DSPMC - PSY

BOLOGNA – 29 OTTOBRE 2015

Risultati ed impatto del Trial GET UP

Relatore: **Mirella Ruggeri & IL GRUPPO GET UP**
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Feasibility and Effectiveness of a Multi-Element Psychosocial Intervention for First-Episode Psychosis: Results From the Cluster-Randomized Controlled GET UP PIANO Trial in a Catchment Area of 10 Million Inhabitants

Mirella Ruggeri*[,1,2], Chiara Bonetto[1], Antonio Lasalvia[1,2], Angelo Fioritti[3], Giovanni de Girolamo[4], Paolo Santonastaso[5], Francesca Pileggi[3], Giovanni Neri[6,7], Daniela Ghigi[8], Franco Giubilini[9], Maurizio Miceli[10], Silvio Scarone[11], Angelo Cocchi[12], Stefano Torresani[13], Carlo Faravelli[14], Carla Cremonese[15], Paolo Scocco[16], Emanuela Leuci[9], Fausto Mazzi[17], Michela Pratelli[8], Francesca Bellini[8], Sarah Tosato[1,2], Katia De Santi[1,2], Sarah Bissoli[1], Sara Poli[1], Elisa Ira[1], Silvia Zoppei[1], Paola Rucci[3,7], Laura Bislenghi[12], Giovanni Patelli[12], Doriana Cristofalo[1], Anna Meneghelli[12], and The GET UP Group[18]

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TRATTAMENTO DELI’ESORDIO PSICOTICO: UN ESEMPIO PARADIGMATICO DELLA COMPLESSITA’ DEGLI ASPETTI ORGANIZZATIVI NECESSARI PER TRASFORMARE GLI INTERVENTI EVIDENCE-BASED IN PARTICA CLINICA DI ROUTINE?

- Le linee guida sul trattamento precoce della psicosi sottolineano l’importanza dell’identificazione precoce e del trattamento delle persone all’esordio psicotico

- Studi clinici hanno dimostrato che la CBT nel trattamento dei sintomi psicotici, associata alla psicoeducazione familiare e al case management, è efficace nel prevenire il deterioramento psicosociale del paziente nel tempo

NICE National Institute for Health and Care Excellence

Psychosis and schizophrenia in adults: treatment and management

Issued: February 2014 last modified: March 2014

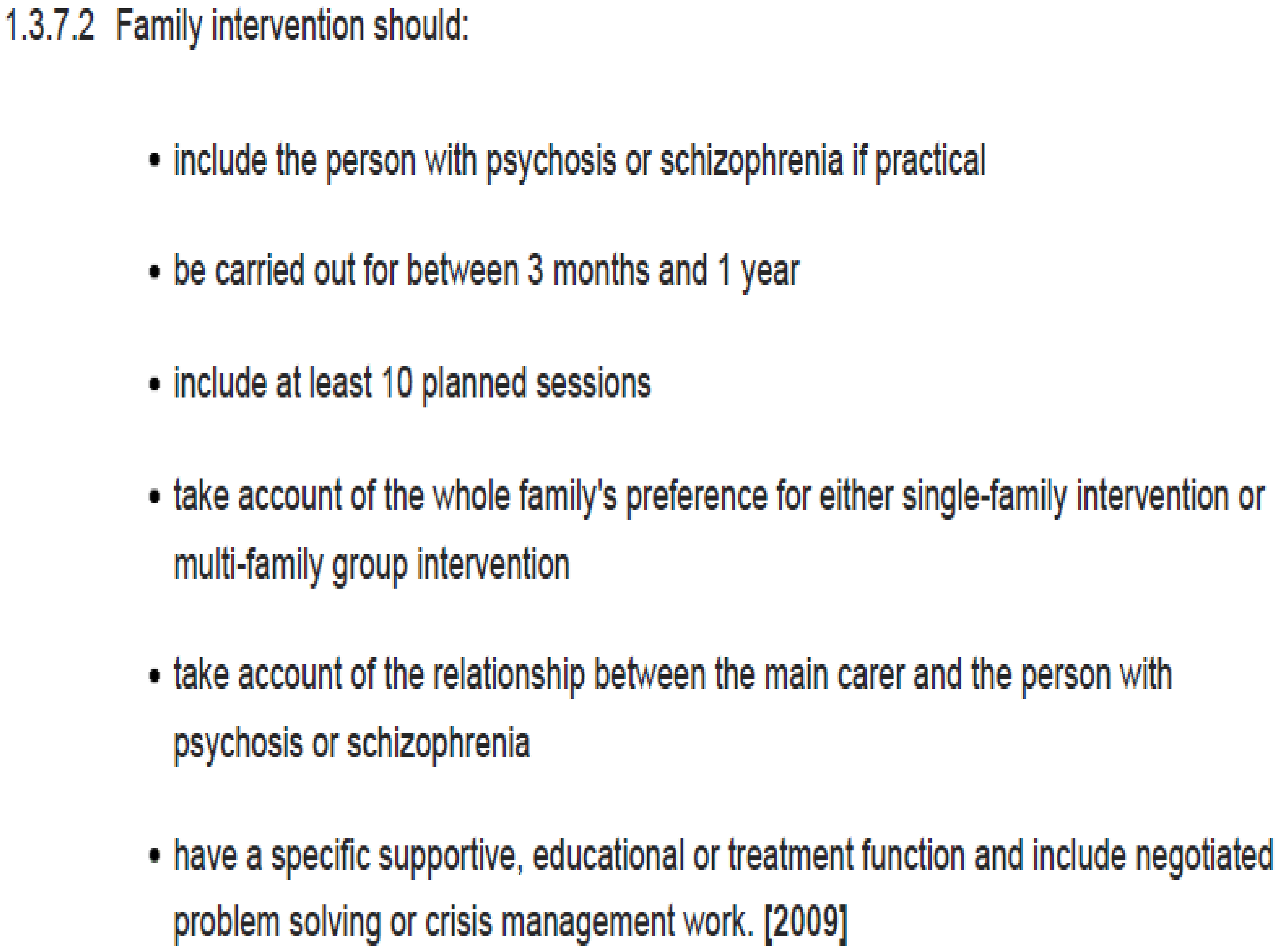
NICE clinical guideline 178

guidance.nice.org.uk/cg178

1.3.7 How to deliver psychological interventions

1.3.7.1 CBT should be delivered on a one-to-one basis over at least 16 planned sessions and:

- follow a treatment manual[2] so that:
  - people can establish links between their thoughts, feelings or actions and their current or past symptoms, and/or functioning
  - the re-evaluation of people's perceptions, beliefs or reasoning relates to the target symptoms
- also include at least one of the following components:
  - people monitoring their own thoughts, feelings or behaviours with respect to their symptoms or recurrence of symptoms
  - promoting alternative ways of coping with the target symptom
  - reducing distress
  - improving functioning. [2009]



1.3.7.2 Family intervention should:

- include the person with psychosis or schizophrenia if practical
- be carried out for between 3 months and 1 year
- include at least 10 planned sessions
- take account of the whole family's preference for either single-family intervention or multi-family group intervention
- take account of the relationship between the main carer and the person with psychosis or schizophrenia
- have a specific supportive, educational or treatment function and include negotiated problem solving or crisis management work. [2009]

1.3.8.1 When providing psychological interventions, routinely and systematically monitor a range of outcomes across relevant areas, including service user satisfaction and, if appropriate, carer satisfaction. **[2009]**

1.3.8.2 Healthcare teams working with people with psychosis or schizophrenia should identify a lead healthcare professional within the team whose responsibility is to monitor and review:

- access to and engagement with psychological interventions
- decisions to offer psychological interventions and equality of access across different ethnic groups. **[2009]**

1.3.9 Competencies for delivering psychological interventions

1.3.9.1 Healthcare professionals providing psychological interventions should:

- have an appropriate level of competence in delivering the intervention to people with psychosis or schizophrenia
- be regularly supervised during psychological therapy by a competent therapist and supervisor. **[2009]**

1.3.9.2 Trusts should provide access to training that equips healthcare professionals with the competencies required to deliver the psychological therapy interventions recommended in this guideline. **[2009]**

TRATTAMENTO DELI’ESORDIO PSICOTICO: UN ESEMPIO PARADIGMATICO DELLA COMPLESSITA’ DEGLI ASPETTI ORGANIZZATIVI NECESSARI PER TRASFORMARE GLI INTERVENTI EVIDENCE-BASED IN PARTICA CLINICA DI ROUTINE?

- Le linee guida sul trattamento precoce della psicosi sottolineano l’importanza dell’identificazione precoce e del trattamento delle persone all’esordio psicotico
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MA

- **Sono stati svolti pochi studi in “contesti reali” e con coorti di pazienti rappresentative dal punto di vista epidemiologico**
- **Si sa ancora poco sugli ostacoli che possono impedirne l’applicazione e sulle situazioni in cui questo tipo di intervento può risultare inefficace o inappropriato se messo in atto nella pratica clinica dei Servizi di Salute Mentale**
- **La maggior parte degli operatori della salute mentale non ha le competenze per fornire interventi specializzati evidence-based**

