, the Schedule for Assessment of Insight-SAI-E (David et al., 1992) for insight into illness and a modified version of the Nottingham Onset Schedule-NOS (Singh et al., 2005) for the DUP. These clinical measures, together with baseline socio-demographics (gender, age at first-contact, citizenship, education) were analyzed as putative predictors/moderators.

3.2.5 Statistical analyses

Analyses were conducted using an intention-to-treat (ITT) approach. PANSS, GAF and HRSD scores were analyzed separately in mixed-effects random regression models. In order to take into account the trial design in which patients (level 1) were nested within CMHCs (level 2) [Campbell et al., 2012], the individual CMHCs were included in the models as a random effect. In order to identify predictors and moderators of treatment outcome according to MacArthur’s approach (David et al., 1992), we selected a priori, on clinical or empirical grounds and derived from the literature, a subset of demographic and baseline clinical variables. Specifically, we investigated gender, age at first-contact, citizenship (Italian/non-Italian), educational level (high/low), DUP, type of psychosis (affective/non-affective), pre-morbid functioning (four components: school and social functioning, in both childhood and adolescence) and insight into illness (three components: attribution of symptoms, illness awareness and treatment adherence). Each model included treatment allocation (T coded as +1/2 for patients in the Experimental Treatment Group and −1/2 for those in the Treatment as Usual Group), one predictor/moderator (M standardized), their interaction (T x M) and the baseline score of the outcome investigated (B standardized). When the main effect of a variable was significant but the interaction was not, the variable was considered a non-specific predictor of outcome. When the interaction was significant (regardless of the significance of main effects), the variable was considered as a moderator. For each variable, the
predictor and moderator effect size was calculated using the formulae provided by Kraemer (2013). In a secondary analysis, missing data on outcomes were estimated using a multiple imputation approach by chained equations (MICE), which generates several different plausible imputed data sets and combines results from each of them. Multiple imputation by chained equations was applied because it allows to handle different variable types; specifically, we used predictive mean matching to deal with possible non-normality when imputing continuous variables and logistic regression to impute binary variables. The alpha level was set to 0.05 for all main effects and interactions. All statistical analyses were carried out using the STATA software package, version 1336 (2013).

3.3 Results

Demographic and clinical variables of the 444 study participants examined as potential predictors or moderators of treatment outcome are presented in the table 3.1.
Table 3.1 Demographic and clinical variables examined as potential predictors or moderators of treatment outcome.

<table>
<thead>
<tr>
<th></th>
<th>Treatment as usual group (n=172)</th>
<th>Experimental treatment group (n=272)</th>
<th>p-value</th>
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<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>94 (54.7%)</td>
<td>166 (61.0%)</td>
<td>0.184</td>
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<tr>
<td>Female</td>
<td>78 (45.3%)</td>
<td>106 (39.0%)</td>
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<tr>
<td><strong>Age at first contact with services, mean (sd)</strong></td>
<td>31.5 (9.2)</td>
<td>29.3 (9.8)</td>
<td>0.017</td>
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<tr>
<td><strong>Educational level, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Low (primary-middle school)</td>
<td>68 (42.8%)</td>
<td>95 (36.1%)</td>
<td>0.174</td>
</tr>
<tr>
<td>High (secondary school, university)</td>
<td>91 (57.2%)</td>
<td>168 (63.9%)</td>
<td></td>
</tr>
<tr>
<td><strong>Nationality, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>149 (86.6%)</td>
<td>241 (88.6%)</td>
<td>0.535</td>
</tr>
<tr>
<td>Other*</td>
<td>23 (13.4%)</td>
<td>31 (11.4%)</td>
<td></td>
</tr>
<tr>
<td><strong>Diagnosis (SCAN-confirmed at 9 months), n (%)</strong></td>
<td>132 (76.7%)</td>
<td>214 (78.7%)</td>
<td>0.632</td>
</tr>
<tr>
<td>Non affective psychosis</td>
<td>40 (23.3%)</td>
<td>58 (21.3%)</td>
<td></td>
</tr>
<tr>
<td>Affective psychosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Duration (months) of untreated psychosis (DUP), mean (sd)</strong></td>
<td>5.5 (9.9)</td>
<td>5.5 (10.9)</td>
<td>0.946</td>
</tr>
<tr>
<td>Childhood, 5-11 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social area</td>
<td>1.50 (1.22)</td>
<td>1.62 (1.30)</td>
<td>0.433</td>
</tr>
<tr>
<td>School area</td>
<td>1.35 (1.00)</td>
<td>1.31 (1.11)</td>
<td>0.752</td>
</tr>
<tr>
<td>Early adolescence, 12-16 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social area</td>
<td>2.00 (1.43)</td>
<td>2.05 (1.44)</td>
<td>0.785</td>
</tr>
<tr>
<td>School area</td>
<td>1.98 (1.77)</td>
<td>1.83 (1.36)</td>
<td>0.389</td>
</tr>
<tr>
<td><strong>Insight (SAI-E), mean (sd)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attribution of symptoms</td>
<td>5.72 (3.30)</td>
<td>5.41 (3.27)</td>
<td>0.457</td>
</tr>
<tr>
<td>Illness awareness</td>
<td>8.12 (1.64)</td>
<td>7.67 (1.71)</td>
<td>0.121</td>
</tr>
<tr>
<td>Treatment adherence</td>
<td>4.24 (1.73)</td>
<td>3.78 (1.89)</td>
<td>0.032</td>
</tr>
</tbody>
</table>

* Standard care: East Europe (n=11), Africa (n=10), South-America (n=1), Asia (n=0), Other (n=1); Experimental treatment: East Europe (n=17), Africa (n=6), South-America (n=6), Asia (n=2), Other (n=0)

§ 8 outliers (DUP> 5 years) were deleted from the calculation

3.3.1 Predictors

Some attributes of patients predicted outcomes regardless of treatment assignment. Among sociodemographic characteristics (Table 3.2), higher education predicted lower overall symptoms (b=−0.06, p=0.034), negative symptoms (b=−0.11, p=0.009) and general psychopathology (b =−0.06, p=0.046) at 9 months.
### Table 3.2 Socio-demographic characteristics as potential predictors/moderators of treatment outcome. Mixed-effects random regression models estimated on patients who were assessed at both baseline and follow-up (experimental treatment group, n=239; TAU group, n=153)

<table>
<thead>
<tr>
<th>Age at first-contact</th>
<th>Outcome at FU (adjusted for BL)</th>
<th>Main effect (Prediction) b [95% CI], p</th>
<th>Interaction with treatment (Moderation) b [95% CI], p</th>
<th>Predictor Effect Size: r(ΔO, DM)†</th>
<th>Moderator Effect Size: r(ΔO, AM)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>PANSS total</td>
<td>0.04 [-0.02;0.09], p=0.157</td>
<td>-0.12 [-0.23;-0.01], p=0.032*</td>
<td>0.04</td>
<td>-0.06</td>
<td></td>
</tr>
<tr>
<td>PANSS positive</td>
<td>-0.00 [-0.06;0.05], p=0.889</td>
<td>-0.07 [-0.8;0.05], p=0.238</td>
<td>0.00</td>
<td>-0.03</td>
<td></td>
</tr>
<tr>
<td>PANSS negative</td>
<td>0.06 [-0.02;0.14], p=0.155</td>
<td>-0.17 [-0.34;-0.01], p=0.042*</td>
<td>0.04</td>
<td>-0.06</td>
<td></td>
</tr>
<tr>
<td>PANSS general</td>
<td>0.06 [0.00;0.11], p=0.039</td>
<td>-0.14 [-0.25;-0.03], p=0.014*</td>
<td>0.06</td>
<td>-0.07</td>
<td></td>
</tr>
<tr>
<td>GAF score</td>
<td>-0.44 [-1.95;1.07], p=0.570</td>
<td>-0.13 [-3.19;2.93], p=0.934</td>
<td>-0.02</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>HRSd score</td>
<td>0.34 [-0.51;1.18], p=0.432</td>
<td>-0.13 [-1.83;1.56], p=0.878</td>
<td>0.02</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>PANSS total</td>
<td>0.00 [-0.05;0.06], p=0.944</td>
<td>0.04 [-0.07;0.14], p=0.511</td>
<td>0.00</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>PANSS positive</td>
<td>0.04 [-0.02;0.10], p=0.179</td>
<td>0.04 [-0.07;0.16], p=0.438</td>
<td>0.03</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>PANSS negative</td>
<td>-0.02 [-0.10;0.07], p=0.711</td>
<td>-0.04 [-0.21;0.12], p=0.595</td>
<td>-0.01</td>
<td>-0.01</td>
<td></td>
</tr>
<tr>
<td>PANSS general</td>
<td>-0.01 [-0.06;0.05], p=0.725</td>
<td>0.07 [-0.04;0.18], p=0.227</td>
<td>-0.01</td>
<td>0.03</td>
<td></td>
</tr>
<tr>
<td>GAF score</td>
<td>-0.94 [-2.42;0.54], p=0.213</td>
<td>0.30 [-2.67;3.26], p=0.845</td>
<td>-0.03</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>HRSd score</td>
<td>0.50 [-0.32;1.33], p=0.229</td>
<td>0.46 [-1.19;2.10], p=0.588</td>
<td>0.03</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>PANSS total</td>
<td>0.01 [-0.04;0.06], p=0.646</td>
<td>-0.02 [-0.13;0.08], p=0.664</td>
<td>0.01</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>PANSS positive</td>
<td>0.02 [-0.03;0.08], p=0.460</td>
<td>-0.04 [-0.16;0.07], p=0.429</td>
<td>0.02</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>PANSS negative</td>
<td>0.01 [-0.07;0.09], p=0.860</td>
<td>-0.01 [-0.17;0.15], p=0.899</td>
<td>0.00</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>PANSS general</td>
<td>0.01 [-0.04;0.06], p=0.691</td>
<td>-0.05 [-0.15;0.06], p=0.381</td>
<td>0.01</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>GAF score</td>
<td>0.19 [-1.23;1.62], p=0.791</td>
<td>0.79 [-2.07;3.6], p=0.589</td>
<td>0.01</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>HRSd score</td>
<td>0.26 [-0.56;1.09], p=0.529</td>
<td>0.10 [-1.55;1.75], p=0.906</td>
<td>0.02</td>
<td>0.00</td>
<td></td>
</tr>
</tbody>
</table>

* Predictors/moderators which remained significant (p<0.05) after applying multiple imputation procedure by chained equations (MICE)
† See Kraemer for the calculation of predictor and moderator effect size (Kraemer, 2013)

Several clinical characteristics predicted outcomes at 9 months (Table 3.3 and Table 3.4): specifically a longer DUP predicted higher depressive symptoms (b=1.42, p=0.002); poorer premorbid social functioning in adolescence predicted higher levels of overall psychotic symptoms (b=0.07, p=0.043) and depressive symptoms (b=0.90, p=0.039); poorer pre-morbid scholastic functioning in adolescence predicted higher negative symptoms (b=0.11, p=0.035). Moreover, poorer attribution of symptoms predicted higher severity of overall psychotic symptoms (b=−0.07, p=0.036), higher levels of positive symptoms (b=−0.12, p=0.003) and worse global functioning (b=2.75, p=0.008); poorer treatment...
adherence predicted higher level of overall psychotic symptoms (b=−0.08, p=0.015), positive symptoms (b=−0.08, p=0.017), negative symptoms (b=−0.11, p=0.031) and general psychopathology (b=−0.06, p=0.045).
Table 3.3 Duration of untreated psychosis (DUP), insight (SAI) and diagnosis as potential predictors/moderators of treatment outcome. Mixed-effects random regression models estimated on patients who were assessed at both baseline and follow-up (experimental treatment group, n=239; TAU group, n=153)

<table>
<thead>
<tr>
<th>Outcome at FU (adjusted for BL)</th>
<th>Main effect (Prediction) b [95% CI], p</th>
<th>Interaction with treatment (Moderation) b [95% CI], p</th>
<th>Predictor Effect Size: r(ΔO, DM)†</th>
<th>Moderator Effect Size: r(ΔO, AM)†</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DUP (months)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PANSS total</td>
<td>0.04 [-0.02;0.09], p=0.171</td>
<td>0.00 [-0.11;0.11], p=0.967</td>
<td>0.04</td>
<td>0.00</td>
</tr>
<tr>
<td>PANSS positive</td>
<td>0.03 [-0.03;0.09], p=0.266</td>
<td>0.01 [-0.11;0.13], p=0.855</td>
<td>0.03</td>
<td>0.00</td>
</tr>
<tr>
<td>PANSS negative</td>
<td>0.08 [-0.00;0.17], p=0.055</td>
<td>0.01 [-0.16;0.18], p=0.927</td>
<td>0.05</td>
<td>0.00</td>
</tr>
<tr>
<td>PANSS general</td>
<td>0.03 [-0.02;0.09], p=0.267</td>
<td>0.00 [-0.11;0.12], p=0.978</td>
<td>0.03</td>
<td>0.00</td>
</tr>
<tr>
<td>GAF score</td>
<td>-0.84 [-2.46;0.77], p=0.308</td>
<td>0.15 [-3.04;3.34], p=0.927</td>
<td>-0.03</td>
<td>0.00</td>
</tr>
<tr>
<td>HRS&amp;D score</td>
<td><strong>1.42 [0.53;3.31], p=0.002</strong>†</td>
<td>-0.83 [-2.62;0.95], p=0.361</td>
<td>0.08</td>
<td>-0.03</td>
</tr>
<tr>
<td><strong>SAI-E attribution of symptoms</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PANSS total</td>
<td>-0.07 [-0.14;0.00], p=0.036</td>
<td>-0.04 [-0.18;0.09], p=0.538</td>
<td>-0.08</td>
<td>-0.02</td>
</tr>
<tr>
<td>PANSS positive</td>
<td><strong>-0.12 [-0.20;0.04], p=0.003</strong>†</td>
<td>-0.06 [-0.21;0.09], p=0.447</td>
<td>-0.11</td>
<td>-0.03</td>
</tr>
<tr>
<td>PANSS negative</td>
<td>-0.09 [-0.19;0.01], p=0.084</td>
<td>-0.16 [-0.36;0.04], p=0.120</td>
<td>-0.06</td>
<td>-0.06</td>
</tr>
<tr>
<td>PANSS general</td>
<td>-0.06 [-0.13;0.01], p=0.108</td>
<td>-0.01 [-0.14;0.13], p=0.919</td>
<td>-0.06</td>
<td>0.00</td>
</tr>
<tr>
<td>GAF score</td>
<td><strong>2.75 [0.71;4.80], p=0.008</strong>†</td>
<td>-2.08 [-5.98;1.82], p=0.297</td>
<td>0.10</td>
<td>-0.04</td>
</tr>
<tr>
<td>HRS&amp;D score</td>
<td>-0.87 [-1.75;0.00], p=0.051</td>
<td>0.10 [-1.64;1.84], p=0.910</td>
<td>-0.07</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>SAI-E illness awareness</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PANSS total</td>
<td>0.02 [-0.07;0.10], p=0.711</td>
<td>0.10 [-0.06;0.26], p=0.231</td>
<td>0.02</td>
<td>0.06</td>
</tr>
<tr>
<td>PANSS positive</td>
<td>-0.02 [-0.10;0.07], p=0.668</td>
<td>0.02 [-0.16;0.19], p=0.852</td>
<td>-0.02</td>
<td>0.01</td>
</tr>
<tr>
<td>PANSS negative</td>
<td>0.04 [-0.08;0.17], p=0.471</td>
<td>0.08 [-0.17;0.32], p=0.334</td>
<td>0.04</td>
<td>0.03</td>
</tr>
<tr>
<td>PANSS general</td>
<td>0.01 [-0.07;0.09], p=0.865</td>
<td>0.13 [-0.04;0.29], p=0.125</td>
<td>0.01</td>
<td>0.07</td>
</tr>
<tr>
<td>GAF score</td>
<td>-0.29 [-2.72;2.14], p=0.815</td>
<td>-2.17 [-7.17;2.83], p=0.394</td>
<td>-0.01</td>
<td>-0.04</td>
</tr>
<tr>
<td>HRS&amp;D score</td>
<td>-0.11 [-1.27;1.05], p=0.858</td>
<td>2.32 [0.02;4.62], p=0.048</td>
<td>-0.01</td>
<td>0.09</td>
</tr>
<tr>
<td><strong>SAI-E treatment adherence</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PANSS total</td>
<td>-0.08 [-0.14;0.02], p=0.015</td>
<td>-0.07 [-0.20;0.05], p=0.268</td>
<td>-0.07</td>
<td>-0.04</td>
</tr>
<tr>
<td>PANSS positive</td>
<td>-0.08 [-0.15;0.01], p=0.017</td>
<td>-0.07 [-0.20;0.06], p=0.312</td>
<td>-0.08</td>
<td>-0.03</td>
</tr>
<tr>
<td>PANSS negative</td>
<td><strong>-0.11 [-0.21;0.01], p=0.031</strong>†</td>
<td>-0.11 [-0.31;0.08], p=0.265</td>
<td>-0.07</td>
<td>-0.04</td>
</tr>
<tr>
<td>PANSS general</td>
<td>-0.06 [-0.13;0.00], p=0.045</td>
<td>-0.07 [-0.19;0.06], p=0.285</td>
<td>-0.07</td>
<td>-0.04</td>
</tr>
<tr>
<td>GAF score</td>
<td>1.30 [-0.56;3.16], p=0.170</td>
<td>1.75 [-1.88;5.38], p=0.344</td>
<td>0.05</td>
<td>0.03</td>
</tr>
<tr>
<td>HRS&amp;D score</td>
<td>-0.51 [-1.32;0.29], p=0.212</td>
<td>-0.72 [-2.34;0.89], p=0.381</td>
<td>-0.04</td>
<td>-0.03</td>
</tr>
<tr>
<td><strong>Type of psychosis (ref. affective)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PANSS total</td>
<td>0.02 [-0.04;0.07], p=0.558</td>
<td>-0.02 [-0.14;0.09], p=0.659</td>
<td>0.02</td>
<td>-0.01</td>
</tr>
<tr>
<td>PANSS positive</td>
<td>0.03 [-0.03;0.08], p=0.310</td>
<td>-0.02 [-0.13;0.01], p=0.763</td>
<td>0.03</td>
<td>-0.01</td>
</tr>
<tr>
<td>PANSS negative</td>
<td>0.02 [-0.06;0.10], p=0.645</td>
<td>-0.06 [-0.23;0.11], p=0.471</td>
<td>0.01</td>
<td>-0.02</td>
</tr>
<tr>
<td>PANSS general</td>
<td>0.01 [-0.04;0.07], p=0.631</td>
<td>-0.02 [-0.13;0.10], p=0.779</td>
<td>0.01</td>
<td>-0.01</td>
</tr>
<tr>
<td>GAF score</td>
<td>-1.38 [-2.92;0.15], p=0.077</td>
<td>-0.15 [-3.18;2.88], p=0.922</td>
<td>-0.05</td>
<td>0.00</td>
</tr>
<tr>
<td>HRS&amp;D score</td>
<td>0.47 [-0.35;1.30], p=0.261</td>
<td>-0.88 [-2.54;0.77], p=0.296</td>
<td>0.03</td>
<td>-0.03</td>
</tr>
</tbody>
</table>