SOCIETÀ ITALIANA DI EPIDEMIOLOGIA PSICHIATRICA

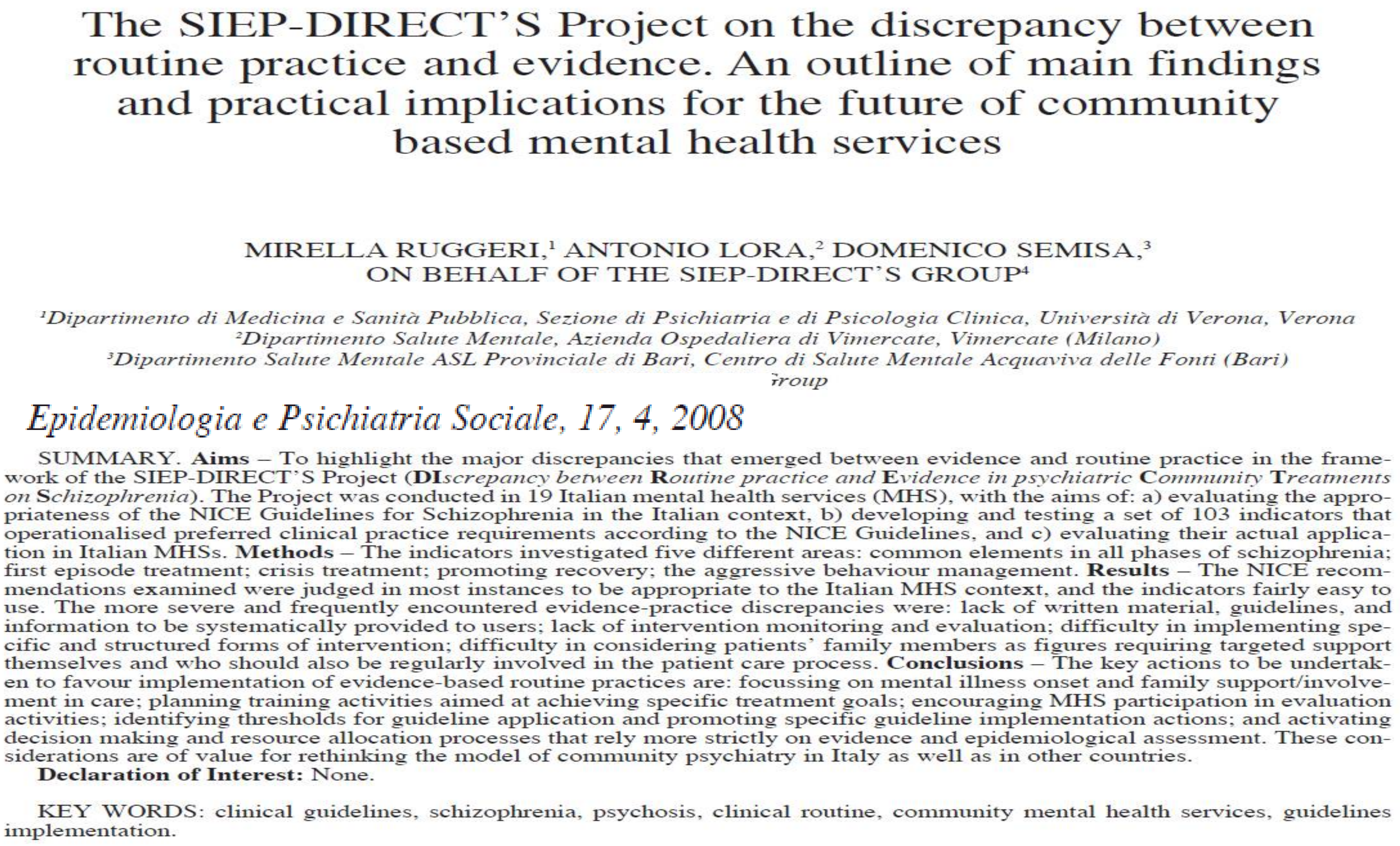
WWW.SIEP.IT

SIEP-DIRECT’S PROJECT

DIscrepancies between
Routine practice and
Evidence in
Community Psychiatry
Treatment of
‘ Schizofrenia

Project Coordinators: D. Semisa & M. Ruggeri
Scientific Committee: SIEP Executive Board 2003-2007

SIEP-DIRECT'S PROJECT



The SIEP-DIRECT'S Project on the discrepancy between routine practice and evidence. An outline of main findings and practical implications for the future of community based mental health services

MIRELLA RUGGERI,[1] ANTONIO LORA,[2] DOMENICO SEMISA,[3]
ON BEHALF OF THE SIEP-DIRECT'S GROUP[4]

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[2]*Dipartimento Salute Mentale, Azienda Ospedaliera di Vimercate, Vimercate (Milano)*
[3]*Dipartimento Salute Mentale ASL Provinciale di Bari, Centro di Salute Mentale Acquaviva delle Fonti (Bari)*
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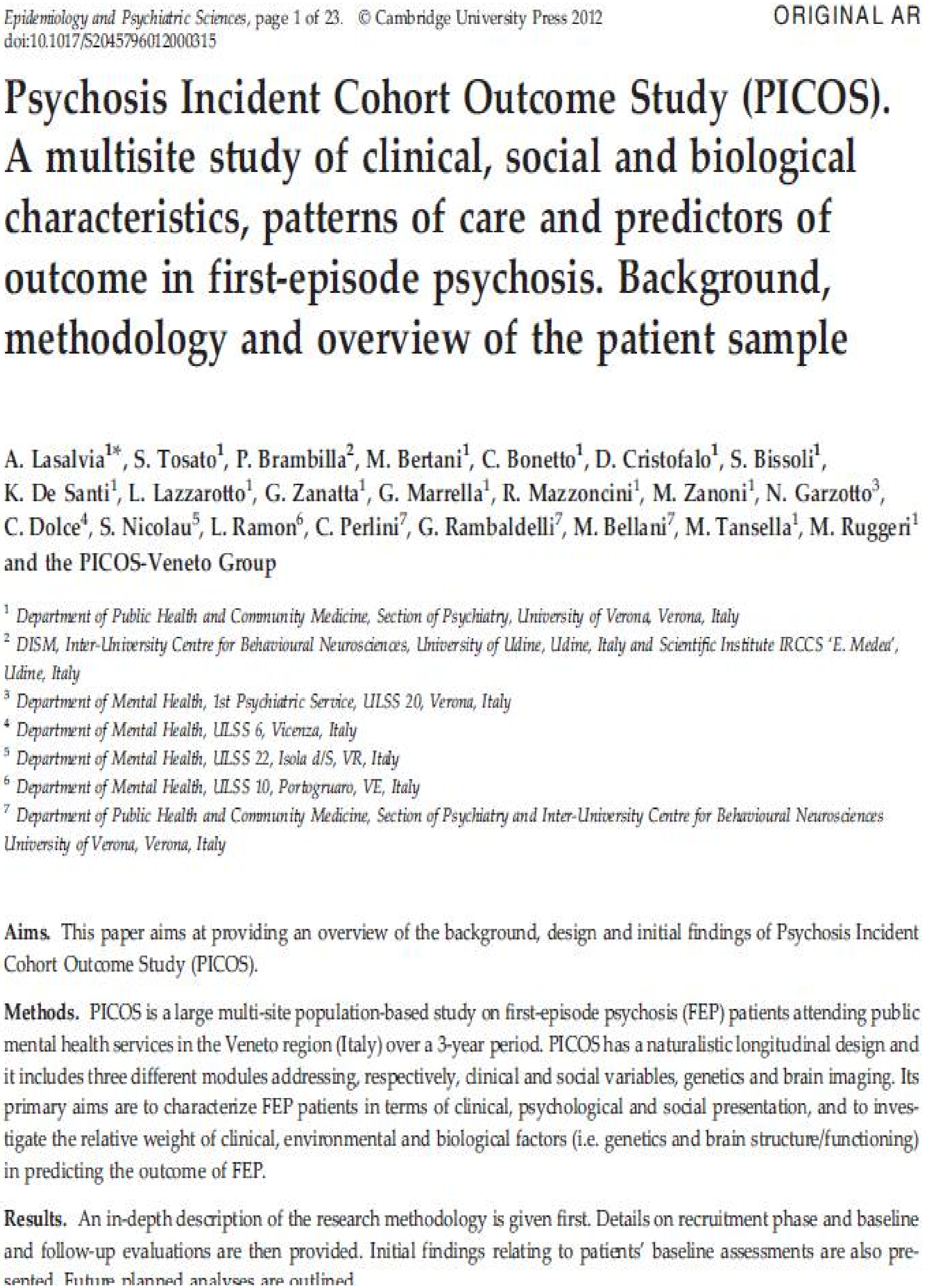
Epidemiologia e Psichiatria Sociale, 17, 4, 2008

SUMMARY. **Aims** – To highlight the major discrepancies that emerged between evidence and routine practice in the framework of the SIEP-DIRECT'S Project (**DI***screpancy between* **R***outine practice and* **E***vidence in psychiatric* **C***ommunity* **T***reatments on* **S***chizophrenia*). The Project was conducted in 19 Italian mental health services (MHS), with the aims of: a) evaluating the appropriateness of the NICE Guidelines for Schizophrenia in the Italian context, b) developing and testing a set of 103 indicators that operationalised preferred clinical practice requirements according to the NICE Guidelines, and c) evaluating their actual application in Italian MHSs. **Methods** – The indicators investigated five different areas: common elements in all phases of schizophrenia; first episode treatment; crisis treatment; promoting recovery; the aggressive behaviour management. **Results** – The NICE recommendations examined were judged in most instances to be appropriate to the Italian MHS context, and the indicators fairly easy to use. The more severe and frequently encountered evidence-practice discrepancies were: lack of written material, guidelines, and information to be systematically provided to users; lack of intervention monitoring and evaluation; difficulty in implementing specific and structured forms of intervention; difficulty in considering patients' family members as figures requiring targeted support themselves and who should also be regularly involved in the patient care process. **Conclusions** – The key actions to be undertaken to favour implementation of evidence-based routine practices are: focussing on mental illness onset and family support/involvement in care; planning training activities aimed at achieving specific treatment goals; encouraging MHS participation in evaluation activities; identifying thresholds for guideline application and promoting specific guideline implementation actions; and activating decision making and resource allocation processes that rely more strictly on evidence and epidemiological assessment. These considerations are of value for rethinking the model of community psychiatry in Italy as well as in other countries.

Declaration of Interest: None.

KEY WORDS: clinical guidelines, schizophrenia, psychosis, clinical routine, community mental health services, guidelines implementation.



Epidemiology and Psychiatric Sciences, page 1 of 23. © Cambridge University Press 2012
doi:10.1017/S2045796012000315

ORIGINAL AR

Psychosis Incident Cohort Outcome Study (PICOS). A multisite study of clinical, social and biological characteristics, patterns of care and predictors of outcome in first-episode psychosis. Background, methodology and overview of the patient sample

A. Lasalvia[1*], S. Tosato[1], P. Brambilla[2], M. Bertani[1], C. Bonetto[1], D. Cristofalo[1], S. Bissoli[1], K. De Santi[1], L. Lazzarotto[1], G. Zanatta[1], G. Marrella[1], R. Mazzoncini[1], M. Zanoni[1], N. Garzotto[3], C. Dolce[4], S. Nicolau[5], L. Ramon[6], C. Perlini[7], G. Rambaldelli[7], M. Bellani[7], M. Tansella[1], M. Ruggeri[1] and the PICOS-Veneto Group