† Predictors/moderators which remained significant (p<0.05) after applying multiple imputation procedure by chained equations (MICE)
†† See Kraemer for the calculation of predictor and moderator effect size (Kraemer, 2013)
Table 3.4 Premorbid social adjustment (PAS) as potential predictor/moderator of treatment outcome. Mixed-effects random regression models estimated on patients who were assessed at both baseline and follow-up (experimental treatment group, n=239; TAU group, n=153)

<table>
<thead>
<tr>
<th>Outcome at FU (adjusted for BL)</th>
<th>Main effect (Prediction) b [95% CI], p</th>
<th>Interaction with treatment (Moderation) b [95% CI], p</th>
<th>Predictor Effect Size: r(ΔO, DM)†</th>
<th>Moderator Effect Size: r(ΔO, AM)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAS social childhood</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PANSS total</td>
<td>-0.01 [-0.08;0.06], p=0.790</td>
<td>0.07 [-0.06;0.21], p=0.279</td>
<td>-0.01</td>
<td>0.04</td>
</tr>
<tr>
<td>PANSS positive</td>
<td>-0.01 [-0.08;0.05], p=0.694</td>
<td>0.07 [-0.06;0.20], p=0.300</td>
<td>-0.01</td>
<td>0.04</td>
</tr>
<tr>
<td>PANSS negative</td>
<td>-0.02 [-0.13;0.08], p=0.656</td>
<td>0.18 [-0.02;0.39], p=0.083</td>
<td>-0.02</td>
<td>0.06</td>
</tr>
<tr>
<td>PANSS general</td>
<td>0.00 [-0.06;0.07], p=0.892</td>
<td>0.04 [-0.10;0.17], p=0.599</td>
<td>0.00</td>
<td>0.02</td>
</tr>
<tr>
<td>GAF score</td>
<td>-0.01 [-1.96;1.93], p=0.990</td>
<td>-1.75 [-5.63;2.13], p=0.376</td>
<td>0.00</td>
<td>-0.03</td>
</tr>
<tr>
<td>HRSD score</td>
<td>0.27 [-0.59;1.13], p=0.534</td>
<td>0.68 [-1.03;2.39], p=0.436</td>
<td>0.02</td>
<td>0.03</td>
</tr>
<tr>
<td>PAS school adolescence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PANSS total</td>
<td>0.05 [-0.02;0.12], p=0.132</td>
<td>-0.02 [-0.16;0.12], p=0.759</td>
<td>0.06</td>
<td>-0.01</td>
</tr>
<tr>
<td>PANSS positive</td>
<td>0.05 [-0.02;0.11], p=0.154</td>
<td>0.01 [-0.12;0.14], p=0.881</td>
<td>0.05</td>
<td>0.01</td>
</tr>
<tr>
<td>PANSS negative</td>
<td>0.07 [-0.04;0.18], p=0.196</td>
<td>-0.09 [-0.30;0.12], p=0.396</td>
<td>0.05</td>
<td>-0.03</td>
</tr>
<tr>
<td>PANSS general</td>
<td>0.05 [-0.02;0.12], p=0.149</td>
<td>-0.01 [-0.15;0.13], p=0.888</td>
<td>0.05</td>
<td>-0.01</td>
</tr>
<tr>
<td>GAF score</td>
<td>-1.85 [-3.83;0.14], p=0.069</td>
<td>1.35 [-2.59;5.28], p=0.503</td>
<td>-0.06</td>
<td>0.02</td>
</tr>
<tr>
<td>HRSD score</td>
<td>0.79 [-0.08;1.66], p=0.076</td>
<td>-0.12 [-1.87;1.62], p=0.890</td>
<td>0.06</td>
<td>-0.01</td>
</tr>
<tr>
<td>PAS social adolescence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PANSS total</td>
<td>0.07 [0.00;0.14], p=0.043</td>
<td>0.01 [-0.12;0.15], p=0.851</td>
<td>0.07</td>
<td>0.01</td>
</tr>
<tr>
<td>PANSS positive</td>
<td>0.04 [-0.03;0.11], p=0.246</td>
<td>-0.05 [-0.18;0.08], p=0.463</td>
<td>0.04</td>
<td>-0.03</td>
</tr>
<tr>
<td>PANSS negative</td>
<td>0.10 [-0.00;0.21], p=0.063</td>
<td>0.08 [-0.13;0.28], p=0.473</td>
<td>0.07</td>
<td>0.03</td>
</tr>
<tr>
<td>PANSS general</td>
<td>0.06 [-0.00;0.13], p=0.063</td>
<td>0.01 [-0.13;0.14], p=0.915</td>
<td>0.07</td>
<td>0.00</td>
</tr>
<tr>
<td>GAF score</td>
<td>-1.24 [-3.18;0.71], p=0.212</td>
<td>-2.27 [-6.09;1.56], p=0.246</td>
<td>-0.04</td>
<td>-0.04</td>
</tr>
<tr>
<td>HRSD score</td>
<td>0.90 [0.05;1.76], p=0.039</td>
<td>-0.74 [-2.44;0.96], p=0.395</td>
<td>0.07</td>
<td>-0.03</td>
</tr>
<tr>
<td>PANSS total</td>
<td>0.05 [-0.02;0.12], p=0.169</td>
<td>0.02 [-0.11;0.16], p=0.729</td>
<td>0.05</td>
<td>0.01</td>
</tr>
<tr>
<td>PANSS positive</td>
<td>0.04 [-0.03;0.10], p=0.276</td>
<td>0.06 [-0.07;0.19], p=0.349</td>
<td>0.04</td>
<td>-0.04</td>
</tr>
<tr>
<td>PANSS negative</td>
<td>0.11 [0.01;0.22], p=0.035</td>
<td>-0.10 [-0.31;0.11], p=0.366</td>
<td>0.07</td>
<td>-0.03</td>
</tr>
<tr>
<td>PANSS general</td>
<td>0.03 [-0.04;0.10], p=0.407</td>
<td>0.06 [-0.07;0.20], p=0.359</td>
<td>0.03</td>
<td>0.03</td>
</tr>
<tr>
<td>GAF score</td>
<td>-1.67 [-3.63;0.29], p=0.094</td>
<td>1.49 [-2.41;5.40], p=0.453</td>
<td>-0.06</td>
<td>0.03</td>
</tr>
<tr>
<td>HRSD score</td>
<td>0.77 [-0.08;1.63], p=0.077</td>
<td>0.74 [-0.97;2.45], p=0.397</td>
<td>0.06</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Predictors/moderators which remained significant (p<0.05) after applying multiple imputation procedure by chained equations (MICE)

† See Kraemer for the calculation of predictor and moderator effect size (Kraemer, 2013)
Multiple imputation analysis confirmed that lower education predicted a higher severity of symptoms at follow-up (PANSS total score, $b=-0.10$, $p=0.016$) and that a poorer attribution of symptoms predicted a higher severity of positive symptoms (PANSS positive score). Notably, lower educational level ($b=-0.10$, $p=0.016$), poorer school performance in adolescence ($b=0.11$, $p=0.022$) and poorer treatment adherence ($b=-0.10$, $p=0.042$) predicted a higher severity of negative symptoms (PANSS negative score). A longer duration of untreated psychosis predicted a higher severity of depression ($b=1.11$, $p=0.005$), while a poorer attribution of symptoms predicted a worse global functioning at follow-up ($b=2.14$, $p=0.020$).

### 3.3.2 Moderators

We found a differential effect of age at first-contact on PANSS total score ($b=-0.12$, $p=0.032$), negative symptoms ($b=-0.17$, $p=0.042$) and general psychopathology ($b=-0.14$, $p=0.014$) (Table 5.2). Specifically, the experimental treatment was more beneficial than TAU as age increased. When analyses were rerun using multiple imputation of missing data, the finding that age at first contact was a moderator of PANSS total score ($b=-0.11$, $p=0.052$), negative symptoms ($b=-0.18$, $p=0.032$) and general psychopathology ($b=-0.12$, $p=0.030$) was confirmed. In a sensitivity analysis using different age cut-offs, we found that the experimental treatment was significantly superior to usual treatment starting from the age of 35 years (PANSS total: $b=-0.12$, $p=0.023$, moderator effect size=$-0.06$; PANSS negative: $b=-0.18$, $p=0.032$, moderator effect size=$-0.06$; PANSS general: $b=-0.13$, $p=0.015$, moderator effect size=$-0.07$) (Figure 3.1).
Figure 3.1 Strength of moderation by patient’s age at first contact on the effect of the intervention (experimental EXP) vs treatment as usual (TAU group) on the Positive and Negative Syndrome Scale (PANSS)

Left-hand graphs <35 years at first contact; Right-hand graphs: ≥35 years at first contact.  
a) Total score; b) negative symptoms; c) general psychopathology. Mean scores are reported on the y-axis (1, absent; 2, minimal; 3, mild; 4, moderate; 5, moderate severe; 6, severe; 7, extremely severe).
Table 3.5 (lower part) shows that in the TAU arm patients with an age of onset ≥35 years experienced no reduction of overall psychotic symptoms, negative symptoms and general psychopathology at 9 months (see delta scores in bold), whereas patients with an age of onset less than 35 years (Table 3.5, upper part) experienced some benefit from both treatments, with a higher beneficial effect of experimental treatment in terms of reduction in PANSS total, negative and general scores.

Table 3.5 Strength of moderation played by patient’s age at first-contact (upper part <35 years, lower part ≥35 years) on the effect of intervention (Experimental vs. TAU) on the various outcome domains (GAF; PANSS total score, positive symptoms, negative symptoms, general psychopathology; Hamilton depression): mean delta scores are reported.

<table>
<thead>
<tr>
<th>Age</th>
<th>Outcome</th>
<th>Delta Tau</th>
<th>Delta EXP</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;35 yrs</td>
<td>GAF</td>
<td>15.2 (14.9)</td>
<td>19.4 (16.6)</td>
</tr>
<tr>
<td></td>
<td>PANSS Positive</td>
<td>-0.68 (0.81)</td>
<td>-0.77 (0.81)</td>
</tr>
<tr>
<td></td>
<td>PANSS Negative</td>
<td>-0.68 (1.02)</td>
<td>-0.67 (1.00)</td>
</tr>
<tr>
<td></td>
<td>PANSS General</td>
<td>-0.56 (0.70)</td>
<td>-0.66 (0.73)</td>
</tr>
<tr>
<td></td>
<td>PANSS Total score</td>
<td>-0.63 (0.68)</td>
<td>-0.69 (0.70)</td>
</tr>
<tr>
<td></td>
<td>HRSD score</td>
<td>-5.8 (13.3)</td>
<td>-8.8 (1.0)</td>
</tr>
<tr>
<td>≥35 yrs</td>
<td>GAF</td>
<td>13.0 (12.8)</td>
<td>18.3 (16.6)</td>
</tr>
<tr>
<td></td>
<td>PANSS Positive</td>
<td>-0.71 (0.78)</td>
<td>-0.95 (0.72)</td>
</tr>
<tr>
<td></td>
<td>PANSS Negative</td>
<td>-0.21 (0.69)</td>
<td>-0.58 (0.93)</td>
</tr>
<tr>
<td></td>
<td>PANSS General</td>
<td>-0.33 (0.51)</td>
<td>-0.65 (0.60)</td>
</tr>
<tr>
<td></td>
<td>PANSS Total score</td>
<td>-0.41 (0.48)</td>
<td>-0.70 (0.56)</td>
</tr>
<tr>
<td></td>
<td>HRSD score</td>
<td>-6.7 (13.0)</td>
<td>-7.0 (10.2)</td>
</tr>
</tbody>
</table>

These findings were confirmed after multiple imputation of missing data (results not shown). In order to identify possible reasons for this finding, we carried out secondary analyses comparing patients with an age of onset ≥35 years with the rest of the sample. Results indicate that patients with age at onset greater
than 35 years were more often females (41.0 vs. %, 67.0%, \( \chi^2 \) test, \( p<0.001 \)), less frequently diagnosed with schizophrenia (19.4 vs. %, 30.7%, \( \chi^2 \) test, \( p=0.033 \)), less frequently unmarried (37.9% vs. 91.3%, \( \chi^2 \) test, \( p<0.001 \)) and unemployed or student (46.6% vs. 70.4%, \( \chi^2 \) test, \( p<0.001 \)). Lastly, we found that a greater awareness of illness was associated with a higher severity of depression at follow-up in the experimental group but not in the control group (\( b=2.32, \ p=0.048 \)) (Table 3.3); this finding, however, was not confirmed in multiple imputation analysis (\( b=0.38, \ p=0.736 \)). No moderation was found for GAF and HRSD scale.

3.4 Discussion

This is the first study to investigate in a ‘real world’ setting which patient characteristics: (a) predict outcome regardless of treatment assignment (non-specific predictors) and (b) moderate differential response (moderators) to adjunctive multi-element psychosocial intervention supplementing ‘routine care’ for first-episode psychosis. It used a large sample and a robust methodological approach. As expected, we found several non-specific predictors of outcome.

Patients with lower education, longer DUP, poorer pre-morbid functioning in adolescence and poorer insight into illness at FEP showed poorer clinical outcomes at 9 months irrespective of the type of treatment. These findings are consistent with the literature (Crespo-Facorro et al., 2013; Harrington et al., 2013; Bergé et al., 2016; Albert et al., 2011; Allott et al., 2011; Schimmelmann et al., 2008; Malla et al., 2006; Ayesa-Arriola et al., 2013) and suggest that FEP patients with these characteristics warrant specific attention and may require more intensive and/or longer treatment. We found only one significant moderator with acted only on one outcome: patients’ age at first service contact, which operated on negative symptoms and general psychopathology. Specifically, in the control group, where the effect of the intervention was overall lower than in the experimental group, the moderation effect by age at first service contact resulted in lower benefit in older compared to younger patients. Thus, the experimental intervention was not only overall significantly more effective than TAU but was also similar in both age groups showing greater generalizability.
Multi-element psychosocial intervention administered at first episode seems to exert a specific additional beneficial effect on patients who develop onset of psychosis at a later stage (≥35 years); these patients, if treated with usual care alone, would display no or low symptomatic improvement. Moreover, it is important to note that the multi-component intervention showed a specific beneficial effect on negative symptoms, which in general show relatively poorer response to psychopharmacological treatment also in FEP patients (Salimi et al., 2009; Schennach et al., 2012). It is not completely clear what drives the relationship between age at first-contact and experimental treatment outcome in our sample. However, data showing that patients with age at onset greater than 35 years were more often females, less frequently diagnosed with schizophrenia, less frequently unmarried and unemployed or student may in part explain the moderating effect of age at first-contact on treatment outcome in our sample. We may also speculate that patients developing psychosis at a later stage may be more receptive of structured cognitive coping strategies provided with both individual CBT and family therapy, since these patients have found to be less impaired than younger patients on a broad array of cognitive tasks (Howard et al., 2000; Vahia et al., 2010; Smeets-Janssen et al., 2013; Hanssen et al., 2015) which are most relevant to adaptive functioning and treatment response. Future research should investigate further this relationship between age and outcome in FEP samples. In general, however, the lack of significant moderators of treatment outcomes suggests that the effect of experimental intervention does not vary according to patient baseline characteristics. This result seems to suggest that its beneficial effect may be generalizable to all patients treated in services implementing early multi-element psychosocial interventions.

3.4.1 Strengths and limitations

Our moderator analyses should be considered as exploratory, being aimed at providing useful information for designing future clinical studies. The effect size of the moderators identified in the present paper may serve as a guidance to researchers for estimating the sample size needed in confirmation studies. The design of these confirmation studies implies the selection of a group with the
characteristic of interest and the comparison of outcomes in patients receiving different treatments.

3.4.2 Implications for research

These findings are novel, and need replication. Further studies in other geographical contexts and with longer term outcomes are needed to replicate and extend our findings.

3.5 Conclusion

Our findings provide evidence that the GET-UP multi-element psychosocial intervention may be potentially beneficial to a broad array of FEP patients treated within routine community mental health services and especially among those aged >=35 years.
4.1 Concepts of residential facilities

In 1987, the American National Institute of Mental Health attempted to define ‘supported housing’ as an ‘approach’ that focuses on clients goals and preferences, uses an individualized and flexible rehabilitation process, and has a strong emphasis on normal housing, work, and social network. The approach is based on clients' choice of their own living situations, their right to live in normal stable housing, and to have the services and supports required to maximize their opportunities for success over time (NIMH, 1987). More recent definition of ‘community Residential Facilities’ could be found in Rog (2004) who described them as ‘[...] alternatives to the residential continuum, a range of housing options with differentiating levels of staff intensity, from group living situations to progressively more independent housing through which individuals are expected to move as they transition into the community’ or by the World Health Organization, WHO (2005) which classified ‘non hospital, community-based mental health facilities as facilities that provide overnight residence for people with mental illness. Usually these facilities serve users with relatively stable mental disorders, not requiring intensive or acute medical interventions’. Anyway all these definitions, while useful conceptually, are so broad that it is not possible to use them as a framework for classifying different kinds of facilities. Consequently, in literature, different terms are used, often in an interchangeable way, to refer to the different types of housing options existing. Some of these terms are, for example: supervised housing, group homes, un-staffed group homes, group homes with some residential or visiting staff, hostels with day staff, hostels with day and night staff, hostels and homes with 24-hour nursing staff, halfway houses, therapeutic communities. Some authors have attempted to suggest a multi-dimensional system for classifying sheltered and supported housing facilities based on the availability of different kinds of staff cover, number of beds and staff to resident ratios (Lelliott et al., 1996). This classification reflects a traditional view of residential care based on a ‘sheltered housing’ model where the extent of support available from staff in situ is seen as
one of the predominant defining characteristics. However, more recent developments in the housing field have tended to emphasize other models for linking housing and support (Carling, 1993) where staff are used more flexibly to provide high (or low) levels of support according to fluctuating levels of individual need. The main problem in defining supported housing is the diversity of existing housing models (Goldmeier et al., 1977; Carling 1978; Fairweather 1980; Budson 1981; Carling 1981; Carling 1984; Segal and Liese 1991) which makes comparative evaluations of effectiveness very difficult. Furthermore, categories that have traditionally operated for care of elderly people (such as private nursing homes and registered care homes), although often applied in the area of adult mental health, relate in practice to a different set of health problems and, often, different styles of working. Another central dimension underlying different forms of housing concerns expected lengths of stay and of transitional, or ‘move on’, accommodation versus a ‘home for life’ (Bigelow 1998). While it has been suggested that the ideal would be a mix of both, as Bigelow (1998) has noted, there is a need to resolve the question of emphasis.

4.2 The costs of residential programs

Research on the effectiveness of housing provision for people with severe mental disorders must also be considered within the country-specific economic context. Across Europe, health systems are striving for maximum cost effectiveness and efficiency. That means knowing who is living in such accommodations, what care or support they receive, what works, but also how much they cost. However, despite the considerable sums spent on these services, little is known about their actual costs. Information on RF costs in European countries is very scanty and is virtually limited to the Mental Health Residential Care Study, conducted in England (Chisholm et al., 1997), which explored the association between costs of RFs plus other costs (costs of nonresidential services used by patients, and residents’ living expenses) and residents’ characteristics, and to the cost-study from the Groningen case-register, where direct costs of Mental Health care were evaluated and showed that, after the deinstitutionalization costs of inpatients fell by 20% over a 10-year period (Pul et al., 2002). In Italy, the
PROGRES project (de Girolamo et al., 2002) provided the only systematic information about the costs of a sample of national RFs. Its findings showed that, in Italy, each patient who stays within RF costs between 7.851 and 34.650 US$ per year, to which it should be added a sum, ranging from 2.032 to 4.702 US$ per year, covering the psychiatric care provided outside the facility. Though these instances show that the costs of inpatient services are higher than those of residential treatments’, these latter are nonetheless substantial for policymakers.

All these surveys, however, were limited to residential care without considering newer types of services such as supported housing and floating support.

In view of the little information available about their costs, it seems reasonable to expect that housing schemes for people with mental illness would have been subject to rigorous evaluation, both in terms of their effectiveness and efficiency. However, on the one hand there is currently a marked imbalance between the high costs of supported housing, whilst on the other hand there is limited number of evaluative studies.

4.3 Characteristics of residents

The broad range of patients who may benefit from sheltered accommodation has been divided by Macpherson and colleagues (2004) into the following three main groups:

- Old long-stay patients. The ‘old long-stay patients’ are those whose hospitalisation pre-dated the deinstitutionalization movement that started in the 1960s, but have remained in-patients. However, this group is now very small.

- New long-stay patients. The term ‘new long-stay patients’ was created by Mann and Cree (1976) to refer to patients who, despite modern treatment approaches and the ideology of community care, cannot be discharged from hospital, owing to their level of psychopathology, disability or behavioural disturbance.
• The community care generation. The health care system now includes a large group of patients who have responded to treatment, but have residual symptoms and require ongoing care and support, but do not have access to family or similar help. Historically, these patients’ care pathways would have often involved lengthy periods in psychiatric hospitals. However, in the current health care system some of these patients may never have been psychiatric inpatients.

The patients who have better life skills (able to manage self-care, budgeting and shopping) are expected to be able to cope in more independent settings. There is also evidence of higher levels of psychopathology (Simpson et al, 1989) and dependency (Robson, 1995) in hostel residents and rehabilitation patients in hospital rather than in residents of group homes. Shepherd et al (1996) confirmed this in a detailed analysis of twenty-five residential units in London, but interestingly found that staffing ratios in community homes bore no relationship to levels of dependency. A key issue in selection should be patients’ choice, but the literature indicates that patients are increasingly dissatisfied with the traditional, ‘institutional’ model of supported accommodation. When asked, they tend to express a preference for independent accommodation that allows for privacy. They also prefer to have access to flexible levels of support when needed, as opposed to support being provided as part of their accommodation (Tanzman, 1993; Rose and Muijen, 1997). In practice, there is considerable overlap across different types of supported accommodation in terms of the types of patient being cared for. Ideally, a locality-based accommodation system should include a broad range of facilities with differing levels of support that allows individual choice to be accommodated as much as possible. The reality is rather different and presents a picture of extensive geographical variation, with typically fragmented, poorly organized systems for allocating special needs housing and a stark lack of awareness of unmet need within the system.

4.4 Research issues: design and limitations

Despite an increasingly interest and economical investment in supported/residential services for people suffering from severe mental illness,
there is still paucity of high quality research investigating the effectiveness of different models and their efficacy, that would be the positive or negative effects of living in such accommodations on patients’ subjective outcomes, such as their perceived quality of life (QoL), personal and social functioning, physical and psychological health, psychopathology and their needs of care.

The only rigorous systematic literature review in this area reported that no trials of adequate quality had been carried out (Chilvers et al., 2002; Killaspy, 2016). This could be explained by the practical and ethical difficulties of randomizing individuals to different types of supported accommodations since clinicians and service users’ decision is based on a combination of personal preference and professional judgement about the kind of support they feel is required, and the availability of economic resources (Rog and Randolph, 2002).

Hence, most of the studies conducted in this area have been uncontrolled follow-ups, cross-sectional surveys, or non-randomized controlled trials (RCTs). In particular, cross-sectional investigations are the most common type of research conducted in this field, though these designs do not allow to ascertained causality relationship (Seilheimer and Doyle, 1996). Also longitudinal evaluations have some limits as follow-ups’ length normally ranges from a few months (McCarthy and Nelson, 1991) to a year (Nelson et al., 1997) and this lapses could be not long enough to detect meaningful sustainable changes in patients’ outcome modification. Moreover, irrespective of the design, often studies on supported housing have small and heterogeneous sample size that puts into question the representativeness of the sample (McCarthy and Nelson, 1993; Dickerson et al., 1999). Geographic homogeneity is another limitation. Studies often focus on settings selected from a particular geographic area that often share the same profile of residents and housing characteristics (Ryrie et al., 1998; Friedrich et al., 1999). Moreover some studies miss the description of the housing settings under evaluation, thus disallowing comparisons with findings from other settings (Segal et al., 1997; Tempier et al., 1997).
Despite these methodological limitations, researches in this field provided the needed information to improve the organization and the quality of care of residential treatment.

Gaining in-depth knowledge of the outcomes of people with mental disorders receiving community care has been a great challenge for both researchers and clinicians. Due to the lack of an agreed conceptual and methodological framework to assess outcome and, consequently, to the limited amount of empirical evidence available on this topic. However, from a methodological point of view, several important achievements have been fulfilled in the last few decades. It has became clear that in order to be valid, reliable and useful to interventions’ planning and evaluation, outcome studies should be based on some methodological key components; first of all the multidimensionality (i.e. the assessment should consider an intervention’s effect on various dimensions of patients’ lives, including both clinical and social aspects) and the multi-axiality (i.e. the assessment should consider the perspectives of all those involved in the care process, including clinicians, patients, caregivers, users representatives) (Rosenblatt and Hart, 1993; Ruggeri et al., 1995; Salvador Carulla et al., 2006; Thornicroft and Tansella, 1999; Bowis, 2005; Rose et al., 2006; Lasalvia et al., 2007). Moreover, it has been recognised that to be generalizable, studies assessing mental health outcomes should be conducted in ‘real-world health services’ (Ruggeri and Tansella, 2002; Ruggeri and Dall’Agnola, 2000; Ruggeri, 2002) and should be performed using standardized instruments with proven reliability, validity and acceptability (Slade, 2002), preferably administered as part of routine clinical activities (Gilbody et al., 2002).

Despite the general consensus of the scientific community, which suggests that evidence informing clinical practice should be based on the integration of data coming from RCTs (which assess the efficacy or potential of a treatment) and naturalistic studies (which assess the outcome of care in representative samples of patients attending routine clinical settings), naturalistic studies are nonetheless unfortunately scarce in number.
4.5 Literature on outcomes’ evaluation

Despite the paucity of high quality research investigating the effectiveness of different models, non-randomized controlled trials evidence supported that housing schemes can have beneficial effects (McCarthy and Nelson 1993; Nelson et al., 1997) with moderate to high satisfaction levels being reported by most clients (Middleboe et al., 1998; Kaiser et al., 2001).

The most largest study, still existing in literature on outcomes’ evaluation is represented by the Team for the Assessment of Psychiatric Services (TAPS) study. The study generated extensive evidence regarding the progress of over 700 long-stay hospital patients leaving Friern and Claybury hospital in North London (Leff, 1997). In a carefully planned process, which involved the allocation of a ‘funding dowry’ to each discharged patient, patients were carefully followed-up and evaluated over a period of five years after they moved from long-term hospital to community care. One year after discharge, 49% of the patients were living in large hostels, residential or nursing homes; 15% were in community in-patient accommodation (which we take to mean directly provided NHS hospital hostels); 12% were living independently; 6% were in staffed group homes; and 4% were in unstaffed group homes (Beecham et al, 1997). The remainder were in sheltered housing or foster care. Compared with matched controls remaining in hospital, the community group had reduced negative symptoms, improved social functioning, increased social networks and greatly increased levels of satisfaction. Moreover, for these patients the risk of rehospitalisation was low (Culhane et al., 2002). There was no difference, however, in positive symptoms, physical health status or rates of suicide and crime. Overall, costs were slightly lower for the community group. The results of the TAPS programme, together with the results of research into 24-hour nursed care and a large number of uncontrolled studies of patients in the community (e.g. Borge et al, 1999), have been widely viewed as supporting the value of alternative community provision for long-term hospital inpatients.

More recently, studies on supported accommodation have been focused on the 24-hour nursed care provided in high and medium-staffed hostels (Shepherd,
which support most patients referred to them, some of whom can be then resettled to less dependent community placements over a period of years. Results from Macpherson et al. (2004) showed that units providing 24-hour nursed care tended to be associated with an improvement in social functioning, higher levels of social networks and a reduced level of negative symptoms in schizophrenia, but they typically did not affect positive symptoms. Patients and relatives reported also a higher satisfaction with these units rather than with hospitals, but, at the same time, these accommodations resulted to be less attractive to some patients because of the perceptions of stigma and restrictiveness. It has to be considered that in both research and practice, the abovementioned bias in the selection of patients for placement that leaves the most disturbed individuals in hospital environments makes it more difficult to do an overall evaluation of the work of such units within the total health care system. Evidence about staffed care homes or core and cluster accommodation are not so clear, although a review in this area demonstrated a strong user preference for independent private flats and for flexible outreach support (Tanzman, 1993). Other studies, from the USA and Scandinavia respectively, have found high levels of independent social functioning (Segal and Kofler, 1993) and improved QoL (Middleboe et al, 1998) in core and cluster units. A comparative evaluation in the USA undertaken by Nelson et al. (1997) found that residents of supported apartments, group homes and board and care homes (similar to supported lodgings in the UK) all had positive outcomes over time in terms of work and education. Residents in the group facilities reported that they experienced greater support and lower levels of abuse than those in the other settings. Those in supported apartments and group homes spent less on rent and made more decisions about various aspects of their life. There is little evidence in the literature of differing effectiveness between the various forms of community provision. This is perhaps not surprising in a health care system where different units are perceived to cater for different types of patient (i.e. with different levels of dependency) and levels of challenging behaviour.

Some patients benefit from the support and increased contact of group living and may otherwise face loneliness, isolation and neglect. Older patients are
vulnerable to physical decline and poor QoL without support. In practice, it seems that access to a range of different forms of supported accommodation, through which patients may move according to need as well as by choice, at different times in their lives or phases of their illness, is an ideal worth aspiring towards.

Similar findings were been obtained in the Berlin Deinstitutionalization Study (Priebe et al., 2002), a prospective controlled study which investigated whether long-term hospitalised psychiatric patients would benefit from discharge into the community. QoL, treatment satisfaction, needs and psychopathology were re-assessed in 63 non-discharged patients 1.5 year later, and in 65 resettled patients 1 year after discharge. The results showed that discharged patients were younger and had spent less time in psychiatric hospital. While patients who remained in hospital care did not show significant changes over time, discharged patients did. Changes in subjective QoL and total number of needs, but not in psychopathology, unmet needs, and treatment satisfaction were significantly more favourable in resettled patients as compared to the control group.

A core dimension of patients’ outcomes is represented by the needs of care. Mental health needs include broad domains of health and social functioning, necessary to survive and prosper in the community. Needs can be assessed from different perspectives, including staff, patient or caregiver and have been differentiated into unmet needs (current serious problems, whether or not help is given) and met needs (no or moderate problems because of help given) (Phelan et al, 1995). A consensus is emerging across Europe and Australia that mental healthcare should be provided on the basis of need, with an intended goal of improving subjective quality of life (e.g. Mental Health Branch, 1997; Department of Health, 1999; Lasalvia et al, 2000).

The relationship between QoL and needs has been widely studied. Overall, the quality of life was found to be inversely associated with total needs, with a point increase on the QoL scale being associated with an average reduction of half a need, and even more, with unmet needs (Slade et al., 2005). Also well-being was inversely related with the total number of needs and with the number of social
needs (Bengtsson Tops and Hansson 1999; Slade et al. 1999b; UK 700 Group 1999; Ruggeri et al., 2004).

In a cross-sectional study on 268 patients using mental health services in South Verona, Italy, Ruggeri et al. (2004) found that needs were strictly related to clinical, social and service variables. In particular, being male, unemployed, having high symptomatology, disability and functioning problems, as well as a high number of outpatient and community contacts and self-reported low QoL over the past year resulted to be the best predictors of needs. From a services’ point of view much attention is given to understand potential predictors or variables associated with unmet needs. Evidence on unmet need in patients suffering from schizophrenia was fitting.

In this population, unmet needs were most prevalent in the areas of occupation, psychotic symptoms, distress, company, intimate relations, and sexual expression (Slade et al., 1998; Issakidis and Teeson, 1999; Bengtsson-Tops and Hansson, 1999; Middleboe et al., 2001) suggesting that clinicians in all kinds of treatment settings do not seem to be very responsive to these kinds of needs and apparently do not know how to handle them. This could be a special task for psychosocial rehabilitation as a defined service response. For example, in a naturalistic follow-up study among 35 long-term patients mostly with schizophrenia, Wiersma and Busschbach (2001) demonstrated a significant effect of an innovative rehabilitation approach on the number of met and unmet needs.

In these years, the Italian Ministry of Health funded the PROGRES project (de Girolamo et al., 2002) which represented the first systematic attempt in Italy to fill the gap between psychiatric services planning and evaluation, by setting up a network of investigators throughout the country and evaluating an entire typology of services (about 1370 Italian RFs were surveyed) in a consistent fashion. Results showed that after 1 year follow-up, over 37.7% of RFs had not discharged any patients and the 31.5% had discharged only one patient. The PROGRES survey results suggested that many RFs mostly provided long-term accommodation, with very low patients’ turn-over. For many chronic, disabled patients, RFs represented ‘homes for life’ (Trieman et al., 1998), rather than being
active therapeutic centers. However these findings have to be considered with caution because they were limited to residential care without considering newer types of services such as supported housing and floating support which have been developed in the last few years.

More recently Killaspy and colleagues (2013) collected, retrospectively, clinical outcome data on 141 users of a mental rehabilitation service in London and she found that, over five years, 40% of patients moved on to less supported (more independent) accommodation whereas the 26% remained in the same accommodation, without requiring readmission to hospital and without breakdown in their community placement and only the 10% progressed to completely independent living in a permanent tenancy.

Another recent national survey of mental health supported accommodation in England (Killaspy et al., 2016) compared QoL, autonomy, satisfaction of 619 patients and costs associated with three different type of residential settings (residential care, supported housing and floating outreach services). Authors found that of the three main types of supported accommodation provided in England, residential care was the most expensive and provided support to people with the highest needs. Floating outreach services were cheapest and provided support to people with the least severe needs. Self-reported quality of life increased with increasing support, possibly because the gains in autonomy and social inclusion associated with more independent settings also increase risks to personal safety. Service quality was rated highest for supported housing. Users of supported housing and floating outreach services were expected to move to less supported accommodation or manage with less support within two years of entry, but they found that the system was more complex than a simple step-down continuum. The routes into current services were non-linear, with some users moving from more independent to more supported accommodation and vice versa, and some moving between accommodation services with a similar level of support. In keeping with other national (Priebe et al., 2009) and international results, they found that most service users were single unemployed men, and most had previously been admitted to hospital for mental health disorders (Killaspy et
As regards costs, results showed that supported housing and residential care had similar costs, whereas floating outreach was less expensive. However the QoL of patients living in floating outreaches did not differ from that of patients living neither in residential care, nor in supported housing. Hence, these findings suggested that supported housing offered better value for money than floating outreach because it seemed to be associated with better outcomes. However, assessment of cost-effectiveness in longitudinal studies and trials is needed to draw firmer conclusions.