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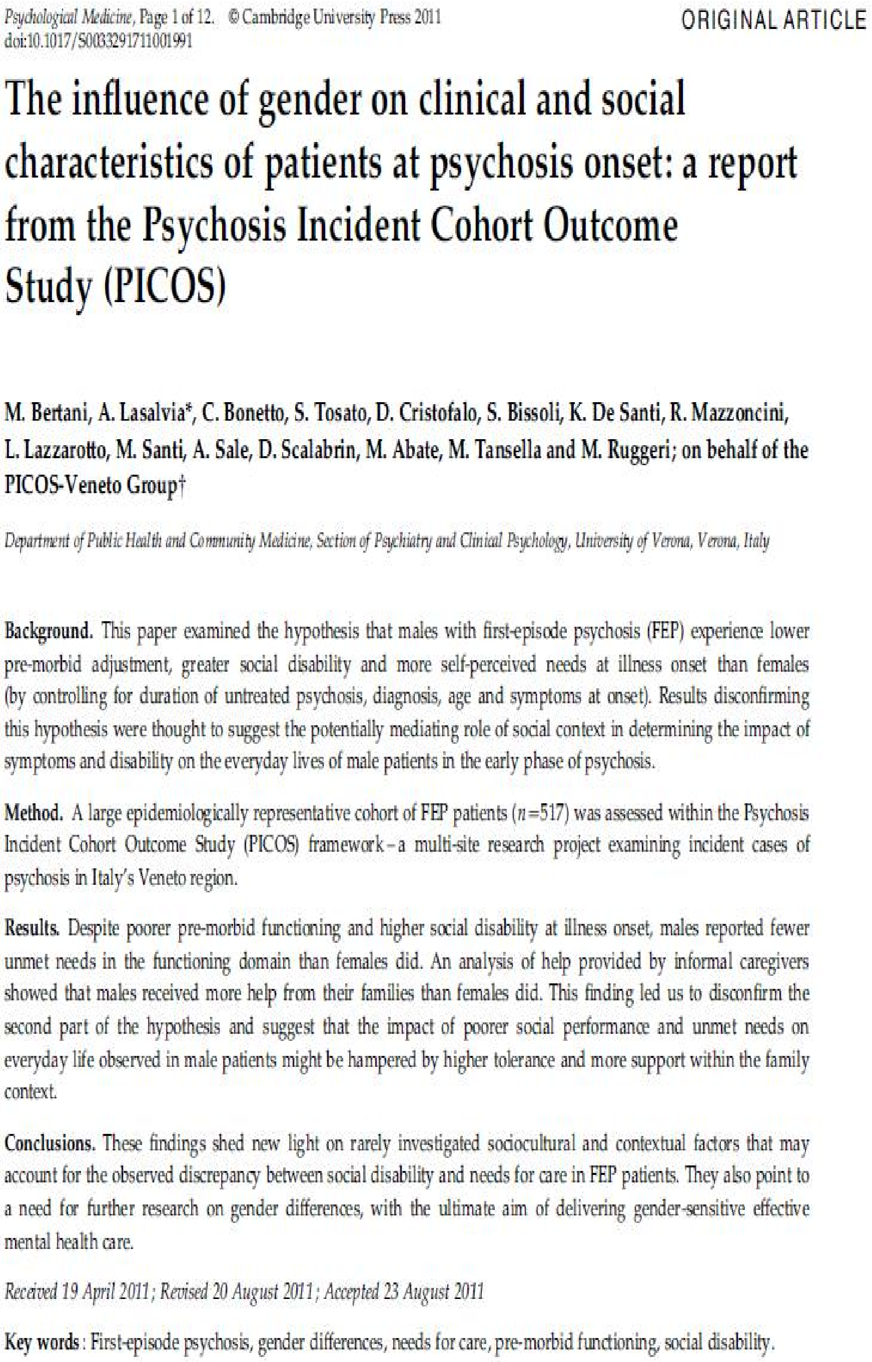
Aims. This paper aims at providing an overview of the background, design and initial findings of Psychosis Incident Cohort Outcome Study (PICOS).

Methods. PICOS is a large multi-site population-based study on first-episode psychosis (FEP) patients attending public mental health services in the Veneto region (Italy) over a 3-year period. PICOS has a naturalistic longitudinal design and it includes three different modules addressing, respectively, clinical and social variables, genetics and brain imaging. Its primary aims are to characterize FEP patients in terms of clinical, psychological and social presentation, and to investigate the relative weight of clinical, environmental and biological factors (i.e. genetics and brain structure/functioning) in predicting the outcome of FEP.

Results. An in-depth description of the research methodology is given first. Details on recruitment phase and baseline and follow-up evaluations are then provided. Initial findings relating to patients' baseline assessments are also presented. Future planned analyses are outlined.



Psychological Medicine, Page 1 of 12. © Cambridge University Press 2011
doi:10.1017/S0033291711001991

ORIGINAL ARTICLE

The influence of gender on clinical and social characteristics of patients at psychosis onset: a report from the Psychosis Incident Cohort Outcome Study (PICOS)

M. Bertani, A. Lasalvia*, C. Bonetto, S. Tosato, D. Cristofalo, S. Bissoli, K. De Santi, R. Mazzoncini, L. Lazzarotto, M. Santi, A. Sale, D. Scalabrin, M. Abate, M. Tansella and M. Ruggeri; on behalf of the PICOS-Veneto Group†

Department of Public Health and Community Medicine, Section of Psychiatry and Clinical Psychology, University of Verona, Verona, Italy

Background. This paper examined the hypothesis that males with first-episode psychosis (FEP) experience lower pre-morbid adjustment, greater social disability and more self-perceived needs at illness onset than females (by controlling for duration of untreated psychosis, diagnosis, age and symptoms at onset). Results disconfirming this hypothesis were thought to suggest the potentially mediating role of social context in determining the impact of symptoms and disability on the everyday lives of male patients in the early phase of psychosis.

Method. A large epidemiologically representative cohort of FEP patients ($n=517$) was assessed within the Psychosis Incident Cohort Outcome Study (PICOS) framework – a multi-site research project examining incident cases of psychosis in Italy's Veneto region.

Results. Despite poorer pre-morbid functioning and higher social disability at illness onset, males reported fewer unmet needs in the functioning domain than females did. An analysis of help provided by informal caregivers showed that males received more help from their families than females did. This finding led us to disconfirm the second part of the hypothesis and suggest that the impact of poorer social performance and unmet needs on everyday life observed in male patients might be hampered by higher tolerance and more support within the family context.

Conclusions. These findings shed new light on rarely investigated sociocultural and contextual factors that may account for the observed discrepancy between social disability and needs for care in FEP patients. They also point to a need for further research on gender differences, with the ultimate aim of delivering gender-sensitive effective mental health care.

Received 19 April 2011; Revised 20 August 2011; Accepted 23 August 2011

Key words: First-episode psychosis, gender differences, needs for care, pre-morbid functioning, social disability.

IL PROBLEMA DEL MODELLO ORGANIZZATIVO MIGLIORE PER TRATTARE I PAZIENTI ALL'ESORDIO DI PSICOSI

In Italia e non solo!

Cornice organizzativa per l’offerta di interventi precoci nella psicosi

- Servizi di intervento a sé stanti – “stand alone services”
- Modello “hub and spoke”
- Team di intervento precoce all’interno dei Servizi di Salute Mentale esistenti

Le evidenze attuali sono inconclusive circa la superiorità in termini di efficacia di questi modelli organizzativi

(Singh and Fisher, 2005)

Servizi di intervento a sé stanti

"stand alone services"

- I servizi di intervento a sé stanti sono stati considerati il gold-standard in UK (Department of Health, 2001), e in varie altre nazioni del mondo.

- Assicurano la messa in atto di un pacchetto completo di interventi precoci fornito da uno staff specializzato

MA

- Richiedono molte risorse
- Possono determinare la perdita di un ingresso unico ai Servizi di Salute Mentale e perdita di pazienti
- Vi sono crescenti evidenze di ricadute negative sulla continuità di cura in quanto l'intervento è temporalmente limitato (Pelosi & Birchwood, 2003; Pelosi, 2008; Friis, 2010).
- Potenzialmente possono causare una diminuzione delle competenze del personale dei Servizi di Salute Mentale nel gestire gli esordi psicotici (Castle, 2011).

Sono disponibili numerosi studi sulla loro efficacia nel breve-medio periodo e sulle loro modalità organizzative

I modelli «hub and spoke»

- Un servizio specializzato centrale (the “hub”= il perno) gestisce I pazienti più complessi e al contempo supporta le équipes periferiche (the “spokes”=i raggi)
- Richiedono meno risorse di un servizio a sé stante
- Possono essere un utile punto di riferimento per i Servizi alle prime armi e per favorire un processo continuo di aggiornamento

MA

- C’è il rischio di **incertezza e confusione** circa le responsabilità di queste due tipologie di Servizi e della perdita di continuità delle cure (Sing and Fisher, 2005; 2003).

Sono disponibili pochi studi su questioni organizzative e di efficacia

Team di intervento precoce all'interno dei Servizi di Salute Mentale esistenti

- Si tratta di un'opzione economica (Whitwell, 2001), soprattutto nelle aree con poche risorse (Craig, 2003)
- Laddove i Servizi di Salute Mentale sono presenti su larga scala (modello di comunità) possono assicurare una maggiore accessibilità ai trattamenti

MA

- Implicano la **formazione di tutta l'équipe** o l'impiego di personale specializzato
- **Potrebbero non assicurare un trattamento specifico di qualità ottimale** per questa tipologia di pazienti (Yung,2003).

Sono disponibili pochissimi studi
su questioni organizzative e di efficacia…
ma il tema suscita crescente interesse

Epidemiology and Psychiatric Sciences (2013), 22, 111–117. © Cambridge University Press 2013
doi:10.1017/S2045796013000127

EDITORIAL

A new generation of pragmatic trials of psychosocial interventions is needed

M. Ruggeri*, **A. Lasalvia** and **C. Bonetto**

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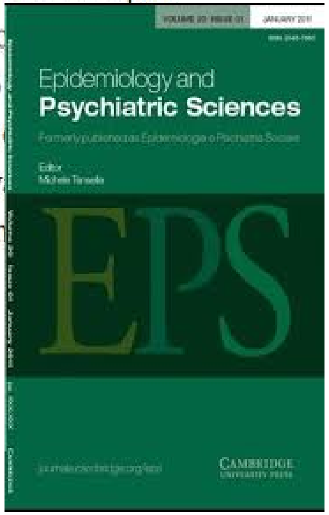
This Editorial addresses the crucial issue of which research methodology is most suited for capturing the complexity of psychosocial interventions conducted in 'real world' mental health settings. It first examines conventional randomized controlled trial (RCT) methodology and critically appraises its strengths and weaknesses. It then considers the specificity of mental health care treatments and defines the term 'complex' intervention and its implications for RCT design. The salient features of pragmatic RCTs aimed at generating evidence of psychosocial intervention effectiveness are then described. Subsequently, the conceptualization of pragmatic RCTs, and of their further developments – which we propose to call 'new generation' pragmatic trials – in the broader routine mental health service context, is explo
tools for planning pragmatic RCTs, such as the CONSORT extension for pragmatic trials, and the PRECIS
examined. We then discuss some practical challenges that are involved in the design and implementation
trials based on our own experience in conducting the GET UP PIANO Trial. Lastly, we speculate on the w
current ideas on the purpose, scope and ethics of mental health care research may determine further challen
cal research and evidence-based practice.

First published online 20 March 2013

Key words: Outcome assessment, pragmatic trials, psychosocial interventions, RCTs.



IMPLEMENTATION SCIENCE

Adm Policy Ment Health (2009) 36:24–34
DOI 10.1007/s10488-008-0197-4

ORIGINAL PAPER

Implementation Research in Mental Health Services: an Emerging Science with Conceptual, Methodological, and Training challenges

Enola K. Proctor · John Landsverk · Gregory Aarons ·
David Chambers · Charles Glisson · Brian Mittman

Published online: 23 December 2008
© Springer Science+Business Media, LLC 2008

Abstract One of the most critical issues in mental health services research is the gap between what is known about effective treatment and what is provided to consumers in routine care. Concerted efforts are required to advance implementation science and produce skilled implementation researchers. This paper seeks to advance implementation science in mental health services by over viewing the emergence of implementation as an issue for research, by addressing ceptualization, by presen the study of implementa the implications for rese field.

Keywords Implementa Mental health services ·

BJPsych
The British Journal of Psychiatry (2013)
202, s3–s4. doi: 10.1192/bjp.bp.112.119222

Editorial

Prevention, innovation and implementation science in mental health: the next wave

al ill health on human ecognised, it is only as been acknowledged mic productivity mental disorders ng adolescence and disproportionate es of life. With ealth estimated a greater emphasis on prevention and early intervention has become even more imperative. Although prevention largely remains aspirational for many reasons, early intervention is well within our current reach and offers the potential to significantly reduce the impact of mental ill health on our health, happiness and prosperity in the immediate future.