4.6 Factors affecting outcomes

Although outcome assessment is clearly essential to evaluate the success of a supported housing scheme, importance should also be placed on the understanding of the multiple factors that may exert an influence on the quality of care as well as on outcomes. According to Donabedian (1966) the literature on quality of residential care may be grouped into ‘structural’ and ‘process’ elements. The structure of a service describes ‘the setting in which the intervention takes place and the instrumentalties of which it is the product, while the process is ‘those activities triggered by any patient who enters the setting.’ So far, there has been no comprehensive study on the effects of these elements. However, a number of other studies have addressed individual elements that may be placed within this framework. In addition, there has been considerable interest in self-reported satisfaction, QoL measures and some interesting special measures of organizational process, e.g., the ‘Environmental Index’ (Leff, 1997). Privacy, independence, personal choice, convenient location, and proximity to mental health services have been reported to be significantly important to residents (Massey and Wu 1993). On the contrary, there is mixed evidence regarding the influence of living with others on psychological health are mixed (Borge et al.,1999; Friedrich et al., 1999). There is currently also little information regarding the optimal ‘fit’ between case-mix, staffing levels, and outcomes. Nevertheless, there is evidence showing that a slight understaffing may encourage greater levels of participation (Nelson et al., 1998). Therefore, the quantity of staff may not be as important as how they are organized and managed. One organizational and
management dimension that has received special attention is the ‘restrictiveness’ of the environment. The less restrictive the housing regime is, the more the opportunities for normal ‘rhythms’ of life occur and the less institutionalized the ‘feel’ of the accommodation (McCarthy and Nelson 1991, Leff, 1997). This aspect of organizational ‘culture’ has a clear effect on subjective satisfaction and QoL (Shepherd et al. 1996).
Chapter 5. Assessing outcomes in community-based residential services: the VALERE (VALutazione E monitoraggio RESidenze protette) project

5.1 Introduction

5.1.1 Mental health services in Italy: organizational issues

Italy is divided into administrative regions, and the reform of Title V of the Constitution of 2001 that (Italian Governement, 2001) stipulated each local government makes policy decisions concerning health. Nationally, there was, and still is considerable heterogeneity and differences in programming in the field of public health and mental health services (Ferrannini et al., 2014; de Girolamo et al., 2007). In 2006, the Group of Interregional Coordination of Mental Health was established as a link between national and regional programming, in order to reorganize and standardize, as much as possible, the offer of care throughout the country. From the collaboration between the Ministry of Health and the Group of Interregional Coordination of Mental Health, the National Action Plan for Mental Health 2013-15 was born, a document based on a precise mandate of the Ministry of Health and approved by the Council of Ministers (GISM, 2013). This document took into account a series of national and international laws, guidelines, and papers. The introduction of the National Action Plan for Mental Health stressed that, given the growing importance that took psychiatric residential and diurnal treatments and the differences among the various regions, it is necessary to produce guidelines defining specifically the objectives, the tools, and the feedback of the outcomes from a clinical and social rehabilitation. The the National Action Plan for Mental Health emphasizes the importance, at the methodological level, to work with projects of specific and differentiated interventions that have to be primarily centered on a personalized assessment of needs. These projects, developed by the Mental Health Services (particularly CMHCs) and by services for neuropsychiatric disorders in childhood, must also intercept the demands of the population and, at the same time, contribute to the renewal of the organization of the services. In the the National Action Plan for Mental Health guidelines,
some clinical and organizational models are also proposed, in order to guide the care process characterized by an increasing intensity of intervention according to the needs of the patient: collaboration/consultation, treatment, and taking charge. The territorial path of a patient with severe personal and social dysfunctions and complex needs that require multidisciplinary interventions results in the CMHC processing an Individual Treatment Plan. As part of this plan, the temporary placement in a RF for psychiatric rehabilitation treatment can be expected. The Individual Treatment Plan must contain the signature of an ‘agreement/commitment of care’ between CMHC and the user, with the participation of families and possibly involving the supportive network, in order to assure the voluntariness and the adherence of the patient to the treatment. It is important that the patient be accepted into a RF located in the district of the MHD, or at least within the region, in order to encourage continuity of care and involvement of family and a supportive network. The CMHC follows, through its own reference operator (case manager), the trend of the interventions until discharge. The psychiatric RFs, within regional structure directives, operate on the basis of guidelines for clinical care, nationally and internationally validated by the scientific community. Moreover, each facility adopts its own service list, which defines its characteristics. For a proper use of RFs, the Individual Treatment Plan of patients offered by CMHC for insertion in RF should refer to specific criteria, that is, diagnosis at inclusion; severity and complexity of the disorder; impairment of personal and social functioning of the patient, determined on the basis of standardized assessment tools (e.g., Health of the Nation Outcome Scale- HoNOS, Brief Psychiatric Rating Scale-BPRS, Personal and Social Performance-PSP, Valutazione Attività e Definizione di Obiettivi-VADO); resources or rehabilitative potential; resistance to change; and clinical stability. The goal is to find an appropriate response to the specific needs of the patient by establishing a correlation between two levels: the level of rehabilitation requiring therapeutic intervention (intensity of rehabilitation) and the level of care required (intensity of care). Based on these data, the team of the RF, consistent with the Individual Treatment Plan and in accordance with the CMHC, processes the Personalized Rehabilitation Project care.
According to the National Plans of Mental Health (Ministry of Health 1993, 1999), in Italy, psychiatric residential facilities are distinct in both the level of therapeutic and rehabilitation intervention offered (related to the level of impairment of patient's functions and abilities) and in the level of intensity of assistance offered (related to the degree of overall autonomy). Depending on the intensity of rehabilitation programs implemented and the level of intensity of care offered, there are three types of residential structures:

- RF for intensive rehabilitation, in which patients with serious impairment of personal and social functioning, who need intensive rehabilitation, are received. These can be appropriate for a range of different situations, including the beginning of a psychotic disease or the post-acute phase of a recent onset disorder (SRP1).

- RF for therapeutic rehabilitative treatments of extensive nature (medium intensity rehabilitation, SRP2) for patients with impairments of personal and social functioning of a severe or moderate degree but persistent and disabling (occurring a long ago and/or previously treated with rehabilitation programs).

- RF for social rehabilitation interventions (SRP3), with different levels of intensity of care, divided into three subgroups in function of staff presence: 24-hour-, 12-hour-, and time-slot- staffed (Conference of Regions and Autonomous Provinces).

5.1.2 A focus on the Veneto Region

Consistent with the national plan, RFs in the Veneto Region are represented by:

(1) Comunità Terapeutico-Riabilitativa Protetta (CTRP) which could be divided into type A and type B, depending on the level of intensity of assistance (respectively high and intermediate). They are non-hospital therapeutic communities designed to meet the health and social welfare needs of psychiatric patients requiring fixed-term therapeutic and rehabilitative assistance. They are
located in larger-sized separate buildings in the city and provide from 8 to 14 places. Nursing staff is present within the facility 24h per day (staff-patient ratio 2:1); psychologists, psychotherapists and occupational therapists provide time-limited services (1–3 h per week). A fixed period of residence is 12-24 months.

(2) Comunità Alloggio (CA). This facility offers residents psychiatric and social therapeutic care tailored to their individual problems and needs in order to underpin and develop their residual capacity for autonomy. The facility usually serves between 6 and 12 residents living together with separate functional areas. Medical specialist care is provided by physicians in private practice or by the social psychiatric services. This residential service is located in larger-sized separate buildings in the community; nursing staff is present within the facility 12-24h per day (staff-patient ratio 1:3); occupational therapists and social workers run a day-structuring program including leisure time activities. The maximum length of stay is fixed and should be no longer than 3 years.

(3) Group homes (GAP) were designed to provide care in the least restrictive environment and to integrate individuals with mental illness into the community, reducing stigma and improving QoL. The environment of a group home was intended to simulate typical family life as much as possible. Thus, they are located within a community. Residents are usually encouraged or required to take an active role in the maintenance of the household, such as performing chores or helping to manage a budget. Staff is present within the facility only 4h per day (staff-patient ratio 1:3).

Whereas CTRP type A belongs to SRP1’s group, type B refers to SRP2, and both CA and GAP are classify as SRP3.

The Veneto Region is organized in 22 LHUs. Each district covers a geographical area corresponding to small towns or a part of a large town, with their/its related suburbs and provides mental health services through its own MHD. Figures 5.1 and 5.2 show detailed information about the number and type of supported accommodations of each LHUs of the Veneto Region in 2014 and
the amount of services’ users, in residential treatment and day of care (Report of the Veneto Region, 2014).

Figure 5.1 Psychiatric RFs in the Veneto Region (2014)

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<th>Az. ULSS</th>
<th>CTRP tipo A</th>
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<th>CA di base</th>
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Figure 5.2 Service users and day of care in the Veneto Region (2013)

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<th>Year</th>
<th>CRP</th>
<th>CA</th>
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In 2013, 2,357 patients with a diagnosis of severe mental illness received residential treatment with a total amount of 644,553 days spent in RFs. Generally, the percentage of patients receiving residential treatment represents the 3.4% of the entire population in charge with the Verona MHD.

The area of Verona is covered by the LHU no.20 which provides, by means of Verona MHD, mental health services. In 2005 the South-Verona CMHC has become part of the Verona MHD that is currently constituted by 4 CMHCs and according to 2013 estimates, covers a catchment area of 472,816 (with 392,119 inhabitants aged 18 years or older) and provides comprehensive care.

Based on 2014 estimates residential services takes around the 33.7% of the MHD costs (Figure 5.3).
Despite the amount of costs and the increasing number of people who need psychiatric residential treatment, little is known about these patients. Evaluative research is foster in order to obtain needs and outcome information, and carry on the process of monitoring and evaluating the quality of real practices.

5.1.3 Outcomes evaluation in the Italian RFs

The PROGRES study (de Girolamo et al., 2002), is the only wide national survey that provided data and monitored the developing of the network of RF in Italy. The PROGRES survey suggested that many RFs provide mostly long-term accommodation with no formal limitation to the length of stay, a low resident turnover. Data on discharge rate to independent accommodation showed that for many chronic, disabled patients, RFs represented ‘a home for life’, rather than a transitional facility. Moreover, even RFs had several external activities targeted at integrating patients within the local community, 45% of the patients resulted to be completely inactive, not even assisting with their facility’s daily activities. Leisure
and socializing activities, psychomotor and creative interventions prevailed in the rehabilitative interventions (i.e. aimed at basic, interpersonal and social skills training); family addressed activities were not frequent (Santone et al., 2005). However, fifteen years have passed since the PROGRES survey, and except for a limited number of studies, there are still no update information available on the situation of the Italian RFs.

The more recent study, which provided comprehensive data on RF patients’ characteristics, course and outcomes is the PERDOVE study (Progetto Epidemiologico Residenze Dimissione Ospiti e Valutazione Estiti-Epidemiological Project on Discharge from Residential Facilities and Outcome Assessment), a prospective observational cohort study involving 23 medium-long-term RFs located in Northern Italy (de Girolamo et al., 2014). Beyond describing the socio-demographic, clinical, and treatment-related characteristics of 403 RF patients, the study aimed at verifying whether discharge to independent accommodations was a real option for many patients, and at identifying discharge-associated predictors and characteristics at 1-year follow-up. The survey showed that residents were predominantly middle aged, single men suffering from unremitting schizophrenic symptoms from early adulthood, with high levels of disability in psychosocial functioning and a moderate degree of cognitive impairment and symptom severity. After 1 year, only 25% of residents were discharged (of these 14 % were home discharged). These data are similar to those observed in other studies (Leff, 1993, Rasanen et al., 2000; D’Avanzo et al., 2003; 2004, Killaspy and Zis, 2012). The strong stayer predictor were the severity of psychopathological symptoms and the degree of psychosocial and functional impairment. Another main factor that impeded discharge was social support system unavailability. Only approximately one-third of patients had an effective social support system available (usually their families), which could also provide key assistance in case of discharge. These results were in line with other studies which found that social support, lower psychopathology and higher job skill levels were important home discharge predictors (Anderson et al., 1993; Segal and Kotler, 1993; Priebe et al., 2002; D’Avanzo et al., 2004). In addition, this study demonstrated that patients who were likely to be discharged improved in many areas of the social functioning and
psychopathology scale score suggesting that selected patients, with a long history of illness, can improve during an RF stay and achieve discharge to the community (de Girolamo et al, 2014). The principal limitation of these studies is the lack of descriptive information about the RFs, their accreditation and their rules. Anyway, no similar detailed data were available for other Italian Regions. This gap is probably due to the Italian’ geographic inhomogeneity for that concern the mental health organization and policies.

5.1.4 Aims and hypothesis

The current study focuses on the evaluation of residential services for people with severe mental disorders in the catchment area of Verona, and aims at providing a detailed description of people who are living in RFs, what care or support they receive and investigate whether the level of support in the different types of housing setting is appropriately matched to service users’ global and social functioning and mental health needs. In particular, the project aims i) to study the socio-demographic and clinical characteristics of patients in different residential settings; ii) to assess their needs, services’ satisfaction and QoL; iii) to identify potential factors associated with unmet needs; iv) to assess quality indicators for services provided; v) to compare these findings with results from literature.

For that concern patients characteristics, we expected to find differences in socio-demographic and clinical variables. We expected patients living in Gap to be younger than the other two groups and to have a better functioning and less psychopathological symptoms. We also hypothesize patients living in GAPs to be characterized by less needs, better perceived QoL and to be more satisfied with services delivered compared to the other two groups. We also expected to find the same differences between patients in CA and CTRP. On the basis of the evidence about the low patients’ turnover in RFs, we expected to find a low number of admissions and discharged from all RFs, and, in particular, from CA. We hypothesize all RFs to be characterized by an adequate number of staff operators and to deliver different type of interventions according to the specific needs of the three patients’ group.
5.2 Material and Methods

5.2.1 Design and Setting

This is a naturalistic, cross-sectional survey involving 25 out of 30 RFs of the Verona MHD’ catchment area.

5.2.2 Facilities assessment

We used RFs specific quality indicators to assess the RFs’ staff characteristics, general organization and RF-provided rehabilitative activities.

5.2.3 Patient recruitment and assessment

The sample consisted of a subgroup of patients (N=191) in charge with the 4 CMHCs of the Verona MHD and staying in the RFs of the catchment area during an index period (January-June 2014). These services comprised 5 CTRP, 12 CA and 8 GAP. Two nursing homes were also included in the study, because they hosted patients in charge with adult mental health services (LHU no. 20). All patients were identified through the MHD database and the South-Verona Psychiatric Case Register (PCR; Tansella et al., 1991).

The study was approved by the Azienda Ospedaliera Universitaria Integrata Verona Ethical Committee. A research assistant, together with the treating clinicians and staff, conducted a standardized assessment for each resident. Socio-demographic, service utilization and diagnostic data were extracted from the PCR. Global functioning was measured by the Global Assessment of Functioning (GAF; APA, 1994) as well as the psychosocial functioning was measured by the Personal and Social Performance (PSP) scale, a modified version of the DSM-IV Social and Occupational Functioning Assessment Scale (SOFAS; Morosini et al., 2000).

Psychopathology was assessed through the Italian version of Brief Psychiatric Rating Scale, expanded version (BPRS; Ventura et al., 1993), which consists of 24 items rated on a seven-point Likert scale (from 1 = no symptom to 7 = extremely severe symptom). A factor analytic study (Ruggeri et al., 2005)
proposed a four-component solution constituted by depression/anxiety (six items: somatic concern, anxiety, depression, suicidality, guilt and tension), positive symptoms (five items: grandiosity, suspiciousness, hallucinations, unusual thought content and conceptual disorganization), negative symptoms (seven items: blunted affect, emotional withdrawal, motor retardation, uncooperativeness, self-neglect, disorientation and mannerism and posturing) and maniac excitement/disorganization (six items: hostility, elevated mood, bizarre behaviour, excitement, distractibility and motor hyperactivity).

Needs for care were assessed using the Italian version of the Camberwell Assessment of Need-staff version (CAN-S; Phelan et al., 1995; Slade et al., 1999), which comprises 22 items grouped into five conceptual domains: health (physical health, psychotic symptoms, drugs, alcohol, safety to self, safety to others, psychological distress), basic (accommodation, food, daytime activities), social (sexual expression, social networks, intimate relationships), service (information, telephone, transport, benefits) and functioning (basic education, money, childcare, self-care, looking after the home). Each item was assessed on a 3-point scale with 0 = no problem, 1 = no/ moderate problem because of continuing interventions (met need) and 2 = current serious problem whether or not help is offered or given (unmet need), and 9 = unknown. The number of needs (scores of 1 or 2) and unmet needs (scores of 2) are aggregated over the 22 items. Ratings of not known (9) were re-coded to zero (meaning no problem) since subjectively not knowing one has a need is equivalent to not having one (Issakidis et al., 1999). For each need recorded as being present, further questions were asked about who was providing help and whether the patient was satisfied with the kind and amount of help received.

The ‘Valutazione Attività e Definizione di Obiettivi’ (VADO-AR; Morosini et al., 1998) was used to define and monitor psychiatric rehabilitations’ goals in residential contexts.

The VADO-AR consists of 28 items which assess the following areas: Self-care (item 1-7), Community services (item 8-10), personal and social relationship (item 11-16), Respect of the cohabitation rules (item 17-21), activities
of daily livings (item 22-28). Each item is rated on a 4 point Likert scale (from 1= no problems to 4=intervention conclude, problem partially or totally resolved).

Subjective QoL was assessed using the Manchester Short Assessment of Quality of Life (MANS; Priebe et al, 1999), a 16-item measure derived from the Lancashire Quality of Life Profile (Oliver et al, 1997). MANS comprises 4 objective questions and 12 subjective questions.

The subjective items assess satisfaction with life as a whole, job (or sheltered employment, or training/education, or unemployment/retirement), financial situation, number and quality of friendships, leisure activities, accommodation, personal safety, people that the individual lives with (or living alone), sex life, relationship with family, physical health and mental health. Each item is rated on a seven-point satisfaction scale, from 1 ‘Couldn’t be worse’ to 7 ‘Couldn’t be better’. The summary score used in this study is the mean of the 12 subjective items (range 1 to 7, the higher the score the better the QoL).

Satisfaction with mental health services was assessed using the Verona Service Satisfaction Scale-RF (Ruggeri et al., 1996). The VSSS-RF consists of 23 items, which conceptually cover six dimensions: Overall satisfaction, Professionals’ skills and behaviour, Information, Access, Efficacy and Types of intervention. The instrument is designed for self administration and can be completed without prior training in 10–15 min. Subjects are asked to give overall rating about their experience of the mental health services they have attended in the previous year. For items 1–18, satisfaction ratings are on a 5-point Likert scale (1, terrible; 2, mostly unsatisfactory; 3, mixed; 4, mostly satisfactory; 5, excellent). The items are presented with alternate directionality to reduce stereotypic responses. Items 19–23 consist of three questions each: first the subject is asked if he/she has received the specific intervention (Question A: Did you receive the intervention x in the last year?). If the answer is yes, he/she is asked his/her satisfaction on a 5- point Likert scale, as above (Question B). If the answer is no, he/she is asked Question C: Do you think you would have liked to receive intervention x? (6, no; 7, do not know; 8, yes). These questions allow measurement of the subjects satisfaction both with interventions provided and
with the professionals decision not to provide an intervention. The latter may be considered a measure of under-provision of care from the patients point of view.

In the final Section of the VSSS, two open-ended questions ask the subjects to state ‘the thing I liked most is…’ and ‘the thing I disliked most is…’.

5.2.4 Statistical analysis

Analyses were done with SPSS (version 17.0) for Windows. All p values were two-tailed with an accepted significance level of 0.05. Non-normality of continuous variables was checked by visual inspection of distribution and probability–probability plots and confirmed with Kolmogorov-Smirnov tests; non-parametric tests were chosen to account for skewed distributions. Summary statistics for independent groups were compared with χ², Mann-Whitney U test, ANOVA and BONFERRONI post-hoc tests, depending on the data. Bivariable correlations between scores were assessed with Spearman’s rank correlation coefficient. A series of univariable regression models were estimated with number of unmet needs for the subscales of CAN-S as dependent variables and a set of potential explanatory variables (age, gender [male gender as reference category], working status [employed as reference category], age at first contact with the services, number of lifetime hospitalization, length of stay in the current RF (in years), BPRS mean total score, PSP mean score, VSSS ‘satisfaction’ subscale’s score, VSSS ‘information’ subscale’s score and MANSA total score) specifically selected to address the third research question. For pairs of highly correlated independent variables, only one was chosen; the number of compulsory admissions since the first contact with the service was not included because it is significantly associated with the lifetime number of hospital admissions; GAF score was similarly excluded because it was significantly associated with PSP and BPRS scores. Subsequently, multivariable regression models were estimated, introducing, as independent variables, only those that were significantly associated (p<0.1) with the dependent variable in the univariable models.

5.3 Results

Table 5.1 Sample’s main socio-demographic and clinical characteristics (N=191)
| **Total sample**  |  
| **(N=191)**  |  
| **N , %** |  
| **Gender** |  
| **Male** |  
| **N. of compulsory admisions in the last year** |  
| **none** |  
| **1-3** |  
| **≥4** |  
| **Lifetime N. of inpatients admissions** |  
| **none** |  
| **1-10** |  
| **11-20** |  
| **≥21** |  
| **Age , mean (SD)** |  
| **Marital status** |  
| **Never married** |  
| **Currently married** |  
| **Separated/widowed/divorced** |  
| **Education** |  
| **Elementary school** |  
| **Middle school** |  
| **Secondary school** |  
| **Master degree** |  
| **Working status** |  
| **Employed** |  
| **Unemployed or looking for a job** |  
| **Retired** |  
| **Other** |  
| **Living conditions before the current accommodation** |  
| **Other RF** |  
| **Living alone at home or with a partner/parents or other** (e.g. prison, homeless, general hospital, etc.) |  
| **Primary clinical diagnosis** |  
| **Schizophrenia** |  
| **Affective disorders** |  
| **Unipolar depression** |  
| **Personality disorder** |  
| **Other** |  
| **Presence of organic comorbidity** |  
| **Yes** |  
| **No** |  
| **Age at first contact with the MHS (years), mean (SD)** |  
| **N. of compulsory admission since the first contact with MHS** |  
| **none** |  
| **1-3** |  
| **≥4** |  
| **125** |
A total of 191 patients were assessed. Table 5.1 shows the sample’s main socio-demographic and clinical characteristics; missing data were few and never exceeded 13%.

The patients’ mean age was 50.3 (SD=12.4; range 21–79) and 64.9% were male. As for their marital status, almost the 80% of patients were unmarried, and just a small percentage resulted to be separated, divorced or widowed (9.2%). More than a half had a low degree of education (N=101). Only a small percentage of patients (N=13) were employed; to a large degree people did not actively participate in the labor force (almost 50% were out of work or were looking for a first job and 30% resulted to be occupationally disabled or retired).

In terms of clinical characteristics, schizophrenia was the most frequent diagnosis (63.2% of the entire study population) followed by affective disorders (19.5%), while other diagnosis only play a marginal role. Mean age at first mental health service contact was 30.1 years (SD = 10.6). About 33% (N=62) of the patients resulted to stay in another RF before entering the current accommodation. More in detail, out of 62 patients who already received residential treatment, 13 came from a CTRP, 37 from a CA, 6 from GAP and 6 from a nursing home. Appendix A shows the path of residential treatment in patients already living in RFs before the start of the study. From the 62 initial patients, 8 were excluded because they were currently living in private nursing facilities. From January 2008 to January 2014, out of 54, fourteen patients (25.9%) moved from RFs for intensive rehabilitation to RFs providing a lower level of care intensity, in particular, nine patients shifted from CTRP to CA, four from CA to GAP and one from CTRP to GAP. During the same period, twenty-two patients (40.8%) moved to accommodations of the same typology (twenty-one from CA to CA and one from CTRP to CTRP), whereas the others (N=18, 33.3%) moved to RFs characterized by higher levels of therapeutic assistance.

Clinical records showed that the presence of organic comorbidity was high among the sample (45% of patients); the most common problems that affect residents were cardiovascular diseases (diabetes and hypertension) and mental retardation or intellectual disabilities affecting, respectively, the 12 and 14.5 % of
the sample. Other comorbidities (above all endocrine-metabolic diseases and substance abuse) were less frequent and did not exceed 6 % of the sample.

Overall in the last twelve months before the study’s start, the number of compulsory admission was very low; out 166 patients, only three were hospitalized.

Table 5.2. Principal differences in socio-demographic, clinical characteristics, level of functioning and psychopathology among RFs

<table>
<thead>
<tr>
<th></th>
<th>CTRP (N=45) Mean (SD)</th>
<th>CA (N=108) Mean (SD)</th>
<th>GAP (N=14) Mean (SD)</th>
<th>p-value</th>
<th>Bonferroni</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>46.5 (11.7)</td>
<td>50.1 (11.5)</td>
<td>39.2 (8.8)</td>
<td>0.002*</td>
<td>CA-GAP</td>
</tr>
<tr>
<td>Lifetime mean number of inpatients admissions</td>
<td>13.8 (13.1)</td>
<td>9.9 (14.1)</td>
<td>3.4 (5.4)</td>
<td>0.040*</td>
<td>CTRP-GAP</td>
</tr>
<tr>
<td>Length of stay in the current RF (years)</td>
<td>4.8 (3.1)</td>
<td>5.8 (3.5)</td>
<td>3.6 (2.3)</td>
<td>0.043*</td>
<td>CA-GAP</td>
</tr>
<tr>
<td>GAF score (0, very severe dysfunction; 90 very good functioning)</td>
<td>40.6 (15.0)</td>
<td>44.9 (15.7)</td>
<td>52.4 (11.7)</td>
<td>0.050*</td>
<td>CTRP-GAP</td>
</tr>
<tr>
<td>PSP Score (0, very severe dysfunction; 90 very good functioning)</td>
<td>39.1 (14.0)</td>
<td>45.8 (14.9)</td>
<td>47.4 (18.9)</td>
<td>0.035*</td>
<td>CTRP-CA</td>
</tr>
<tr>
<td>BPRS score (1, no symptom; 7 very severe symptom)</td>
<td>3.2 (1.0)</td>
<td>2.8 (1.1)</td>
<td>2.4 (0.8)</td>
<td>0.030*</td>
<td>CTRP-GAP</td>
</tr>
<tr>
<td>Anxiety-depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative symptoms</td>
<td>3.6 (1.4)</td>
<td>3.0 (1.4)</td>
<td>2.5 (1.2)</td>
<td>0.021*</td>
<td>CTRP-GAP</td>
</tr>
<tr>
<td>Positive symptoms</td>
<td>3.5 (1.4)</td>
<td>2.7 (1.4)</td>
<td>1.9 (1.0)</td>
<td>0.000*</td>
<td>CTRP-CA/CTRPGAP</td>
</tr>
<tr>
<td>Mania/excitement</td>
<td>2.5 (1.3)</td>
<td>2.4 (1.5)</td>
<td>1.9 (1.1)</td>
<td>0.487</td>
<td></td>
</tr>
<tr>
<td>Cognition</td>
<td>3.2 (1.2)</td>
<td>2.6 (1.5)</td>
<td>2.2 (1.1)</td>
<td>0.015*</td>
<td>CTRP-CA/CTRPGAP</td>
</tr>
<tr>
<td>BPRS mean score</td>
<td>3.2 (0.9)</td>
<td>2.7 (1.1)</td>
<td>2.2 (0.6)</td>
<td>0.003*</td>
<td>CTRP-CA/CTRPGAP</td>
</tr>
</tbody>
</table>

*p-value <0.05. GAF, Global Assessment of Functioning; PSP, Personal and Social Functioning; BPRS, Brief Psychiatric Rating Scale

Comparisons among groups were conducted excluding patients staying in nursing homes (N=24) because of this group was characterized by older ages and, consequently lower level of social and personal functioning and different types of needs. Moreover, although private nursing homes and registered care homes, which operated for elderly peoples’ care often applied in the area of adult mental
health, in practice, they relate to a different set of health problems and often different styles of working.

Table 5.2 shows the principal characteristics of the three comparison groups. Significant differences were found for patients’ age. People living in the CA were the oldest, while the youngest were those living in GAP (F=6.4, p=0.002).

The data on lifetime mean number of inpatients admissions corroborate that compared to the other groups, and, in particular, to patients staying in GAP, patients living in CA and CTRP had been hospitalized, for the most part, many times prior to their move to the current facility (F=3.3, p=0.040). In line with this results, the three group were also characterized by different levels of global, personal and social functioning (for GAF score F=3.1, p=0.050; for PSP score F=3.4, p=0.035), and the severity of psychopathological symptoms (for BPRS total mean F=6.3, p=0.003). In particular, the strongest difference about the level of functioning were found between patients living in CTRP (who had a worse functioning) and CA and CTRP and GAP. As far as psychopathological symptoms are concerned, people in GAP were characterized by less severe depressive (F=3.6, p=0.030), negative (F=4.0, p=0.021) and positive symptoms (F=9.1, p<0.001), above all hallucinations (F=6.4, p=0.002), unusual thought contents (F=7.3, p=0.001) and conceptual disorganization (F=7.1, p=0.001) compared to those in CTRP and a better cognitive functioning (F=4.3, p=0.015). Overall patients living in CTRP showed the greatest manifestation of psychopathologic symptoms except for the mania/excitement subscale (For more detailed information see appendix B).

Significant differences were found in length of stay for patients in CTRP, CA and GAP. On average, patients were living in CTRP for 4.8 (SD=3.1), in CA for 5.6 (SD=3.5) and in GAP for 3.4 years (SD=2.3). Although our results showed that, according to their mission, patients’ length of stay varied among the different residential settings (F=3.2, p =0.043), anyway the period of staying resulted to be longer than regional law mental health plans provide for.
Table 5.3 Differences in the needs of care (CAN domains) among RFs

<table>
<thead>
<tr>
<th></th>
<th>CTRP (N=45) Mean (SD)</th>
<th>CA (N=108) Mean (SD)</th>
<th>GAP (N=14) Mean (SD)</th>
<th>p-value Bonferroni</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Met needs</td>
<td>2.9 (1.3)</td>
<td>3.1 (1.6)</td>
<td>3.6 (1.2)</td>
<td>0.565</td>
</tr>
<tr>
<td>Unmet needs</td>
<td>1.5 (1.3)</td>
<td>1.0 (1.2)</td>
<td>0.8 (1.1)</td>
<td>0.069</td>
</tr>
<tr>
<td>Ratio met/unmet</td>
<td>1.9</td>
<td>3.1</td>
<td>4.5</td>
<td></td>
</tr>
<tr>
<td><strong>Basic</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Met needs</td>
<td>2.0 (0.9)</td>
<td>2.3 (0.8)</td>
<td>2.4 (0.8)</td>
<td>0.083</td>
</tr>
<tr>
<td>Unmet needs</td>
<td>0.5 (0.8)</td>
<td>0.4 (0.6)</td>
<td>0.4 (0.6)</td>
<td>0.686</td>
</tr>
<tr>
<td>Ratio met/unmet</td>
<td>4</td>
<td>5.7</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td><strong>Social</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Met needs</td>
<td>0.3 (0.5)</td>
<td>0.7 (0.7)</td>
<td>0.6 (0.5)</td>
<td>0.005*</td>
</tr>
<tr>
<td>Unmet needs</td>
<td>1.0 (1.0)</td>
<td>0.4 (0.6)</td>
<td>0.4 (0.9)</td>
<td>0.000*</td>
</tr>
<tr>
<td>Ratio met/unmet</td>
<td>0.3</td>
<td>1.7</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td><strong>Service</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Met needs</td>
<td>1.5 (1.2)</td>
<td>1.7 (1.2)</td>
<td>1.2 (1.1)</td>
<td>0.286</td>
</tr>
<tr>
<td>Unmet needs</td>
<td>0.5 (0.9)</td>
<td>0.4 (0.7)</td>
<td>0.1 (0.3)</td>
<td>0.124</td>
</tr>
<tr>
<td>Ratio met/unmet</td>
<td>3</td>
<td>4.2</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td><strong>Functioning</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Met needs</td>
<td>1.4 (1.0)</td>
<td>2.5 (1.1)</td>
<td>1.9 (1.3)</td>
<td>0.000*</td>
</tr>
<tr>
<td>Unmet needs</td>
<td>1.1 (1.2)</td>
<td>0.5 (0.9)</td>
<td>1.1 (1.4)</td>
<td>0.008*</td>
</tr>
<tr>
<td>Ratio met/unmet</td>
<td>1.2</td>
<td>5</td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Met needs</td>
<td>8.1 (3.3)</td>
<td>10.2 (3.5)</td>
<td>9.4 (3.2)</td>
<td>0.004*</td>
</tr>
<tr>
<td>Unmet needs</td>
<td>4.5 (3.9)</td>
<td>2.7 (3.0)</td>
<td>2.8 (2.8)</td>
<td>0.008*</td>
</tr>
<tr>
<td>Ratio met/unmet</td>
<td>1.8</td>
<td>3.7</td>
<td>3.3</td>
<td></td>
</tr>
</tbody>
</table>

*p-value <0.05; CAN, Camberwell Assessment of Needs

Table 5.3 shows the mean score for the number of needs met and unmet and the ratio between the two for each area. All patients had needs in all five areas. On average, the number of needs of care was moderate (M=12.8, SD= 3.1, range: 0-22) and the ratio between met and unmet needs was overall positive (ratio=3). The total number of needs did not significantly vary across groups (F=0.357, p=0.700). On the contrary, the global number of met and unmet needs, and consequently, the ratio between the two (the higher is the ratio, the higher is the number of patients’ needs met by services), resulted to be statistically different for patients staying in CA and CTRP (for met needs F=5.7, p=0.004; for unmet needs F=5.0; p=0.008). Although the ratios were overall positive (higher than 1) and the total number of need did not differ among groups, data showed that were the number of unmet needs that made the difference. People staying in CTRP had an equal number of needs compared to patients in CA and GAP, but an higher
number of unmet needs ($F=5.0$, $p=0.008$). The same applied for the area of social and functioning needs of care. For both, the number of unmet needs were higher for people in CTRP than in CA (for social needs $F=8.4$, $p=<.001$; for functioning needs $F=5.0$, $p=0.008$). The single areas in which the differences between the two RF reached the significance were the safety to self ($F=4.6$, $p=0.011$), company ($F=5.0$, $p=0.008$), sexual expression ($F=7.4$, $p=0.003$), household skills ($F=3.9$, $p=0.022$) and transport ($F=5.2$, $p=0.006$) (See appendix C).
Figure 5.4 % of CTRP patients receiving intervention for each item of the VADO scale (N=44)
Figure 5.5 % of CA patients receiving intervention for each item of the VADO scale (N=103)
Figure 5.4, 5.5 and 5.6 show the percentage of patients for each RF (respectively, CTRP, CA and GAP) who were receiving a specific intervention, as assessed through the items of the VADO scale. Irrespective of the type of housing, overall the majority of patients received interventions focused on the self-care (from item 1 to item 7) and community services (from item 8 to item 11) areas.
The main differences that raised the statistical significance regarded the number of patients receiving interventions in the physical health \( (x^2=15.4, p=0.052) \), mental health \( (x^2=15.2, p=0.055) \), safety \( (x^2=20.6, p=0.008) \), information \( (x^2=16.8, p=0.032) \), transport \( (x^2=21.4, p=0.006) \) and management of the emergencies \( (x^2=17.2, p=0.028) \) areas.

Compared to CTRPs and GAPs, patients staying in CAs received more interventions focused on the promotion of the physical (nearly 72% of patients) and mental health (about 85% of the patients). As for the other area of interventions, overall patients in CTRPs were resulted to receive a major number of interventions than patients in other RFs: almost 50% were consistently monitored and educate to identify and avoid dangerous situations, to the 45.5% were given information about who contact in the time of need and another 45.5% were carried during their transfer. In some cases (for safety and information domain, for example) the number of patients receiving treatment in CTRPs was twice as much that in CAs and four times greater than that in GAPs.
Table 5.4 Mean satisfaction scores for patients and relatives and QoL scores.