Declaration of interest
None.

Improving Mental Health Care
THE GLOBAL CHALLENGE

EDITED BY
Graham Thornicroft,
Mirella Ruggeri and
David Goldberg

WILEY-BL

BMJ

BMJ 2013;347:f6753 doi: 10.1136/bmj.f6753 (Published 20 November 2013)

RESEARCH METHODS

Implementation research: what it is

Implementation research is a growing but not well understood field of heal contribute to more effective public health and clinical policies and progr a broad definition of implementation research and outlines key p

David H Peters *professor*[1], Taghreed Adam *scientis* *nt scientist*[1], Irene Akua Agyepong *specialist public health*[3], Nhan Tran *n*

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RESEARCH METHODS & REPORTING

evaluation of complex interventions: Medical Research guidance

oore,[1] Suzanne A [3] Lyndal Bond,[4] Chris Bonell,[5] Wendy Hardeman,[6] oore,[7] Alicia [3] Daniel Wight,[7] Janis Baird[3]

nce conducting ss evaluation

s and Health, Institute of ucation, University of ondon, London, UK
Primary Care Unit, Department f Public Health and Primary are, University of Cambridge, ambridge, UK
MRC/CSO Social and Public ealth Sciences Unit, University f Glasgow, Glasgow, UK
School of Health and Related esearch, University of heffield, Sheffield, UK
orrespondence to: F Moore MooreG@cardiff. c.uk
ite this as: *BMJ* 2015;350:h1258
oi:10.1136/bmj.h1258
ccepted: 13 January 2015

ckle problems such as smoking and obe gly use complex interventions. These are ined as interventions that comprise mul ing components, although additional complexity include the difficulty of their on and the number of organisational levels they target.[1] Randomised controlled trials are regarded as the gold standard for establishing the effectiveness of interventions, when randomisation is feasible. However, effect sizes do not provide policy makers with information on how an intervention might be replicated in their specific context, or whether trial outcomes will be reproduced. Earlier MRC guidance for evaluating complex interventions focused on randomised trials, making no mention of process evaluation.[2] Updated guidance recognised the value of process evaluation within trials, stating that it "can be used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes."[3] However, it did not provide guidance for carrying out process evaluation.

experience and expertise in evaluating complex interventions was assembled to produce the guidance. In line with the principles followed in developing earlier MRC guidance documents, draft guidance was produced drawing on literature reviews, process evaluation case studies, workshops, and discussions at conferences and seminars. It was then circulated to academic, policy, and practice stakeholders for comment. Around 30 stakeholders provided written comments on the draft structure, while others commented during conference workshops run throughout the development process. A full draft was recirculated for further review, before being revised and approved by key MRC funding panels.

Although the aim was to provide guidance on process evaluation of public health interventions, the guidance is highly relevant to complex intervention research in other domains, such as health services and education. The full guidance (www.populationhealthsciences.org/Process-Evaluation-Guidance.html) begins by setting out the need for process evaluation. It then presents a review of influential theories and frameworks which informed its development, before offering practical recommendations, and six detailed case studies. In this article, we provide an overview of the new framework and summarise our practical recommendations using one of the case studies as an example.

MRC process evaluation framework

The new framework builds on the process evaluation

Un progetto multicentrico su larga scala basato su un DISEGNO DI STUDIO

RANDOMIZZATO CONTROLLATO A BLOCCHI

che esamina gli **esordi psicotici** reclutati nei Servizi di Salute Mentale localizzati in alcune aree dell’Italia Centro-Settentrionale **in un anno** e seguiti per 9 mesi

- **PIANO**
- **TRUMPET**
- **GUITAR**
- **CONTRABASS**

- **FINANZIATO DAL MINISTERO DELLA SALUTE**
- **3 MILIONI DI EURO**

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Feasibility and Effectiveness of a Multi-Element Psychosocial Intervention for First-Episode Psychosis: Results From the Cluster-Randomized Controlled GET UP PIANO Trial in a Catchment Area of 10 Million Inhabitants

Mirella Ruggeri[*,1,2], Chiara Bonetto[1], Antonio Lasalvia[1,2], Angelo Fioritti[3], Giovanni de Girolamo[4], Paolo Santonastaso[5], Francesca Pileggi[3], Giovanni Neri[6,7], Daniela Ghigi[8], Franco Giubilini[9], Maurizio Miceli[10], Silvio Scarone[11], Angelo Cocchi[12], Stefano Torresani[13], Carlo Faravelli[14], Carla Cremonese[15], Paolo Scocco[16], Emanuela Leuci[9], Fausto Mazzi[17], Michela Pratelli[8], Francesca Bellini[8], Sarah Tosato[1,2], Katia De Santi[1,2], Sarah Bissoli[1], Sara Poli[1], Elisa Ira[1], Silvia Zoppei[1], Paola Rucci[3,7], Laura Bislenghi[12], Giovanni Patelli[12], Doriana Cristofalo[1], Anna Meneghelli[12], and The GET UP Group[18]

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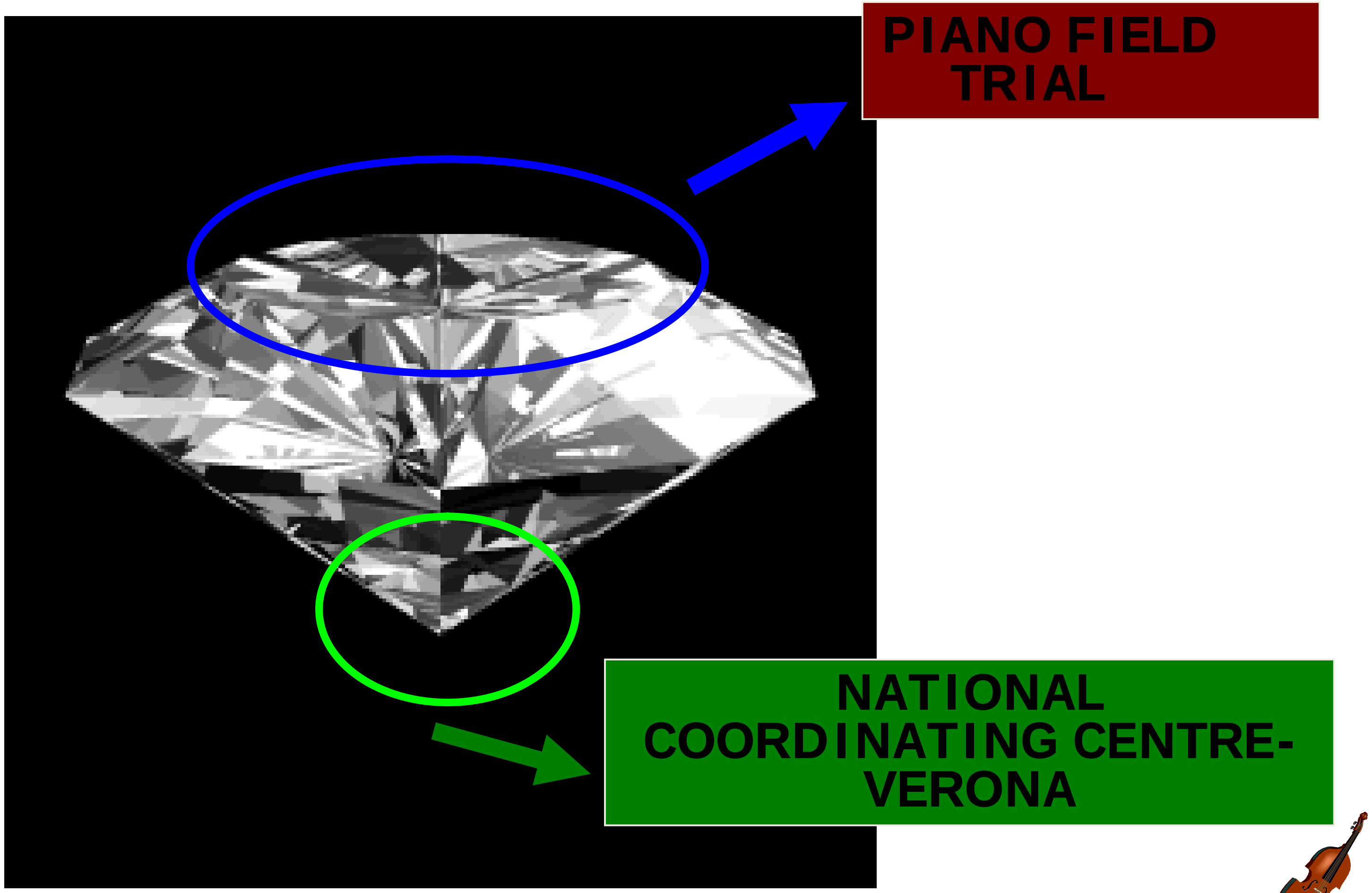


PIANO FIELD TRIAL

NATIONAL COORDINATING CENTRE-VERONA

GENETIC ENDOPHENOTYPES TREATMENT: UNDERSTANDING EARLY PSYCHOSIS

GET UP

NATIONAL SCIENTIFIC COORDINATOR : Mirella Ruggeri (Verona)

- **PIANO (Head Project) - Psychosis: Early Intervention and Assessment of Needs and Outcome**
  Scientific Coordinator: Mirella Ruggeri – VR; **Institutional Recipient:** Azienda Ospedaliera Universitaria Integrata Verona

- **TRUMPET - TR**aining and **U**nderstanding of service **M**odels for **P**sychosis **E**arly **T**reatment
  Scientific Coordinator: Giovanni de Girolamo – BO-BR; **Institutional Recipient:** Servizio Salute Mentale, Dipendenze Patologiche, Salute Nelle Carceri, Regione Emilia-Romagna

- **GUITAR - G**enetic data **U**tilization and **I**mplementation of **T**argeted drug **A**dministration in the clinical **R**outine
  Scientific Coordinator: Massimo Gennarelli – BR; **Institutional Recipient:** IRCCS Fatebenefratelli San Giovanni di Dio, Brescia

- **CONTRABASS - CO**gnitive **N**euroendophenotypes for **T**reatment and **R**eh**A**bilitation of psychoses: **B**rain imaging, infl**A**mmation and Stres**S**
  Scientific Coordinator : Paolo Brambilla – UD-VR; **Institutional Recipient:** Azienda Ospedaliera Universitaria Integrata Verona