<table>
<thead>
<tr>
<th></th>
<th>CTRP (N=45) Mean (SD)</th>
<th>CA (N=108) Mean (SD)</th>
<th>GAP (N=14) Mean (SD)</th>
<th>Total Mean (SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VSSS patient score</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall Satisfaction</td>
<td>3.8 (0.8)</td>
<td>4.0 (0.8)</td>
<td>4.3 (1.0)</td>
<td>4.0 (0.8)</td>
<td>0.232</td>
</tr>
<tr>
<td>Professionals’ skills and behavior</td>
<td>3.7 (0.9)</td>
<td>3.9 (0.7)</td>
<td>4.2 (0.8)</td>
<td>3.9 (0.8)</td>
<td>0.161</td>
</tr>
<tr>
<td>Efficacy</td>
<td>3.7 (0.8)</td>
<td>3.6 (0.8)</td>
<td>3.9 (0.7)</td>
<td>3.7 (0.8)</td>
<td>0.351</td>
</tr>
<tr>
<td>Type of intervention</td>
<td>3.8 (0.5)</td>
<td>3.7 (0.5)</td>
<td>3.7 (0.6)</td>
<td>3.7 (0.5)</td>
<td>0.608</td>
</tr>
<tr>
<td>Information</td>
<td>3.5 (0.8)</td>
<td>3.4 (1.0)</td>
<td>3.8 (0.9)</td>
<td>3.5 (0.9)</td>
<td>0.312</td>
</tr>
<tr>
<td>Access</td>
<td>3.7 (0.7)</td>
<td>3.9 (0.6)</td>
<td>4.1 (0.7)</td>
<td>3.9 (0.6)</td>
<td>0.090</td>
</tr>
<tr>
<td><strong>VSSS total mean score</strong></td>
<td>3.7 (0.5)</td>
<td>3.8 (0.5)</td>
<td>3.9 (0.6)</td>
<td>3.8 (0.5)</td>
<td>0.431</td>
</tr>
<tr>
<td><strong>VSSS relatives score</strong> (N=52)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall Satisfaction</td>
<td>4.3 (0.6)</td>
<td>4.1 (0.8)</td>
<td>4.3 (0.5)</td>
<td>4.2 (0.7)</td>
<td>0.730</td>
</tr>
<tr>
<td>Professionals’ skills and behavior</td>
<td>4.3 (0.6)</td>
<td>4.1 (0.6)</td>
<td>4.0 (0.7)</td>
<td>4.2 (0.6)</td>
<td>0.631</td>
</tr>
<tr>
<td>Efficacy</td>
<td>4.3 (0.6)</td>
<td>4.1 (0.6)</td>
<td>3.8 (0.7)</td>
<td>4.1 (0.6)</td>
<td>0.231</td>
</tr>
<tr>
<td>Type of intervention</td>
<td>4.0 (0.5)</td>
<td>3.8 (0.6)</td>
<td>4.0 (0.3)</td>
<td>3.9 (0.6)</td>
<td>0.468</td>
</tr>
<tr>
<td>Information</td>
<td>4.1 (0.8)</td>
<td>3.8 (1.1)</td>
<td>3.7 (1.0)</td>
<td>3.9 (1.0)</td>
<td>0.652</td>
</tr>
<tr>
<td>Access</td>
<td>4.2 (0.7)</td>
<td>4.3 (0.5)</td>
<td>3.5 (0.4)</td>
<td>4.2 (0.6)</td>
<td>0.013*</td>
</tr>
<tr>
<td><strong>VSSS total mean score</strong></td>
<td>4.2 (0.6)</td>
<td>4.1 (0.5)</td>
<td>3.9 (0.3)</td>
<td>4.1 (0.5)</td>
<td>0.442</td>
</tr>
<tr>
<td><strong>MANSA score</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living situation</td>
<td>5.1 (1.3)</td>
<td>5.1 (1.1)</td>
<td>5.5 (0.9)</td>
<td>5.1 (1.2)</td>
<td>0.405</td>
</tr>
<tr>
<td>Health</td>
<td>5.1 (1.0)</td>
<td>4.7 (1.4)</td>
<td>5.3 (0.8)</td>
<td>4.8 (1.2)</td>
<td>0.115</td>
</tr>
<tr>
<td><strong>MANSA total mean score</strong></td>
<td>5.0 (0.8)</td>
<td>4.8 (0.7)</td>
<td>5.0 (0.8)</td>
<td>4.9 (0.8)</td>
<td>0.329</td>
</tr>
</tbody>
</table>

*p-value <0.05; VSSS, Verona Service Satisfaction Scale; MANSA, Manchester Short Assessment of Quality of Life

No differences were detected in the three groups for that concerns services’ satisfaction expressed by patients and subjective QoL domains (Table 5.4). Overall on a 5-point Likert scale, the mean level of satisfaction was moderate (mean=3.8; F=0.8, p=0.431). Appendix D shows the % of people who were not satisfied by the services provided. More than the half of the sample rated to be unsatisfied with the information received by professionals on diagnosis and prognosis of their illness, about 40% stated to be unsatisfied with the type of intervention (medical prescription, recreational and rehabilitation activities and help received to find employment) and with the efficacy of services received (help received to maintain and establish good relationship outside the facility).

The only significant difference was found in the questionnaires filled in by relatives for the ‘access’ subscale. Parents of patients living in GAP showed a
lower level of services’ satisfaction than those of patients staying both in CTRPs and in CAs (F=4.8, p=0.013). As for the subjective QoL referred by patients, we did not find any differences in the level of satisfaction expressed (F=1.1, p=0.329).
Table 5.5 Univariable regression models showing demographic, clinical, social and service utilization variables associated with categorized unmet needs in five areas

<table>
<thead>
<tr>
<th>Health</th>
<th>Basic</th>
<th>Social</th>
<th>Service</th>
<th>Functioning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression coefficient (95% CI)</td>
<td>p</td>
<td>Regression coefficient (95% CI)</td>
<td>p</td>
<td>Regression coefficient (95% CI)</td>
</tr>
<tr>
<td>Age</td>
<td>0.019 (-0.015-0.019)</td>
<td>0.807</td>
<td>0.051 (-0.006-0.011)</td>
<td>0.518</td>
</tr>
<tr>
<td>Gender</td>
<td>0.080 (-0.194-0.600)</td>
<td>0.315</td>
<td>0.157 (0.004-0.411)</td>
<td>0.046</td>
</tr>
<tr>
<td>Working status (employed vs unemployed)</td>
<td>-0.051 (-0.970-0.494)</td>
<td>0.522</td>
<td>-0.086 (-0.597-0.173)</td>
<td>0.282</td>
</tr>
<tr>
<td>Age at first contact</td>
<td>-0.077 (-0.029-0.010)</td>
<td>0.349</td>
<td>-0.008 (-0.011-0.010)</td>
<td>0.921</td>
</tr>
<tr>
<td>Hospitalisation</td>
<td>0.200 (0.003-0.032)</td>
<td>0.016</td>
<td>0.138 (-0.001-0.014)</td>
<td>0.096</td>
</tr>
<tr>
<td>Length of stay (years)</td>
<td>-0.108 (-0.097-0.018)</td>
<td>0.172</td>
<td>0.070 (-0.044-0.017)</td>
<td>0.380</td>
</tr>
<tr>
<td>BPRS_mean</td>
<td>0.337 (0.195-0.562)</td>
<td>&lt;0.001</td>
<td>0.164 (-0.014-0.232)</td>
<td>0.083</td>
</tr>
<tr>
<td>PSP</td>
<td>-0.261 (-0.034--0.009)</td>
<td>0.001</td>
<td>-0.184 (-0.014--0.001)</td>
<td>0.020</td>
</tr>
<tr>
<td>VSSS_satisfaction</td>
<td>-0.123 (-0.430-0.079)</td>
<td>0.175</td>
<td>-0.107 (-0.208-0.052)</td>
<td>0.239</td>
</tr>
<tr>
<td>VSSS_information</td>
<td>-0.043 (-0.279-0.171)</td>
<td>0.637</td>
<td>-0.174 (-0.224-0.002)</td>
<td>0.054</td>
</tr>
<tr>
<td>MANSA_mean</td>
<td>-0.237 (-0.590--0.095)</td>
<td>0.007</td>
<td>-0.113 (-0.215-0.046)</td>
<td>0.204</td>
</tr>
</tbody>
</table>

Coefficients significant at p<0.1; BPRS, Breif Psychiatric Rating Scale; PSP, Personal and Social Performance scale ; VSSS, Verona Service Satisfaction Scale; MANSA, Manchester Short Assessment of Quality of Life
Table 5.6 Multivariable regression models showing demographic, clinical, social and service utilization variables associated with categorized unmet needs in five areas.

<table>
<thead>
<tr>
<th>Health</th>
<th>Basic</th>
<th>Social</th>
<th>Service</th>
<th>Functioning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gender</td>
<td>-</td>
<td>-</td>
<td>0.123 (-0.026-0.586) 0.072</td>
<td>0.084 (-0.119-0.339) 0.341</td>
</tr>
<tr>
<td>Working status (employed vs unemployed)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Age at first contact</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Hospitalisation</td>
<td>0.014 (-0.019-0.022) 0.904</td>
<td>0.173 (-0.004-0.024) 0.150</td>
<td>0.152 (-0.002-0.020) 0.097</td>
<td></td>
</tr>
<tr>
<td>Length of stay (years)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>BPRS_mean</td>
<td>0.297 (0.078-0.539)</td>
<td>0.009</td>
<td>0.027 (-0.138-0.172) 0.825</td>
<td>-</td>
</tr>
<tr>
<td>PSP</td>
<td>-0.102 (-0.024-0.009) 0.373</td>
<td>-0.077 (-0.014-0.008) 0.553</td>
<td>-0.230 (-0.019-0.002)</td>
<td>0.034</td>
</tr>
<tr>
<td>VSSS_satisfaction</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>VSSS_information</td>
<td>-</td>
<td>-1.55 (-0.278-0.055) 0.184</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>MANSA_mean</td>
<td>-0.232 (-0.650-0.027)</td>
<td>0.034</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

- denotes not significant when first considered for entry the model; BPRS, Brief Psychiatric Rating Scale; PSP, Personal and Social Performance scale; VSSS, Verona Service Satisfaction Scale; MANSA, Manchester Short Assessment of Quality of Life
Table 5.5 and 5.6 show the results of univariable and multivariable regression models with unmet needs in the five separate areas of the CAN as the outcomes. Unmet needs in the area of ‘health’ were predicted by the severity of the psychopathological symptoms; the more severe is the symptom, the more needs patients have ($b=0.297$), and by the subjective QoL perceived by patients ($b=-0.232$). Unmet ‘basic’ and ‘functioning’ unmet needs did not seemed to be associated with any variables. On the contrary, a young age, a good level of functioning and satisfaction with services are predictors of less social unmet needs.

5.3.1 Quality indicators

Although RFs quality indicators were not available for every RFs entered in the study, we used these data to collect some basic information on RFs’ staff characteristics, general organization and rehabilitative activities provided.

Data on quality indicators were available for three CTRP. The mean number of beds available in these RFs were 14.6 which resulted to be fully occupied. The mean number of admission in the last twelve months were 9.3, and were balanced out of the number of incoming patients. The mean number of hospitalization during the patients’ staying in RF were 4.0. In each CTRP worked from twelve to fifteen staff operators. Generally, there was a coordinator who was represented by a psychologist or a physician, a nurse and nine or ten healthcare professionals. In some cases there was also one operator specialized in psychiatric rehabilitation and a social worker. Patients spent, on average, from seven to fifteen hours a week out of the RF, mostly together with their relatives. Few hours a week were spent in rehabilitative or creative activities (on average five-six hours a week). Only three patients resulted to be engaged in work activities.

For that concern CA, data were available for eight RFs. The mean number of beds per RFs was 12.3, and on average, there were no free beds. In the last twelve months, the mean number of discharged patients was 2.5 versus 1.4 new admissions. The number of hospitalization was very low (overall there were 11 hospital admission during the year). As for CTRP, healthcare professionals were
the most representative figures in the RFs (the number ranged from seven to thirteen), followed by psychologists (almost one per RF), nurses and operator specialized in psychiatric rehabilitation. The time spent by patients outside the facilities varied across RFs and depended on the amount of activities organized by each RF. Overall, only sixteen patients worked or were engaged in internship.

Information on five group homes showed that in some cases the number of patients hosted was higher than the number of beds available. Compared to the other RFs the patients’ turnover was higher. As a matter of fact, in the last twelve months, six patients were discharged and four new patients were admitted. No hospital admissions were recorded. According to the restricted number of beds, patients were followed on average by four or five healthcare professionals (a psychologist, and a nurse). On average, patients were involved in more activities and spent almost three hours a day outside the RF. Seven patient were officially employed.

5.4 Discussion

This is the first national study that assessed characteristics of patients and their pattern of care in three different types of housing services including CTRP, CA and GAP which have been established only recently. The three forms of housing services included in the study had, on average, different patients and provided different elements of care. Yet, characteristics of clientele and care provision overlap substantially.

Except for age, no differences were found on socio-demographic characteristics among RFs. In line with other previous findings, residents were predominantly male, unmarried, with a medium-low level of education. The most representative diagnosis was schizophrenia. On the contrary, some significant differences were found in patients clinical profiles. According to RFs’ mission, patients who were younger and had better living skills and level of functioning were assigned to more independent housing solutions (GAP) than those living in CA. Yet, although the younger age, the better level of functioning and also less severe psychopathological symptoms of patients in GAPs, there were still no
differences in number of people employed among the three different groups. RFs’ quality indicators corroborated these data.

The presence of significant differences in social needs among RFs and the lack of a regular work could be explained, however, by the severity of many patients’ disability rather than insufficient support through staff in the housing services (Hawthorne, 2008). In fact, despite the differences found, GAF and PSP scores were overall medium-low in all groups, suggesting for a chronic condition of the mental disease. The fact that only 9.6% of patients were involved in occupational activities indicated that concepts of therapeutic communities, which involve all patients in the running of the project, are not common in housing services. In this field, more detailed research is need to assess whether this is a sign of positive flexibility or a problematic lack of clarity and focus.

These results should be taken into great consideration to define a rehabilitative intervention. Literature suggest that social support, lower psychopathology and higher job skill levels are important home discharge predictors (Anderson et al., 1993; Segal and Kotler, 1993; Priebe et al., 2002; D’Avanzo et al., 2004).

No significant differences were found in the number of needs of care among the three groups of patients. Each group show a remarkable number of needs. All patients showed a moderate number of needs of care that did not differ among groups. The principal differences depend on the services’ abilities to satisfy patients’ secondary needs, above all in the social and functioning areas. In particular, patients social needs did not refer to the help received to maintain intimate relationship, but, more generally, to maintain social contacts outside the RF (in the social domain unmet needs were slightly prevailing over met needs). Indeed, whilst there was regular contact with staff and fellow patients in the services, many patients had only limited contacts with friends outside the service. However, involving patients in some sort of activities and providing various support with activities of daily living may be regarded as indicators of reasonable quality.
CAN-S’ results were only partially in line with data on the ‘rehabilitative areas’ of the VADO instrument. Both in the area of the ‘safety’ and the ‘transport’ the differences among needs of care rated by staff operators are sustained by an increased number of people who received interventions. Even if the number of needs in the basic, physical and health area did not differ among groups, the number of patients receiving intervention in the same area did. In particular a major number of patients staying in CAs received these type of interventions. The same applied in the area of ‘Information’.

Overall, except for the promotion of physical and mental well-being (in which patients in CAs had more needs and more interventions), patients staying in CTRPs had an higher number of needs of care and so more patients received a rehabilitative treatment in these areas (safety, information, transport, emergency). In some cases these differences did not raise the statistical significance but, anyway, the trend was the same.

Overall, services seem to be able to provide an acceptable environment and meet the fundamental primary needs for most of their patients. Yet, one may speculate as to whether the overall care with limited input from mental health services represents optimal treatment, particularly for the substantial number of patients in these services who wish to move to more independent forms of living (Fakhoury et al., 2005) rather to be content with the perspective of staying in RFs for a long time, or the rest of their lives. In this framework, although concerning a small number of patients, our data demonstrated that the current situation in Italian RFs is not promising. During a period of six years, only a small minority of patients moved from RFs for intensive rehabilitation to RFs providing a lower level of care’s intensity. These shifts could be explained by an improvement in patients’ personal and social functioning and living skills due to focused therapeutic interventions provided by residential services. If so, in a medium-long term view, residential treatments result to be effective only for a scant percentage of patients living in RFs.

Anyway, needs are important for at least two reasons. Firstly, they have direct treatment implications, and should be the basis for planning care. Secondly, the
best available evidence indicates they are a better predictor of QoL than either clinical (e.g. symptomatology, diagnosis) or socio-demographic variables (UK 700 Group, 1999). Slade and colleagues (1999) and the UK700 Group (1999) observed that as needs increased, QoL decreased and that unmet needs had more influence on QoL than met needs. Findings were also replicated by Lasalvia and collaborators (2002) who found that an improvement in clinical conditions and a reduction in unmet needs predicted a lower follow-up QoL, suggesting self-perceived social need rather than reduction in psychopathology improved QoL in people with severe mental disorders. In our sample, although the differences about met-unmet needs among CAN scores, we did not found anyone in QoL scores. Overall, patients in RFs referred to be moderately satisfied with their global life and a good level of services’ satisfaction.

Identifying unmet needs can provide information for gaps in services and implication for improvement. Similarly, meeting unmet needs result to be important not only because the number of unmet needs is related to reduced health and ongoing health related expenses; but also because it will enable providers and patients to assess a range of different forms of supported accommodation, through which patients may move according to needs as well as by choice, at different times in their lives or stage of their illness.

5.4.1 Limitations

The study used a systematic approach to obtain representative data on patients and housing services in the catchment area of the South-Verona CMHC. However, there are several factors that may have biased the results. Most importantly, this was a cross-sectional survey aimed at investigating the characteristic of patients staying in specific type of accommodations. This design makes it difficult to infer causality between variables that are associated with each other; a prospective study would make aetiological inferences easier. Despite this limitation, the study may be considered as a starting point in order to better comprehend which type of users addressed this type of housing and examine if the type of care provided is suitable for them. Another weak point is that the gather information is not comprehensive of all the RFs of the area. Some services were
contacted but did not respond to the request and this introduces an obvious selection bias.

The CAN-S, used to assess patients’ needs of care was filled in by housing staff or clinicians and not by patients themselves. A comprehensive needs’ assessment, which takes systematically into account both staff and users’ view, may contribute to improve communication between patients and professionals with the result of a more active users’ involvement in the care provided and a parallel increase of the adherence to interventions being offered (Lasalvia et al., 2008).

In addition, we could not check the accuracy of the information in the questionnaires. Service managers may have misunderstood the terminology in some questions, filled in questions without having valid information, and tended to over-report service input and patient activities expecting that this may show their services in a better light despite the guaranteed data confidentiality. Thus, the results might provide too positive a picture of the reality of housing services assessed. This has to be taken into account in the interpretation of the findings although it may not substantially alter some of the main conclusions. Also, the sampling procedure provided too few placement schemes for statistical comparisons with other service types. Finally, the study did not assess predefined quality indicators, and the findings of a survey using a simple quantitative methodology, as this study, can only provide limited insight into the reality of daily life and care in housing services.

5.4.2 Implications

More transparency and clarity is required on what care different types of housing services provide, so that patients and referring clinicians know what to expect from such services. For this, quality standards may have to be defined in the context of substantial cost differences between different housing service types. The wide application of such standards and their potential link to funding might require some controls and inevitable bureaucracy, but should also help to ensure that all patients in housing services receive appropriate care. Achieving
independent living and employment may be an unrealistic goal for many patients, but it should hardly be a reason for withdrawing ongoing input from mental health professionals in CMHCs to facilitate the maximum possible level of recovery in every individual patient. Support for people with severe mental illness may be provided through supported housing schemes with the intention of increasing treatment success rates and reducing cycles of hospital readmissions.

All these implications apply to the situation in Italy, and this type of research is inevitably linked to the specific context of the national social and health care system. In most other countries, health care in general, and community mental health care in particular, are differently organized and housing services, as well as the care provided by mental health professionals for people in housing services, might be very different. Thus, the results cannot be generalized beyond the context in which they were generated. Yet, some issues and challenges that are highlighted in this study are likely to be relevant beyond Italy. Across Europe precise and transparent data on the characteristics of patients in housing services, the components and costs of care, and the clinical and social outcomes for the patients in such services are very scarce (Priebe et al., 2009). International comparisons may utilize the existing substantial differences in service provision between countries to assess a wider range of care models and their association with outcome criteria (Lloyd-Evans et al., 2007). Research evidence should be generated on what type of care is most helpful for patients in housing services, and whether alternative services may provide better care. This exploratory study has reported mainly descriptive data. This can and should form the starting point for more specific research evaluating care processes in housing services and alternative services using quantitative and qualitative methods.