OBIETTIVI GLOBALI

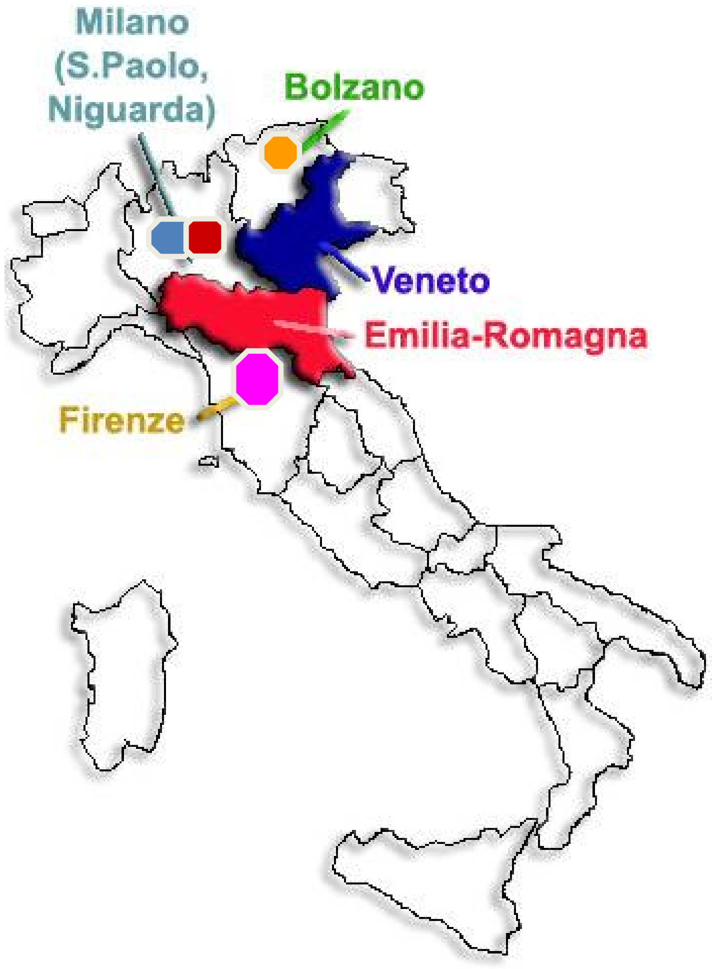
Lo Studio mira a:

1.Utilizzare un disegno di studio randomizzato controllato a blocchi per testare la fattibilità clinica, l’efficacia e la costo-efficacia di un intervento psicosociale integrato precoce;

2.Identificare gli ostacoli che possono impedirne l’applicazione e le situazioni in cui questo tipo di intervento può risultare inefficace o inappropriato se messo in atto nella pratica clinica dei Servizi di Salute Mentale;

3.Caratterizzare i nuovi casi di psicosi, all'esordio e in relazione ai predittori di esito, da diverse prospettive (genetiche, morfologico-cerebrali, endofenotipiche e cliniche), tra cui quella della presenza di stress ambientale.

- Data collection in a 10 million inhabitant catchment area (5 million adults 18-54)
- Italy: 18 incident cases/100.000 adults/year (Tarricone et al., 2012; Lasalvia et al, 2012)
- Supposing that 75% ask for treatment in public MH services, about **700** incident cases/year were expected in the GET UP catchment area
- 18 Research Units, **8** of which coordinate groups of Mental Health Centres (MHCs), dedicated to the enrollment and treatment of patients and their families in the catchment area
- **MORE THAN 500 RESEARCHERS AND CLINICIANS WERE ACTIVELY INVOLVED IN THE PROJECT**



THE GET UP GROUP

National Coordinator: Mirella Ruggeri (Verona)

MAIN PROJECTS:

LEADING PROJECT: PIANO (Psychosis: Early Intervention and Assessment of Needs and Outcome)

Scientific Coordinator: Mirella Ruggeri (Verona)

Administrative Leading Institution: *Azienda Ospedaliera Universitaria Integrata Verona, Regione Veneto*

Coordinating Centre: Maria Elena Bertani, Mario Ballarin, Sarah Bissoli, Chiara Bonetto, Doriana Cristofalo, Katia De Santi, Antonio Lasalvia, Silvia Lunardi, Valentina Negretto, Sara Poli, Sarah Tosato, Maria Grazia Zamboni.

PROJECT GUITAR (Genetic data Utilization and Implementation of Targeted Drug Administration - in the Clinical Routine)

Scientific Coordinator: Massimo Gennarelli (Brescia)

Administrative Leading Institution: *IRCCS Centro S.Giovanni di Dio Fatebenefratelli, Brescia*

Coordinating Centre: Luisella Bocchio Chiavetto, Catia Scasselatti, Roberta Zanardini.

EXPERTS SUPERVISING TREATMENTS IN THE EXPERIMENTAL ARM:

Andrea Alpi, Laura Bislenghi, Tiziana Bolis, Francesca Colnaghi, Simona Fascendini, Silvia Grignani, Anna Meneghelli, Giovanni Patelli.

PSYCHOTHERAPISTS SUPPORTING TREATMENTS IN THE EXPERIMENTAL ARM:

Chiara Acerbi, Daniele Aquilino, Silvia Azzali, Luca Bensi, Sarah Bissoli, Davide Cappellari, Elisa Casana, Nadia Campagnola, Elisa Dal Corso, Elisabetta Di Micco, Erika Gobbi, Laura Ferri, Erika Gobbi, Laura Mairaghi, Sara Malak, Luca Mesiano, Federica Paterlini, Michela Perini, Elena Maria Puliti, Rosaria Rispoli, Elisabetta Rizzo, Chiara Sergenti, Manuela Soave.

PROJECT TRUMPET (TRaining and Understanding of Service Models for Psychosis Early Treatment)

Scientific Coordinator: Giovanni De Girolamo (Bologna and Brescia)

Administrative Leading Institution: *Agenzia Sanitaria e Sociale Regionale, Regione Emilia Romagna*

Coordinating Centre: Angelo Fioritti, Giovanni Neri, Francesca Pileggi, Paola Rucci.

PROJECT CONTRABASS (COgnitive Neuroendophenotypes for Treatment and RehAbilitation of psychoses: Brain imaging, InflAmmation and StreSS)

Scientific Coordinator: Paolo Brambilla (Udine and Verona)

Administrative Leading Institution: *Azienda Ospedaliera Universitaria Integrata, Verona, Regione Veneto*

Coordinating Centre: Marcella Bellani, Alessandra Bertoldo, Veronica Marinelli, Valentina Negretto, Cinzia Perlini, Gianluca Rambaldelli

INTERNATIONAL ADVISORY BOARD:

Project PIANO: Paul Bebbington, Max Birchwood, Paola Dazzan, Elisabeth Kuipers,Graham Thornicroft; **Project GUITAR:** Carmine Pariante; **Project CONTRABASS:** Steve Lawrie, Carmine Pariante, Jair C. Soares.

INDEPENDENT EVALUATORS AND RESEARCHERS SUPPORTING THE ONSITE DATA COLLECTION:

Stefania Artioli, Marco Baldetti, Milena Bizzocchi, Donatella Bolzon, Elisa Bonello, Giorgia Cacciari, Claudia Carraresi, M.Teresa Cascio, Gabriele Caselli, Karin Furlato, Sara Garlassi, Alessandro Gavarini, Silvia Lunardi, Fabio Macchetti, Valentina Marteddu, Giorgia Plebiscita, Sara Poli, Stefano Totaro.

GET UP RESEARCH PROGRAMME

Genetics, Endophenotypes,Treatment: Understanding Early Psychosis

GET UP

THE GET UP GROUP

National Coordinator: Mirella Ruggeri (Verona)

INTERNATIONAL ADVISORY BOARD:

PIANO:
Paul Bebbington, Max Birchwood, Paola Dazzan, Elisabeth Kuipers, Graham Thornicroft

GUITAR:
Carmine Pariante

CONTRABASS:
Steve Lawrie, Carmine Pariante, Jair C. Soares

RESEARCH UNIT Milano Niguarda

RESEARCH UNIT Emilia:

RESEARCH UNIT Romagna:

Case Management Staff: Massimo Bertozzi, Elisa Canetti, Luca Caricchioli, Elisa Ceccarelli, Stefano Cenni, Glenda Marzola, Vanessa Gallina, Carla Leoni, Andrea Olivieri, Elena Piccolo, Sabrina Ravagli, Rosaria Russo, Daniele Tedeschini.
Biological Sample processing and support to Brain Imaging procedures: Marina Verenini, Walter Abram, Veronica Granata, Alessandro Curcio, Giovanni Guerra, Samuela Granini, Lara Natali, Enrica Montanari, Fulvia Pasi, Umbertina Ventura, Stefania Valenti, Masi Francesca, Rossano Farneti, Paolo Ravagli, Romina Floris, Otello Maroncelli, Gianbattista Volpones, Donatella Casali.

Family Intervention Staff: Cristina Cussoto, Nico Dei, Enrico Fumanti, Manuela Pantani, Gregorio Zeloni.
Case Management Staff: Rossella Bellini, Roberta Cellesi, Nadia Dorigo, Patrizia Gulli, Luisa Ialeggio, Maria Pisanu.
Biological Sample processing and support to Brain Imaging procedures: Graziella Rinaldi, Angela Konze.

Case Management Staff: Lorenzo Andreose, Mario Boemio, Loretta Bressan, Arianna Cabbia, Elisabetta Caresso, Romina Cian, Claudia Dal Piccol, Maria Manuela Dalla Pasqua, Anna Di Prisco, Lorena Mantellato, Monica Luison, Sandra Morgante, Mirna Santi, Moreno Sacillotto, Mauro Scabbio, Patrizia Sponga, MLuisa Sguotto, Flavia Stach, MGrazia Vettorato, Giorgio Martinello, Francesca Dassiè, Stefano Marino, Linda Cibiniel, Ilenia Masetto, Marisa Marcato
Biological Sample processing and support to Brain Imaging procedures: Oscar Cabianca, Amelia Valente, Livio Cabertotto, Alberto Passoni, Patrizia Flumian, Luigino Daniel, Massimo Gion, Saverio Stanziale, Flora Alborino, Vladimiro Bortolozzo, Lucio Bacelle, Leonarda Bicciato, Daniela Basso, Filippo Navaglia, Fabio Manoni, Mauro Ercolin.