5.5 Conclusions

The differences between different types of housing services, although statistically significant in many aspects, are not clear-cut and show that the broad RFs categories used in this study, and also in national policies, do not refer to clearly defined and distinct models of care.
At present, the choice between dedicated supported housing schemes and outreach services is based on a combination of personal preference, professional judgement and availability of resources. Decisions of this nature should be made with the full understanding that no one intervention has been shown to be more effective than another in making a difference to symptoms, future use of services, QoL or other measures of importance. Furthermore, the efficacy of supported housing remains untested. Participating in trials that test the effectiveness of such services should be encouraged.

Policies in favour of dedicated supported housing schemes should be viewed with some caution and should not be implemented without plans for evaluation using rigorous methods or should be delayed pending further evidence of their effectiveness. Forming alliances with researchers within this field may result in a fruitful collaboration that would not only inform local policies on this issue, but would also provide much needed evidence base on its effectiveness.
Chapter 6. General discussion and conclusion

In Italy, the physiognomy of non hospital RFs was conditioned by a context in which the questions that needed urgent responses mainly were time and space. Neglected were the ‘how’ and, consequently, the evolutionary path that would shift the perspective from the structure to the patient. Crucial issues are those related to the type of structures, the number of the patients hosted, the necessity (or lack of necessity) of structures for ‘special’ patients, and the problem of discharge (Ghio et al., 2016). In a paper published in 2004, Sharp outlines a sadly truthful panorama, stressing that in Italy the care of psychiatric patients with chronic problems has been forgotten. ‘Difficult’ patients with chronic and highly debilitating illnesses are actually ‘stored’ in isolated environments, managed by staff limited in number and skills. Many of the aspects of the old custodial large institutions are equally present today in small institutions (the RFs). The author also points out that similarly severe patients in the United Kingdom, are managed in ‘supported group homes’. Young patients and those that society considers acceptable have treatment priority. People with chronic or complex mental disorders are removed from the rest of society, in a forgotten corner of a former psychiatric hospital. In summary, the application of Law no.180 has not been able to prevent the chronicity, but merely allocated elsewhere chronic patients (Ghio et al., 2016). These considerations are derived from a study conducted by the author in Ferrara, a city placed in one of the most virtuous regions in social, economic, and local policies (Sharp, 2004). The steady increase in the number of beds in the RFs from 2000 to 2010, although within a system of community mental health, increases concern that a process of reinstitutionalization might be realized again (Priebe and Fioritti, 2004). However, unlike what is happening in other Western European countries, in Italy other forms of treatment at risk of institutionalization as the number of mandatory treatments, the number of admissions to forensic-psychiatric hospital and to general hospitals are not increasing (Priebe et al., 2008).
Moreover, the national project that aimed at closing the last six forensic psychiatric hospitals has been completed, with the taking over of patients discharged and not considered dangerous by the CMHCs, and with the inclusion of the other patients in small facilities (20 beds) distributed on the region, and yet providing security guarantees.

The length of residential stay assumes crucial significance: the full return of the patient to society is an event that gives meaning to the rehabilitation project. However, it is not always predictable and achievable, posing the problem of determining the drivers of change and how RFs generally work. While structural and organizational aspects of RFs are well described, less attention has been paid to the description of the factors related to a successful conclusion of residential treatments (Sharp, 2004). For instance, even in the face of data showing the effectiveness of residential structures, in both the clinical and psychosocial rehabilitation, treatment goals are often not clear, or at least not well explicated (de Girolamo et al., 2007; Santone et al., 2005; Lora et al., 2004). Initially, the low rate of discharge could be explained by the presence of many patients from mental hospitals, but now the percentages of these patients is of little relevance.

Many questions are still unanswered: 1) the presence of a population of patients (of uncertain entity) with severe psychiatric disorders who need to stay in residential facilities lifelong or, at least, for very long periods; 2) the lack of differentiation of treatment plans, which also raises the question of what is actually rehabilitation in residential work; and 3) the high percentage of admissions based on social needs rather than clinical. In addition, despite several studies showing that living in small, domestic-like environments is associated with better QoL and higher satisfaction than in traditional mental health wards, there is a reduced availability in Italy of beds in houses with a lower level of protection (Barry and Crosby, 1996; Lehman et al., 1986; Picardi et al., 2006).

Consequently, the rehabilitative value is crucial for the RFs to avoid the risk of turning into places that welcome protectively chronic patients for unlimited time. This is also linked to the intensity level of care in the CMHC: the greater the
ability of CMHC to take charge of the needs of patients and to articulate complex and flexible responses, the lower the chance that patients are forgotten in RFs.

The new guidelines of the conference of the state-regions that tend to differentiate the care pathways inside the residential structures and emphasize the need for a strong involvement of CMHC will determine interventions more personalized and potentially more effective.

From clinicians point of view, often the core clinical question when considering whether an intervention warrants support is whether it reduces symptoms or improves functioning. On one hand, the emerging concept of recovery as a process of change that aims to self-determination in order to reach one’s full potential, and on the other hand the development of a more individualized approach in the last twenty years have contributed to ratify that controlling symptoms is no longer an acceptable endpoint of the treatment of a person with mental health problems. The true core recovery question shoule be the degree to which personally defined goals have been achieved, whether in terms of objective indicators of social roles or subjective indicators of personal goals (Slade, 2010). But because resources are always scarce, decision-makers must think carefully about how to use them to deliver interventions aimed at improving recovery-focused outcomes. Decision-makers could employ many criteria in making decisions; economic evaluation provides evidence in relation to the efficiency criterion: how to get maximum health benefits from available resources. However they have also to keep in mind that an intervention does not need to be cost-saving to be efficient; it could be more expensive than the alternative with which it is compared, but the additional effectiveness must be sufficient to make the higher cost worth paying.

There is no fixed set of actions constituting a recovery approach, nor should there be given that the fundamental premise is to respond to evolving personal preferences and changing individual needs. However, some interventions can be seen as broadly consistent with the approach (Slade, 2010).
Peer support covers a spectrum of ways in which people receive help, support and sometimes services from others with lived experience of mental illness, including informal contacts between peers to more complex organised group-based activities and social media. Peer support embodies mutuality and reciprocity, and builds on social capital. Despite interest in the approach, there is currently little economic evidence. An uncontrolled study of 260 community-dwelling adults receiving peer-led self-management found significant improvements in wellbeing and costs that decreased a little over a year (Iemmi et al., 2015). Simpson and colleagues (2014) also found that peer support during the transition from hospital to home could increase hope, reduce loneliness, improve QoL and show cost-effectiveness compared to usual aftercare. Neither study is especially strong from a methodological standpoint.

Self-management that is improving one’s ability to manage symptoms and treatment, is clearly integral to a recovery approach. Components of programmes that train people in self-management could include psycho-education, medication management, setting individual recovery goals and developing life skills. Self-management can reduce relapse, prevent readmissions and improve medication adherence, but again there is little economic evidence (Zou et al., 2013).

Employment is core to recovery for many people with mental health issues. It not only has economic value but confers social benefits such as social networks, status and self-esteem; yet so often they face huge disadvantages in gaining and retaining employment (OECD, 2012), especially during macroeconomic ‘crises’ (Evans-Lacko et al., 2013). There is now plenty of evidence on supported employment, the best known model for which is Individual Placement and Support which helps individuals gain competitive employment as quickly as possible and provides ongoing training and support from employment specialists. Individual Placement and Support has been shown to be effective in many countries (Bond et al., 2012), and a six-city European study demonstrated that it is strongly cost-effective compared to traditional vocational support in many studies (Knapp et al., 2013). A risk is that Individual Placement and Support services may not be implemented as intended; employing Individual Placement and Support
trainers to work with mental health professionals and service users can help. Paid employment may not be achievable for everyone: some people may not feel they want it, and some may not be able to attain it. Having an appropriate economic ‘safety net’ is essential in those circumstances, yet many people with mental health issues fail to get the state support to which they are entitled (Frost-Gaskin et al., 2003). Welfare advice can increase uptake and reduce costs by shortening inpatient stays, preventing homelessness and preventing relapse (Parsonage, 2013). Debt advice services can also be both effective and cost-effective (Pleasance et al., 2007; Knapp et al., 2011). Individuals experiencing crises, for example as a result of symptom exacerbation in schizophrenia, often have unwanted and lengthy hospitalisation. The way that a health system responds varies from country to country, but joint crisis plans and advance directives have been suggested. They empower people at risk of compulsory admission, giving them an opportunity to specify in advance their preferences for treatments, for example (Henderson et al., 2004). Although attracting growing interest, we could find no economic evidence about such approaches.

Homelessness is a risk for some people with severe mental health problems, and supported housing tries to help individuals with complex needs to live independently in the community. If it is well planned and delivered, and of decent quality, supported housing can prevent a damaging spiral of hospitalisation and homelessness, use of emergency services and criminal justice contacts (Russolino et al., 2014; Gilmer et al., 2010).

People with enduring mental health problems are at high risk of physical morbidity and premature mortality, in part linked to poor health behaviours such as high rates of smoking, low rates of exercise and poor diet (McManus et al., 2010). Some medications exacerbate some of these problems through weight-gain and metabolic complications (Knapp et al., 2014). Consequently, physical health promotion is another important aspect of recovery, with supportive economic evidence for smoking cessation and weight management programmes (Foley et al., 2010).
Central to government policy in social care in the some countries, for example in England, is the aim of ‘personalisation’: to give service users more direct choice over how their needs are met. Personal budgets are potentially one route to this: individuals take control of the (public) funds that would otherwise have been spent through conventional channels on their treatment and support. Subject to a certain amount of monitoring, these budgets allow them to choose the services or support arrangements which they feel they need and want. A randomized trial of personal social care budgets in England concluded that they generated better outcomes than standard care arrangements, and, for the subsample of people with mental health issues, were more cost-effective (Netten et al., 2012; Jones et al., 2012). Although the study’s several limitations, it provide encouragement that recovery-informed purchasing models, for those individuals willing and able to take control, can have important benefits and are economically viable (Netten et al., 2012; Jones et al., 2012).

The stigma experienced by many people with mental health issues can affect many aspects of their lives, and can often manifest itself in blatant and harmful discrimination (Thornicroft, 2006). Stigma can limit access to education, employment and housing, can damage social relationships and self-esteem, and can erect barriers in the way of seeking treatment. In these ways it can also be socially costly (Sharac et al., 2010). However, although hard to evaluate, studies of anti-stigma campaigns in Scotland and England show them to have modest but significant positive impacts on population level attitudes, to be low cost and potentially to be costeffective because, among other things, they encourage people to use appropriate services, thus heading off crisisdriven events (McCrone et al., 2010b).

Finally, although without yet an evidence base, have been established recovery colleges. These colleges ‘deliver comprehensive, peer-led education and training programmes within mental health services […] providing education as a route to Recovery, not as a form of therapy. Courses are co-devised and co-delivered by people with lived experience of mental illness and by mental health professionals. Their services should be offered to service users, professionals and
families alike, with people choosing the courses they would like to attend from a prospectus’ (IROC, 2015). An uncontrolled evaluation of one college suggested that a majority of people with mental health issues attending had developed their own recovery plans, were more optimistic about the future, and had become more engaged in employment, education and volunteering (Rinaldi et al., 2012).

Interventions that aim to empower people with mental health issues, helping them to pursue goals which they value as important to them individually, do not appear to increase costs. Indeed, in many cases, they lead to a more cost-effective utilisation of resources.

Aside of this topic is the need to provide intervention in order to prevent illness to become chronic. These type of intervention target patients with different characteristics such as younger age, a better social and personal functioning and preserved job skills. Given the burden of schizophrenia discussed above, its direct and indirect costs, and the importance of improving personal outcomes in patients experiencing mental illness, the need to implement early intervention become clear. Early interventions could be provided through the creation of specific services just dedicated or through the development of integrated intervention delivered by CMHCs. Literature suggest that some intervention, and, in particular, CBT results to be efficacious to treat FEP patients. The analysis of predictors of treatment outcomes confirmed data already existed in the scientific literature. On the contrary, literature on moderators is very scarce. The identification of possible moderators results fundamental because treatment moderators specify for whom and under what conditions the treatment works and they also suggest to clinicians which of patients might be most responsive to the treatment and for which patients other, more appropriate, treatment might be sought. In the context of the GET-UP trial, the age was found to be the only moderator of treatment outcomes, showing that this type of integrated intervention might be appropriate for a large group of patients. In addition, prevention, early detection and intervention in psychosis have the potential to be cost saving in the long term however they do require an initial investment. Although no evidence exists to support the effectiveness of one particular form of service delivery
(inpatients service vs community team models) over any other, these new configurations, though still evolving, have formed an increasingly important element in the management of all forms of severe mental illness, particularly psychoses. They emphasise an alternative to inpatient admission, with treatments and interventions focused on the service user’s usual environment and context as social interventions for people with schizophrenia should strive to promote recovery. An integrated social programme for supporting access to work, education and recreation, is regarded as essential in addressing the impact on social function and isolation caused by schizophrenia. Social support and services looking at independent accommodation/housing, fighting stigma, improving access to meaningful activities addressing the individual’s aspiration and strengths, and health promotion in the wider communities, are all important considerations in realising the social inclusion principle (Repper & Perkins, 2003). Survey results amongst service users have also promoted the importance of social interventions that would improve/enhance better and more personal relationships, minimise discrimination, promote self-management, and ease social isolation through better availability of befriending and peer support schemes (RETHINK, 2003).
References


no difference between patients with history or with no history of violence. 


George and Tourne (1994). Le secteur psychiatrique, Puf, Collection Que Sais-Je, n° 2 911).


Goffman, E. Total institutions. wS.l.x: ws.n.x; 1977.

(2006). Impact of a specialized early intervention service for psychotic
disorders on patient characteristics, service use, and hospital costs in a

New programs in community mental health. *Health & Social Work, 2*(1),
119-140.

incidence studies of schizophrenic disorders: A systematic review of the


Adherence therapy for people with schizophrenia. european multicentre

Green, B. L., Wehling, C., & Talsky, G. J. (1987). Group art therapy as an adjunct
to treatment for chronic outpatients. *Hospital & Community Psychiatry, 38*(9), 988-991.


amplification of emotional expression is associated with emotional blunting. 

*Schizophrenia Research, 95*(1-3), 197-204.


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randomised controlled trial of cognitive therapy to reduce post psychotic trauma symptoms. *Behaviour Research and Therapy, 47*(6), 454-462.


Kissling, W., Hofller, J., Seemann, U., Muller, P., Ruther, E., Trenckmann, U., et al. (1999). Direct and indirect costs of schizophrenia. [Die direkten und


*Psychological Medicine, 41*(7), 1461-1469.


Mason, P., Harrison, G., Glazebrook, C., Medley, I., & Croudace, T. (1996). The course of schizophrenia over 13 years. A report from the international study on schizophrenia (ISoS) coordinated by the world health organization. *The


Ministry of Health (2008) Linee di indirizzo nazionali per la salute mentale [National strategic plans for mental health]. Retrieved from


Ministry of Health (2013) Linee di azioni nazionale per la salute mentale [Italian mental health action plan].


National Association of State Mental Health Program Directors (NASMHPD) (1987) Position statement on housing and support for people with long-term mental illness. NASMHPD, Alexandria. VA.


Organisation for Economic Co-operation and Development


Osborn, D. P., Nazareth, I., & King, M. B. (2007). Physical activity, dietary habits and coronary heart disease risk factor knowledge amongst people with severe


Findings from a national survey in Italy. *European Archives of Psychiatry and Clinical Neuroscience*, 256(6), 372–381.


inpatient facilities: A national survey in Italy. *Social Psychiatry and Psychiatric Epidemiology, 44*(9), 767-776.


Regione Lombardia. Direzione Generale Sanità. Il Sistema di Salute Mentale della

Regione Veneto. La residenzialità psichiatrica nel veneto. Area Sanità e Sociale

Mental Health Practice. London: Bailliere Tindall.

RETHINK (2002). Reaching People Early. RETHINK.

RETHINK (2003) Just one per cent – the experiences of people using mental
health services. Kingston upon Thames: RETHINK.

Rice, D. P., & Miller, L. S. (1998). Health economics and cost implications of
anxiety and other mental disorders in the united states. The British Journal of
Psychiatry.Supplement, (34)(34), 4-9.

Richardson, A. (2007). Dying art. Nursing Standard (Royal College of Nursing
(Great Britain) : 1987), 22(10), 20-21.

Rinaldi, M., Wybourn, S., Clenehan, M. The development, piloting and outcomes
George’s Mental Health NHS Trust 2012.


and HoNOS. *The British Journal of Psychiatry: The Journal of Mental Science, 174*, 404-408.


Appendix A. Path of residential treatment in patients already living in RFs before the study’s start.