GET UP RESEARCH PROGRAMME
Genetics, Endophenotypes, Treatment: Understanding Early Psychosis

Special thanks to those who have coordinated the field work :

Angelo FIORITTI
Paolo SANTONASTASO
Antonio LASALVIA
Francesca PILEGGI
Daniela GHIGI
Gianni NERI
Franco GIUBILINI
Maurizio MICELI
Silvio SCARONE
Angelo COCCHI
Stefano TORRESANI

THE GET UP GROUP

National Coordinator: Mirella Ruggeri (Verona)

Warm thanks to my Collaborators who – since 2007 – worked in the Verona Coordinating Centre:

Antonio Lasalvia
Chiara Bonetto
Carla Comacchio
Doriana Cristofalo
Sarah Tosato
Katia De Santi
Sara Poli
Silvia Zoppei

RESEARCH UNIT Life Eve

Coordinator: Carlo Faravelli
Coordinating Centre: Silvia Casa
Administrative Leading Instituti

RESEARCH UNIT Genetics cia

Coordinator: Massimo Gennarelli
Coordinating Centre: Catia Scass
Administrative Leading Institutio
IRCCS Centro S.Giovanni di Dio F

RESEARCH UNIT Molecul

Coordinator: Mariacarla Ventriglia
Coordinating Centre: Rosanna S
Administrative Leading Institutio
Department of Neuroscience, AFa

RESEARCH UNIT UNIT RU

Coordinator: Matteo Balestrieri
Coordinating Centre: Paolo Br
Marcella Bellani, Gianluca Ramba
Fausto Mazzi, Paolo Carpeggian
Francesca Pizzini, Giada Zoccatell
Administrative Leading Institutio

RESEARCH UNIT Animal Mo no

Coordinator: Marco Andrea Riva
Coordinating Centre: Fabio
Calabrese, Gianluigi Guidotti, Aless
Administrative Leading Institutio

Geneti

GET UP

OBIETTIVI DELLO STUDIO

GET UP

1. testare l’ipotesi che il trattamento sperimentale … nella pratica clinica “ultra-reale” dei Servizi di Salute Mentali territoriali …

OUTCOMES PRIMARI

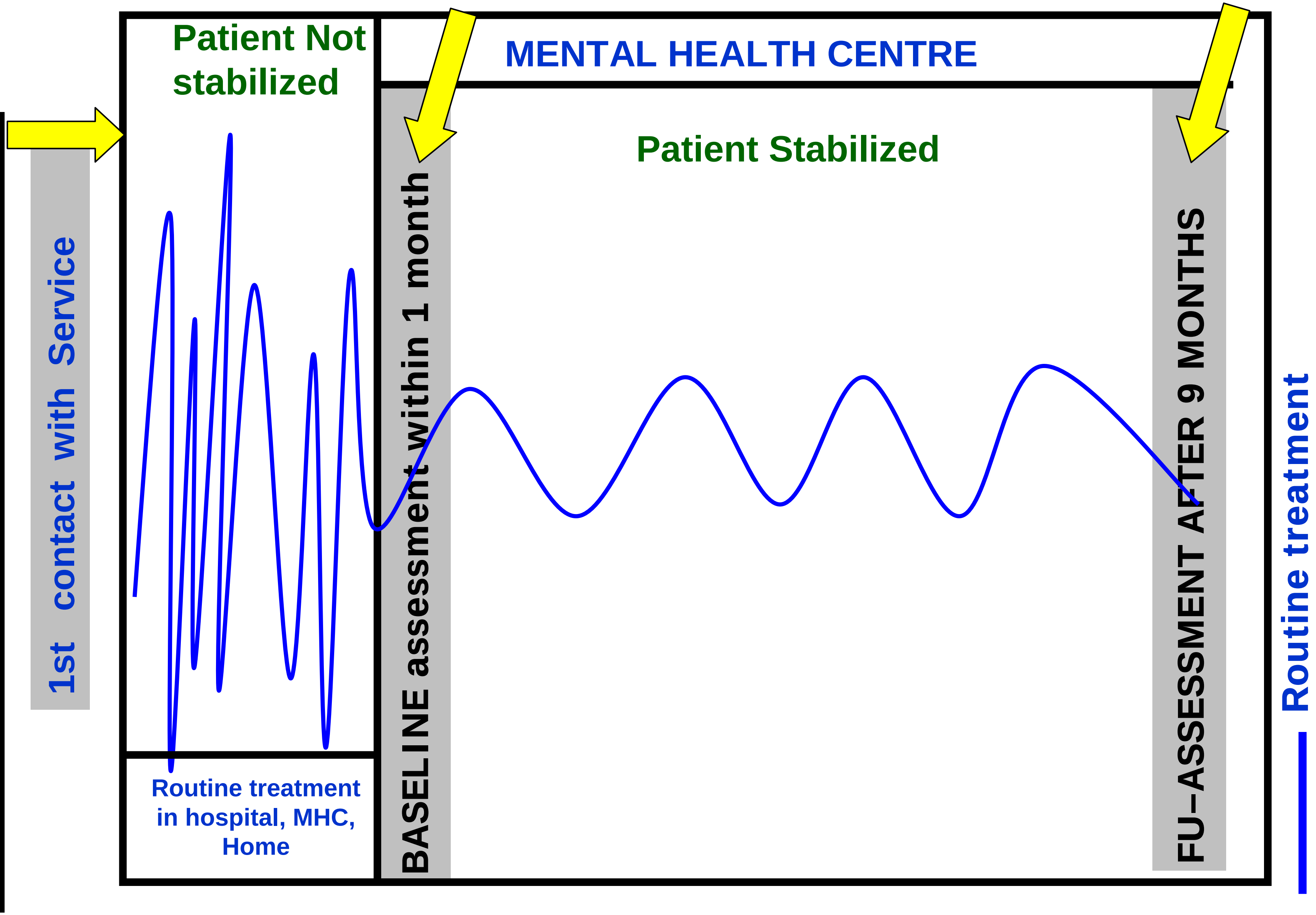
a) Riduzione dei sintomi positivi e negativi
b) Riduzione dei tassi di ricaduta
c) Miglioramento nella percezione soggettiva dei sintomi e del loro impatto sulla vita quotidiana

d) Miglioramento dell’atteggiamento emotivo e del funzionamento sociale
e) Perdita dell’aggancio con il Servizio

PSYCHOSIS: EARLY INTERVENTION AND ASSESSMENT OF NEEDS AND OUTCOME

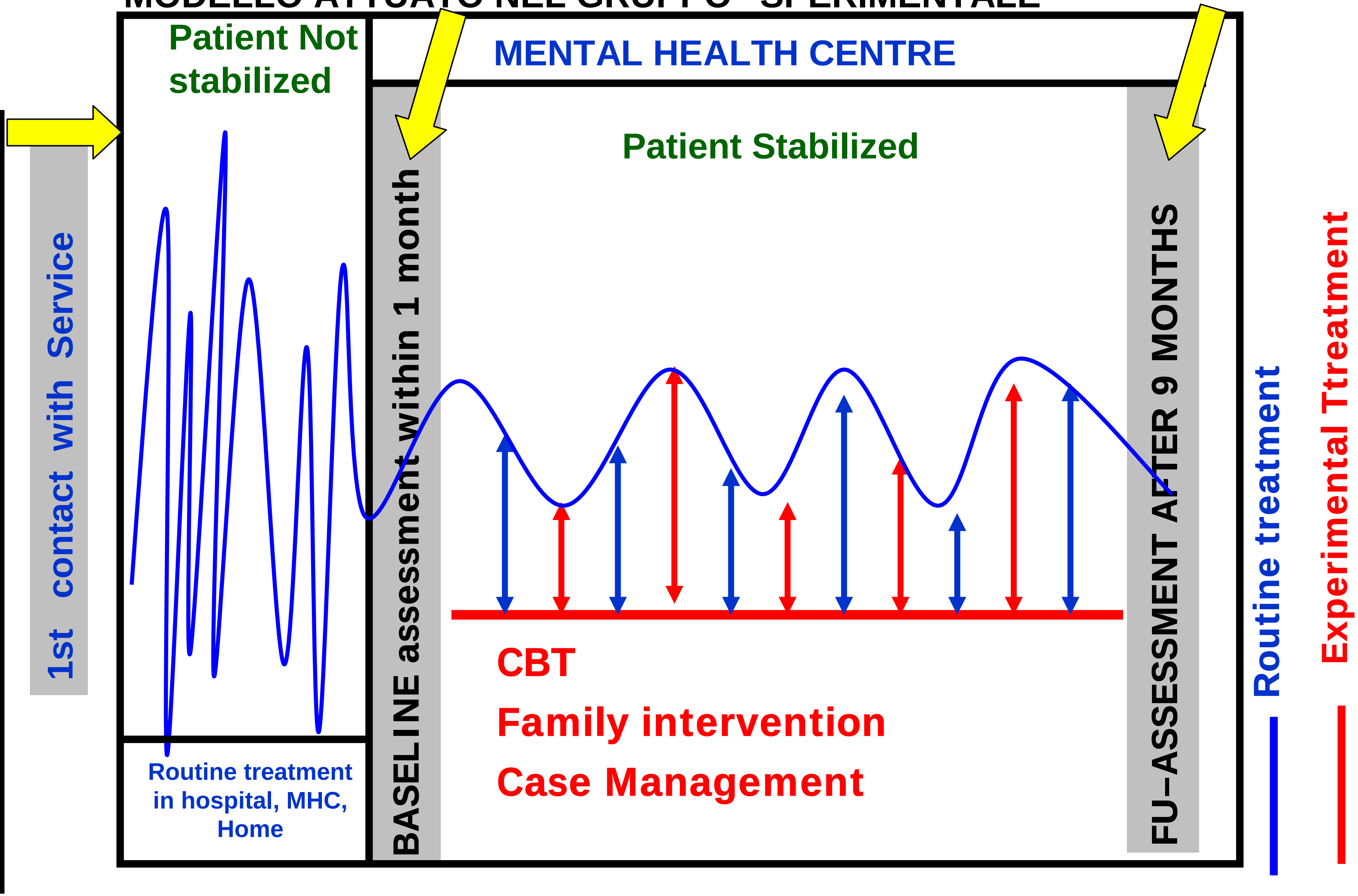
IL DISEGNO DELLO STUDIO:

MODELLO ATTUATO NEL GRUPPO DI CONTROLLO


1st contact with Service
Patient Not stabilized
Routine treatment in hospital, MHC, Home
MENTAL HEALTH CENTRE
BASELINE assessment within 1 month
Patient Stabilized
FU-ASSESSMENT AFTER 9 MONTHS
Routine treatment

IL DISEGNO DELLO STUDIO:

MODELLO ATTUATO NEL GRUPPO “SPERIMENTALE”



1st contact with Service

Patient Not stabilized

Routine treatment in hospital, MHC, Home

MENTAL HEALTH CENTRE

BASELINE assessment within 1 month

Patient Stabilized

CBT

Family intervention

Case Management

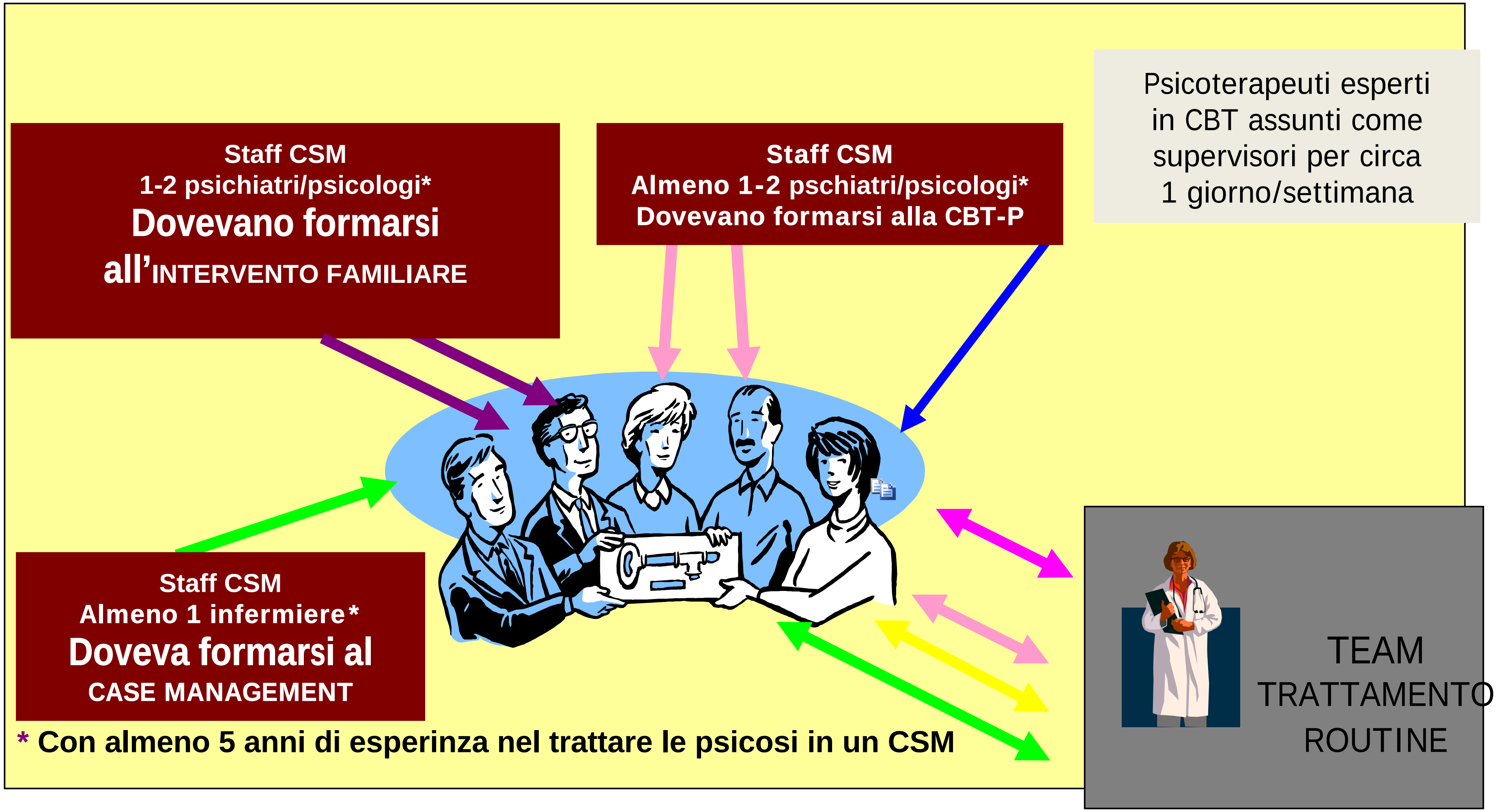
FU-ASSESSMENT AFTER 9 MONTHS

Routine treatment

Experimental Ttreatment

MODELLO DEL “TEAM SPECIALIZZATO”CHE OPERA IN UN CSM STANDARD DEL BRACCIO SPERIMENTALE

(area territoriale di riferimento100.000 ABITANTI)



Staff CSM
1-2 psichiatri/psicologi*
Dovevano formarsi all’INTERVENTO FAMILIARE

Staff CSM
Almeno 1-2 pschiatri/psicologi*
Dovevano formarsi alla CBT-P

Psicoterapeuti esperti in CBT assunti come supervisori per circa 1 giorno/settimana

Staff CSM
Almeno 1 infermiere*
Doveva formarsi al CASE MANAGEMENT

TEAM TRATTAMENTO ROUTINE

*** Con almeno 5 anni di esperinza nel trattare le psicosi in un CSM**

Ruggeri *et al. Trials* 2012, **13**:73
http://www.trialsjournal.com/content/13/1/73

TRIALS

STUDY PROTOCOL **Open Access**

Caratteristiche-chiave del disegno dello studio:

- Si è svolto nel contesto della **pratica clinica ultra-reale** dei Servizi di Salute Mentale

- Sono stati effettuati tutti gli sforzi possibili per garantire la **rappresentatività epidemiologica** della coorte dei pazienti e dei familiari

- Il personale dei Servizi di Salute Mentale è stato inizialmente formato da esperti **e ha successivamente attuato l'intervento in autonomia**

- Il personale dei Servizi di Salute Mentale ha ricevuto per tutta la durata del trattamento supporto e supervisione da parte di esperti ed è stato **sottoposto a regolari controlli qualitativi**

- I promotori e coordinatori dello Studio (Gruppo di Verona) hanno lavorato separatamente dalle équipes cliniche

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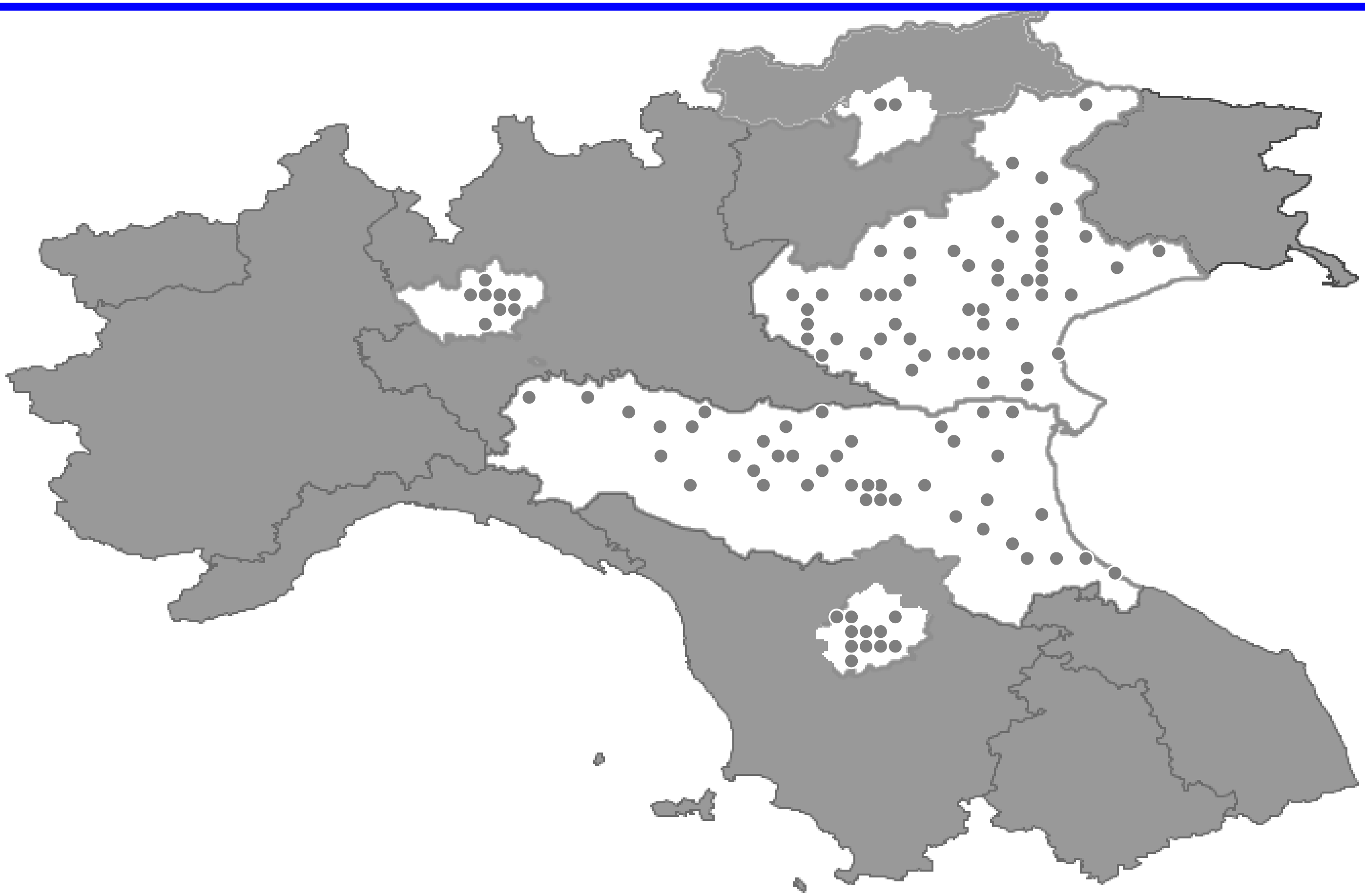
KEY STEPS FOR USING MENTAL HEALTH SERVICE RESEARCH TO IDENTIFYING THE MOST APPROPRIATE STRATEGIES TO TRANSLATING KNOWLEDGE INTO CLINICAL PRACTICE

- Assess services’ representativeness
- Assess capacity building among MH professionals
- Assess patients’ representativeness

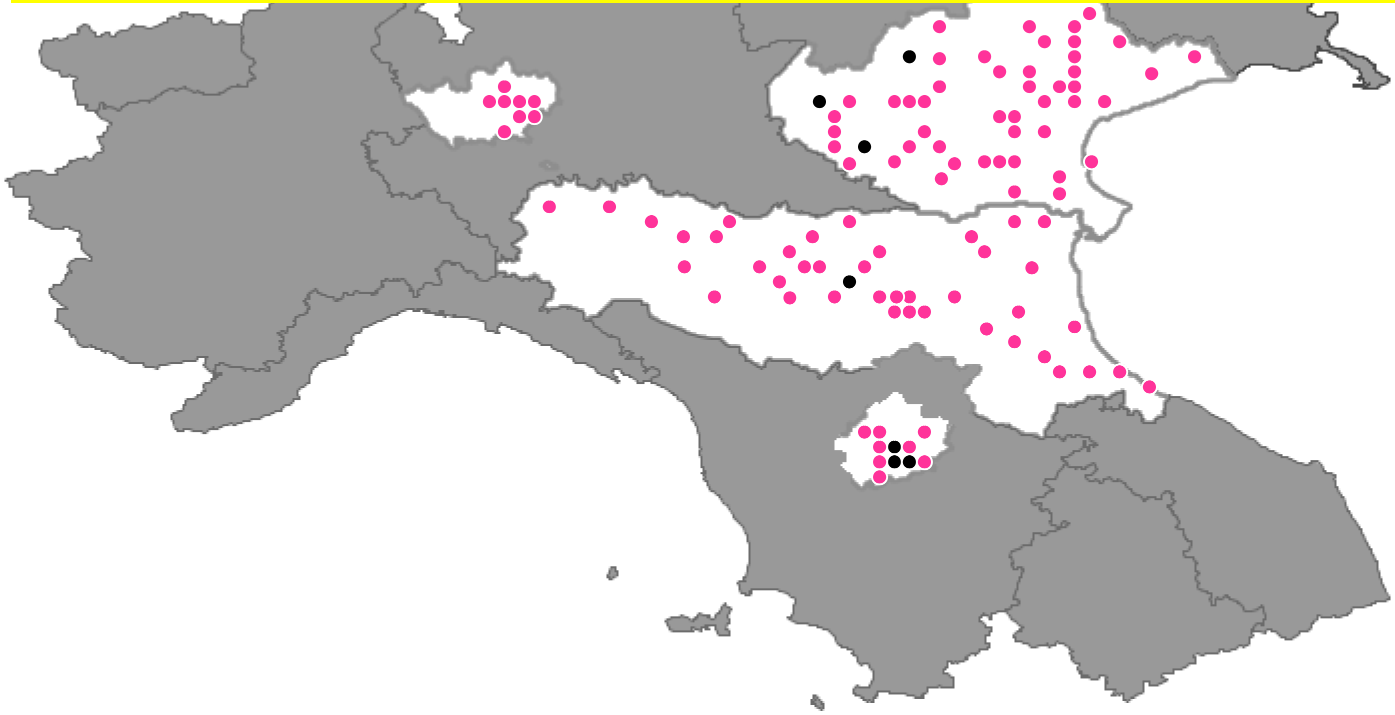
Community Mental Health Centres (CMHCs) asked to participate: N=126