Number of months (72) from 01/01/2008 to 01/01/2014

- CA
- CTRP
- GAP
- Private Nursing home
- Home care

Number of patients already living in RFs before the start of the study (N=54)
Appendix B. Mean scores for BPRS items (1=no symptoms; 2-3=very mild-mild; 4-5=moderate/moderately severe; 6-7=severe/extremely severe) in patients staying in CTRP, CA and GAP

<table>
<thead>
<tr>
<th>BPRS item</th>
<th>CTRP (N=37) Mean (SD)</th>
<th>CA (N=117) Mean (SD)</th>
<th>GAP (N=14) Mean (SD)</th>
<th>F</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression/anxiety</td>
<td>3.2 (1.0)</td>
<td>2.8 (1.1)</td>
<td>2.4 (0.8)</td>
<td>3.6</td>
<td>0.030</td>
</tr>
<tr>
<td>Somatic concern</td>
<td>3.6 (1.6)</td>
<td>3.2 (1.8)</td>
<td>2.6 (1.7)</td>
<td>1.7</td>
<td>0.185</td>
</tr>
<tr>
<td>Anxiety</td>
<td>4.4 (1.2)</td>
<td>3.9 (1.5)</td>
<td>3.5 (1.2)</td>
<td>2.5</td>
<td>0.091</td>
</tr>
<tr>
<td>Depression</td>
<td>3.3 (1.7)</td>
<td>2.4 (1.4)</td>
<td>2.2 (1.5)</td>
<td>4.6</td>
<td>0.012</td>
</tr>
<tr>
<td>Suicidality</td>
<td>1.7 (1.5)</td>
<td>1.7 (1.3)</td>
<td>1.2 (0.8)</td>
<td>0.8</td>
<td>0.458</td>
</tr>
<tr>
<td>Guilt</td>
<td>2.4 (1.6)</td>
<td>2.0 (1.6)</td>
<td>2.0 (1.2)</td>
<td>0.6</td>
<td>0.556</td>
</tr>
<tr>
<td>Tension</td>
<td>4.0 (1.5)</td>
<td>3.3 (1.7)</td>
<td>3.0 (1.7)</td>
<td>2.7</td>
<td>0.070</td>
</tr>
<tr>
<td>Positive symptoms</td>
<td>3.5 (1.4)</td>
<td>2.7 (1.4)</td>
<td>1.9 (1.0)</td>
<td>9.0</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Grandiosity</td>
<td>2.1 (1.5)</td>
<td>2.1 (1.5)</td>
<td>1.9 (1.2)</td>
<td>0.2</td>
<td>0.835</td>
</tr>
<tr>
<td>Suspiciousness</td>
<td>3.4 (1.7)</td>
<td>3.1 (1.8)</td>
<td>2.5 (1.6)</td>
<td>1.4</td>
<td>0.254</td>
</tr>
<tr>
<td>Hallucinations</td>
<td>3.2 (2.0)</td>
<td>2.1 (1.7)</td>
<td>1.5 (1.4)</td>
<td>6.4</td>
<td>0.002</td>
</tr>
<tr>
<td>Unusual thought content</td>
<td>4.5 (1.8)</td>
<td>3.4 (2.1)</td>
<td>2.3 (1.8)</td>
<td>7.3</td>
<td>0.001</td>
</tr>
<tr>
<td>Conceptual disorganization</td>
<td>4.3 (1.7)</td>
<td>3.1 (2.0)</td>
<td>2.3 (1.6)</td>
<td>7.1</td>
<td>0.001</td>
</tr>
<tr>
<td>Negative symptoms</td>
<td>3.6 (1.4)</td>
<td>3.0 (1.4)</td>
<td>2.5 (1.2)</td>
<td>4.0</td>
<td>0.021</td>
</tr>
<tr>
<td>Blunted affect</td>
<td>3.7 (1.9)</td>
<td>3.4 (1.7)</td>
<td>2.8 (1.7)</td>
<td>1.5</td>
<td>0.231</td>
</tr>
<tr>
<td>Emotional withdrawal</td>
<td>3.8 (1.8)</td>
<td>3.4 (1.8)</td>
<td>2.7 (1.5)</td>
<td>1.9</td>
<td>0.152</td>
</tr>
<tr>
<td>Motor retardation</td>
<td>3.0 (1.8)</td>
<td>2.2 (1.3)</td>
<td>1.6 (1.1)</td>
<td>5.9</td>
<td>0.004</td>
</tr>
<tr>
<td>Uncooperativeness</td>
<td>3.1 (1.5)</td>
<td>2.6 (1.8)</td>
<td>2.8 (1.8)</td>
<td>1.1</td>
<td>0.341</td>
</tr>
<tr>
<td>Self-neglect</td>
<td>3.9 (1.9)</td>
<td>3.2 (1.9)</td>
<td>2.9 (2.0)</td>
<td>2.4</td>
<td>0.097</td>
</tr>
<tr>
<td>Disorientation</td>
<td>2.4 (1.8)</td>
<td>2.0 (1.7)</td>
<td>1.4 (0.9)</td>
<td>1.7</td>
<td>0.182</td>
</tr>
<tr>
<td>Mannerism and posturing</td>
<td>2.4 (1.7)</td>
<td>1.9 (1.3)</td>
<td>1.3 (0.8)</td>
<td>3.6</td>
<td>0.030</td>
</tr>
<tr>
<td>Maniac excitement</td>
<td>2.5 (1.3)</td>
<td>2.3 (1.5)</td>
<td>1.9 (1.1)</td>
<td>0.7</td>
<td>0.487</td>
</tr>
<tr>
<td>Hostility</td>
<td>3.0 (1.5)</td>
<td>2.8 (1.6)</td>
<td>2.3 (1.4)</td>
<td>1.0</td>
<td>0.399</td>
</tr>
<tr>
<td>Elevated mood</td>
<td>2.3 (1.6)</td>
<td>2.1 (1.7)</td>
<td>1.6 (1.0)</td>
<td>1.0</td>
<td>0.382</td>
</tr>
<tr>
<td>Bizarre behavior</td>
<td>4.1 (1.9)</td>
<td>3.1 (1.9)</td>
<td>1.9 (1.3)</td>
<td>7.8</td>
<td>0.001</td>
</tr>
<tr>
<td>Excitement</td>
<td>2.2 (1.6)</td>
<td>2.1 (1.7)</td>
<td>1.9 (1.2)</td>
<td>0.2</td>
<td>0.832</td>
</tr>
<tr>
<td>Distractibility</td>
<td>3.8 (1.5)</td>
<td>3.3 (1.7)</td>
<td>2.4 (1.1)</td>
<td>3.7</td>
<td>0.028</td>
</tr>
<tr>
<td>Motor hyperactivity</td>
<td>2.0 (1.5)</td>
<td>2.2 (1.7)</td>
<td>2.0 (1.7)</td>
<td>0.2</td>
<td>0.821</td>
</tr>
<tr>
<td>BPRS total</td>
<td>3.2 (0.9)</td>
<td>2.7 (1.1)</td>
<td>2.2 (0.6)</td>
<td>6.3</td>
<td>0.003</td>
</tr>
</tbody>
</table>
Appendix C. Mean scores for CAN items (0 = no problem; 1 = no/moderate problem because of continuing interventions; 2 = current serious problem whether or not help is offered or given) in patients staying in CTRP, CA and GAP

<table>
<thead>
<tr>
<th>CAN items</th>
<th>CTRP (N=43) Mean (SD)</th>
<th>CA (N=104) Mean (SD)</th>
<th>GAP (N=14) Mean (SD)</th>
<th>F</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic</td>
<td>2.4 (0.7)</td>
<td>2.6 (0.6)</td>
<td>2.8 (0.6)</td>
<td>2.4</td>
<td>0.097</td>
</tr>
<tr>
<td>Accommodation</td>
<td>1.0 (0.6)</td>
<td>0.9 (0.4)</td>
<td>1.0 (0.4)</td>
<td>0.2</td>
<td>0.816</td>
</tr>
<tr>
<td>Food</td>
<td>0.8 (0.6)</td>
<td>0.9 (0.5)</td>
<td>1.1 (0.5)</td>
<td>2.1</td>
<td>0.120</td>
</tr>
<tr>
<td>Daytime activities</td>
<td>1.1 (0.5)</td>
<td>1.2 (0.5)</td>
<td>1.1 (0.5)</td>
<td>0.7</td>
<td>0.514</td>
</tr>
<tr>
<td>Health</td>
<td>4.4 (1.2)</td>
<td>4.1 (1.3)</td>
<td>4.1 (1.3)</td>
<td>0.7</td>
<td>0.476</td>
</tr>
<tr>
<td>Physical health</td>
<td>1.1 (0.7)</td>
<td>1.0 (0.6)</td>
<td>1.0 (0.0)</td>
<td>0.2</td>
<td>0.825</td>
</tr>
<tr>
<td>Psychotic symptoms</td>
<td>1.4 (0.6)</td>
<td>1.3 (0.6)</td>
<td>1.0 (0.7)</td>
<td>2.4</td>
<td>0.090</td>
</tr>
<tr>
<td>Psychological distress</td>
<td>1.6 (0.5)</td>
<td>1.4 (0.6)</td>
<td>1.3 (0.6)</td>
<td>2.6</td>
<td>0.076</td>
</tr>
<tr>
<td>Safety to self</td>
<td>1.0 (0.6)</td>
<td>0.7 (0.6)</td>
<td>0.5 (0.7)</td>
<td>4.6</td>
<td>0.011</td>
</tr>
<tr>
<td>Safety to others</td>
<td>0.6 (0.6)</td>
<td>0.5 (0.6)</td>
<td>0.4 (0.5)</td>
<td>0.5</td>
<td>0.628</td>
</tr>
<tr>
<td>Alcohol</td>
<td>0.2 (0.4)</td>
<td>0.2 (0.5)</td>
<td>0.4 (0.6)</td>
<td>0.7</td>
<td>0.515</td>
</tr>
<tr>
<td>Drugs</td>
<td>0.2 (0.5)</td>
<td>0.1 (0.4)</td>
<td>0.4 (0.6)</td>
<td>1.6</td>
<td>0.211</td>
</tr>
<tr>
<td>Service</td>
<td>2.0 (1.5)</td>
<td>2.1 (1.2)</td>
<td>1.3 (1.1)</td>
<td>2.4</td>
<td>0.090</td>
</tr>
<tr>
<td>Information</td>
<td>0.8 (0.6)</td>
<td>0.7 (0.6)</td>
<td>0.7 (0.6)</td>
<td>0.5</td>
<td>0.622</td>
</tr>
<tr>
<td>Telephone</td>
<td>0.6 (0.7)</td>
<td>0.5 (0.6)</td>
<td>0.1 (0.4)</td>
<td>2.6</td>
<td>0.076</td>
</tr>
<tr>
<td>Transport</td>
<td>0.9 (0.8)</td>
<td>0.9 (0.7)</td>
<td>0.2 (0.4)</td>
<td>5.2</td>
<td>0.006</td>
</tr>
<tr>
<td>Benefits</td>
<td>0.5 (0.6)</td>
<td>0.5 (0.6)</td>
<td>0.3 (0.5)</td>
<td>0.6</td>
<td>0.566</td>
</tr>
<tr>
<td>Social</td>
<td>1.3 (0.9)</td>
<td>1.1 (0.7)</td>
<td>1.0 (0.8)</td>
<td>1.2</td>
<td>0.312</td>
</tr>
<tr>
<td>Company</td>
<td>1.6 (0.7)</td>
<td>1.2 (0.6)</td>
<td>1.3 (0.5)</td>
<td>5.0</td>
<td>0.008</td>
</tr>
<tr>
<td>Intimate relationship</td>
<td>1.5 (0.9)</td>
<td>1.1 (0.9)</td>
<td>1.3 (1.2)</td>
<td>0.7</td>
<td>0.507</td>
</tr>
<tr>
<td>Sexual expression</td>
<td>1.7 (0.7)</td>
<td>0.6 (0.6)</td>
<td>1.0 (1.4)</td>
<td>7.4</td>
<td>0.003</td>
</tr>
<tr>
<td>Functioning</td>
<td>2.5 (1.1)</td>
<td>3.0 (0.9)</td>
<td>3.0 (1.1)</td>
<td>5.1</td>
<td>0.007</td>
</tr>
<tr>
<td>Household skill</td>
<td>1.3 (0.6)</td>
<td>1.1 (0.4)</td>
<td>1.3 (0.5)</td>
<td>3.9</td>
<td>0.022</td>
</tr>
<tr>
<td>Self care</td>
<td>1.2 (0.7)</td>
<td>1.1 (0.5)</td>
<td>1.0 (0.8)</td>
<td>1.1</td>
<td>0.340</td>
</tr>
<tr>
<td>Child care</td>
<td>1.5 (0.8)</td>
<td>2.0 (0.0)</td>
<td>2.0 (0.0)</td>
<td>0.8</td>
<td>0.491</td>
</tr>
<tr>
<td>Basic education</td>
<td>0.2 (0.5)</td>
<td>0.4 (0.6)</td>
<td>0.4 (0.6)</td>
<td>1.7</td>
<td>0.189</td>
</tr>
<tr>
<td>Money</td>
<td>1.0 (0.8)</td>
<td>1.0 (0.6)</td>
<td>1.2 (0.7)</td>
<td>0.9</td>
<td>0.422</td>
</tr>
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<td>CAN total</td>
<td>12.6 (3.8)</td>
<td>12.9 (2.8)</td>
<td>12.2 (3.4)</td>
<td>0.4</td>
<td>0.700</td>
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</table>
Appendix D. Mean satisfaction score together with percentages of dissatisfied patients in the various VSSS dimensions’ scores among the different RFs (dissatisfied=patients with VSSS dimensions’ scores ≤3.5)

<table>
<thead>
<tr>
<th>VSSS-item</th>
<th>CTRP (N=33) Mean (SD)</th>
<th>CA (N=83) Mean (SD)</th>
<th>GAP (N=13) Mean (SD)</th>
<th>Dissatisfied %</th>
<th>F</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall satisfaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Service general sense</td>
<td>3.9 (0.8)</td>
<td>4.0 (0.8)</td>
<td>4.3 (1.0)</td>
<td>23.3</td>
<td>1.5</td>
<td>0.232</td>
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<tr>
<td>Professionals’ skills and behaviour</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Ability</td>
<td>3.7 (0.9)</td>
<td>3.9 (0.7)</td>
<td>4.2 (0.8)</td>
<td>32.6</td>
<td>1.9</td>
<td>0.161</td>
</tr>
<tr>
<td>psychiatrists/psychologists to listen</td>
<td>3.7 (1.1)</td>
<td>3.8 (1.0)</td>
<td>4.1 (1.0)</td>
<td></td>
<td>0.6</td>
<td>0.564</td>
</tr>
<tr>
<td>Behavior and manners of psychiatrists/psychologists</td>
<td>3.8 (0.9)</td>
<td>3.9 (0.9)</td>
<td>4.3 (0.9)</td>
<td>1.7</td>
<td>0.180</td>
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<td>Cooperation between service providers</td>
<td>3.8 (1.1)</td>
<td>3.9 (0.8)</td>
<td>4.2 (1.1)</td>
<td></td>
<td>0.8</td>
<td>0.455</td>
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<tr>
<td>Knowledge of patients’ medical history</td>
<td>3.7 (1.1)</td>
<td>3.9 (0.9)</td>
<td>4.3 (0.9)</td>
<td></td>
<td>2.0</td>
<td>0.133</td>
</tr>
<tr>
<td>Efficacy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Helping patient deal with problems</td>
<td>3.7 (0.8)</td>
<td>3.6 (0.8)</td>
<td>3.9 (0.7)</td>
<td>38.8</td>
<td>1.1</td>
<td>0.351</td>
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<tr>
<td>Improving relationship between patients and relative</td>
<td>3.8 (1.0)</td>
<td>3.8 (0.9)</td>
<td>4.3 (0.8)</td>
<td>1.8</td>
<td>0.162</td>
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</tr>
<tr>
<td>Helping to establish good relationship outside family</td>
<td>3.7 (1.0)</td>
<td>3.6 (1.0)</td>
<td>3.9 (0.9)</td>
<td>0.3</td>
<td>0.749</td>
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</tr>
<tr>
<td>Type of intervention</td>
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<tr>
<td>Response to emergencies</td>
<td>3.8 (0.5)</td>
<td>3.7 (0.5)</td>
<td>3.7 (0.6)</td>
<td>38.0</td>
<td>0.5</td>
<td>0.608</td>
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<tr>
<td>Rehabilitation activities</td>
<td>4.0 (0.9)</td>
<td>3.9 (0.9)</td>
<td>4.1 (0.8)</td>
<td></td>
<td>0.3</td>
<td>0.759</td>
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<td>Medication prescription</td>
<td>3.8 (1.0)</td>
<td>3.8 (0.9)</td>
<td>3.9 (0.9)</td>
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<td>0.0</td>
<td>0.980</td>
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<tr>
<td>Shelter work</td>
<td>3.9 (1.0)</td>
<td>3.7 (1.0)</td>
<td>3.8 (0.9)</td>
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<td>0.3</td>
<td>0.754</td>
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<tr>
<td>Help to find open employment</td>
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<tr>
<td>Recreational activities outside the services</td>
<td>3.8 (1.0)</td>
<td>3.7 (1.1)</td>
<td>3.7 (1.2)</td>
<td>0.2</td>
<td>0.853</td>
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<tr>
<td>Information</td>
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</tr>
<tr>
<td>Information on diagnosis and prognosis</td>
<td>3.5 (0.8)</td>
<td>3.4 (1.0)</td>
<td>3.9 (0.9)</td>
<td>54.3</td>
<td>1.2</td>
<td>0.312</td>
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<td>Access</td>
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<tr>
<td>Appearance, comfort and physical layout of the bedroom</td>
<td>3.7 (0.7)</td>
<td>3.9 (0.6)</td>
<td>4.1 (0.7)</td>
<td>26.4</td>
<td>2.5</td>
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<tr>
<td>Access</td>
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<td>3.9 (0.9)</td>
<td>4.2 (0.8)</td>
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<td>Service</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
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<tr>
<td>-------------------------------------</td>
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<td>-----------</td>
<td>-----------</td>
<td>-----------</td>
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</tr>
<tr>
<td>Food</td>
<td>3.4 (1.4)</td>
<td>3.8 (1.0)</td>
<td>4.1 (0.8)</td>
<td>2.6 (2.1)</td>
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<td>0.075</td>
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<tr>
<td>Appearance, comfort and physical</td>
<td>3.8 (0.8)</td>
<td>3.9 (0.8)</td>
<td>4.3 (0.9)</td>
<td>2.1 (0.8)</td>
<td>0.131</td>
<td>0.131</td>
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<tr>
<td>layout of the common areas</td>
<td></td>
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<tr>
<td>Appearance, comfort and physical</td>
<td>3.7 (1.0)</td>
<td>3.9 (0.9)</td>
<td>4.2 (0.9)</td>
<td>1.2 (1.2)</td>
<td>0.294</td>
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<tr>
<td>layout of the bathroom</td>
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<tr>
<td>Cleaning of the bedroom</td>
<td>3.7 (1.0)</td>
<td>4.1 (0.8)</td>
<td>4.1 (0.8)</td>
<td>2.7 (1.2)</td>
<td>0.071</td>
<td>0.071</td>
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<tr>
<td>Cleaning of the bathroom and the</td>
<td>3.7 (1.1)</td>
<td>4.0 (0.9)</td>
<td>3.8 (1.1)</td>
<td>1.2 (1.4)</td>
<td>0.143</td>
<td>0.143</td>
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<td>common areas</td>
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</tr>
<tr>
<td><strong>VSSS total mean score</strong></td>
<td>3.7 (0.5)</td>
<td>3.7 (0.5)</td>
<td>3.8 (0.5)</td>
<td>24.0</td>
<td>0.8 (0.8)</td>
<td>0.431</td>
</tr>
</tbody>
</table>