GET UP

Participating CMHCs :
117 of the 126 originally contacted

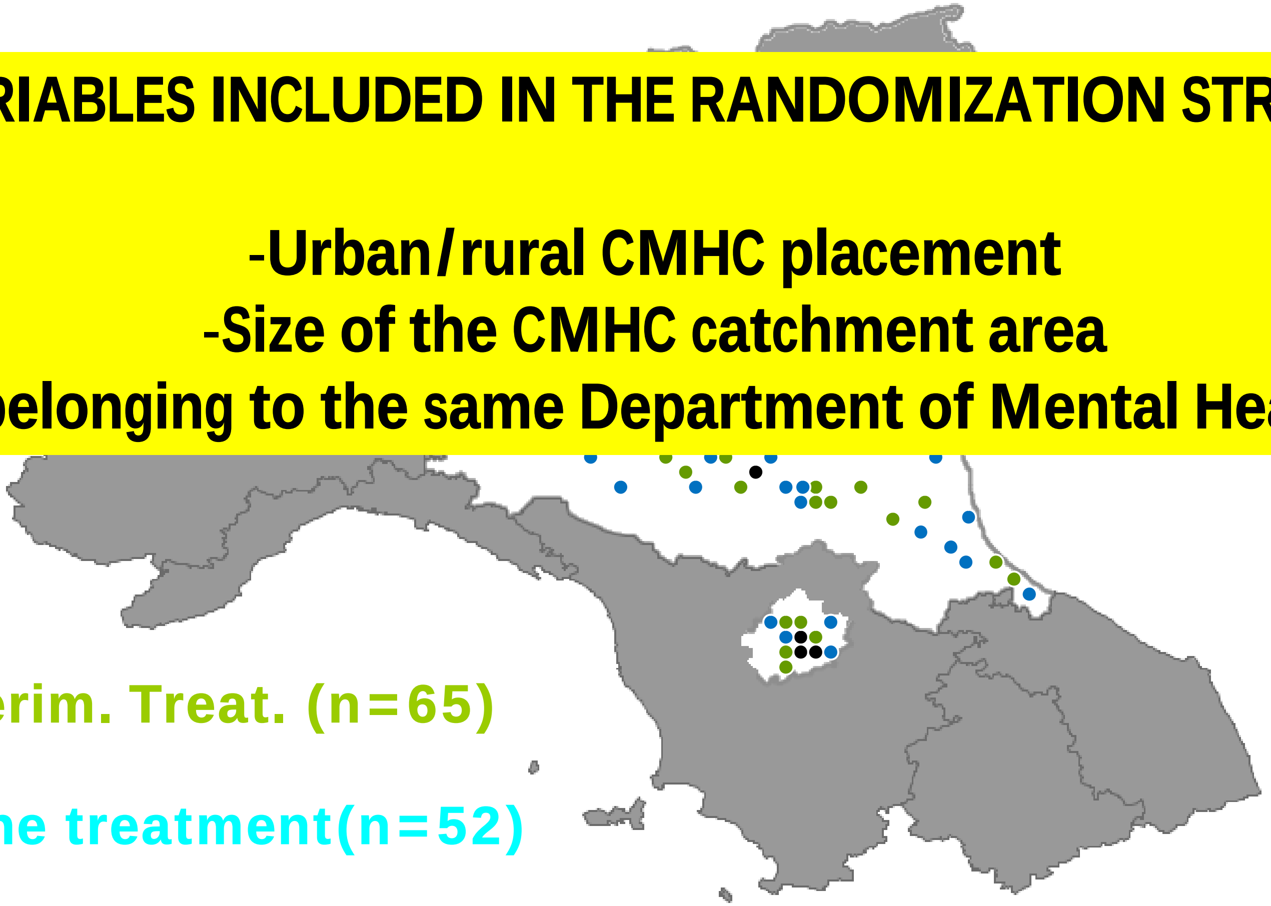
92% OF THE CMHSs SERVING
THE 10 MILLION INHABITANT CATCHMENT AREA



CMHCs that entered the randomization: N=117

VARIABLES INCLUDED IN THE RANDOMIZATION STRATA:

-Urban/rural CMHC placement
-Size of the CMHC catchment area
- belonging to the same Department of Mental Health

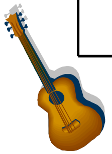


green: Experim. Treat. (n=65)

blue: Routine treatment(n=52)

Randomization of CMHCs across strata

STRATA		**CMHCs**					
Participating unit	**Type of area**	**Standard care group (n=48)**			**Experimental treatment group (n=53)**		
		Catchment area size (inhabitants)			Catchment area size (inhabitants)		
		•100.000	<100.000	**Total**	•100.000	<100.000	**Total**
Veneto[a]	Urban Mixed/rural	3 8	0 9	**3** **17**	3 (+1*) 8	0 9	**4** **17**
Milan[b]	Urban Mixed/rural	3 0	0 0	**3** **0**	3 (+1*) 0	1*	**5**
Florence	Urban Mixed/rural	0	0 4	**0** **4**	0 0	0 4	**0** **4**
Emilia Romagna[c]	Urban Mixed/rural	0 6	2 13	**2** **19**	- 6	2 13	**2** **19**
Bolzano	Urban Mixed/rural	- -	-	-	0	0 2*	**0** **2***



* CMHCs forced into the intervention arm because staff members had received previous training in the intervention

KEY STEPS FOR USING MENTAL HEALTH SERVICE RESEARCH TO IDENTIFYING THE MOST APPROPRIATE STRATEGIES TO TRANSLATING KNOWLEDGE INTO CLINICAL PRACTICE

- Assess services’ representativeness

- Assess capacity building among MH professionals

- Assess patients’ representativeness

Metodi (1): il programma GET UP di formazione per l’approccio CBT per le psicosi precoci

CORSO DI FORMAZIONE:
CORSO DI FORMAZIONE COGNITIVO-COMPORTAMENTALE PER GLI ESORDI PSICOTICI
(Direttore del Corso: Mirella Ruggeri)

- Nel contesto del Progetto GET UP è stato sviluppato un corso breve intensivo per il trattamento precoce della psicosi, come parte della formazione post-lauream dell’Università di Verona

- Il corso di formazione, basato sul modello dell’uso CBT nella psicosi sviluppato da Kuipers, Garety & Fowler (1995, 1998), consta di:

4 Moduli di insegnamento teorico ed esercizio pratico (analisi di casi clinici) per un totale di 112 ore/partecipante

+

Sessioni di supervisione del lavoro clinico (30 ore/partecipante)

Schizophrenia Bulletin vol. 41 no. 5 pp. 1192–1203, 2015
doi:10.1093/schbul/sbv058
Advance Access publication May 20, 2015

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Feasibility and Effectiveness of a Multi-Element Psychosocial Intervention for First-Episode Psychosis: Results From the Cluster-Randomized Controlled GET UP PIANO Trial in a Catchment Area of 10 Million Inhabitants

This paper is dedicated to the memory of Professor Angelo Cocchi

Mirella Ruggeri[*,1,2], Chiara Bonetto[1], Antonio Lasalvia[1,2], Angelo Fioritti[3], Giovanni de Girolamo[4], Paolo Santonastaso[5], Francesca Pileggi[3], Giovanni Neri[6,7], Daniela Ghigi[8], Franco Giubilini[9], Maurizio Miceli[10], Silvio Scarone[11], Angelo Cocchi[12], Stefano Torresani[13], Carlo Faravelli[14], Carla Cremonese[15], Paolo Scocco[16], Emanuela Leuci[9], Fausto Mazzi[17], Michela Pratelli[8], Francesca Bellini[8], Sarah Tosato[1,2], Katia De Santi[1,2], Sarah Bissoli[1], Sara Poli[1], Elisa Ira[1], Silvia Zoppei[1], Paola Rucci[3,7], Laura Bislenghi[12], Giovanni Patelli[12], Doriana Cristofalo[1], Anna Meneghelli[12], and The GET UP Group[18]

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L.A. Scuro 10, 37134 Verona, Italy; [2]Azienda Ospedaliera Universitaria Integrata Verona, Ve
Azienda ULSS Bologna, Bologna, Italy; [4]Scientific Direction, St John of God Clinical Resea
Italy; [5]Department of Neurosciences, University of Padova, Padova, Italy and Azienda Ospe
Mental Health, Azienda ULSS Modena, Modena, Italy; [7]Agenzia Sanitaria e Sociale Region
[8]Department of Mental Health, Rimini, Italy; [9]Department of Mental Health, Parma, Italy;
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2000, Milan, Italy; [13]Department of Mental Health, Bolzano, Italy; [14]Department of Psychia
[15]Department of Mental Health, Azienda Ospedaliera Padova, Padova, Italy; [16]Department
Padova, Italy; [17]Department of Mental Health, Modena, Italy; [18](see online Supplementary

*To whom correspondence should be addressed; Section of Psychiatry, Department of Publi
University of Verona, Policlinico G.B. Rossi, Piazzale L.A. Scuro 10, 37134 Verona, Italy; tel
e-mail: mirella.ruggeri@univr.it

PALTRINIERI ELISABETTA
CASANA ELISA

Metodi (2): i contenuti del Training breve ed intensivo

Module 1	Fundamental principles of CBT: -basic elements theoretical of CBT (therapeutic relationship in CBT; cognitive-behavioral assessment; basic elements of cognitive restructuring); -medical model and psychological model of behavioural disorders; -treatment of the anxiety disorders and the mood disorders;
Module 2	Theoretical basis of CBT for psychosis: -the cognitive model of psychosis ; -introduction to CBT for positive and negative symptoms; -coping strategies of persistent symptoms;
Module 3	Specific CBT for first-episode psychosis: -relational style and therapeutic alliance; -characteristics of patients at the onset; -peculiarities of the approach with adolescents and young people; -empathy, motivation and management of emotions; -psycho-education and problem solving in CBT; -the role and cognitive-behavioral treatment for emotional dysfunctions in early psychosis; -the risk of suicide and models of suicide prevention; -comorbidity with substances abuse (effects of drugs on the psychotic issue and interference on the effectiveness of treatment, strategies to promote the motivation to change and strategies to promote and maintain abstinence or reduction of consumption);
Module 4	Recovery and treatment of specific symptoms: -treatment of delusions and hallucinations; -recognize signs of crisis; -prevention of relapse and individualized coping strategies.

RESIDENTIAL COURSE ON:
COGNITIVE-BEHAVIOURAL APPROACH FOR EARLY PSYCHOSIS PATIENTS

(Director: Mirella Ruggeri)

TEACHERS

Anna Meneghelli
(COORDINATOR AND TEACHER)

- **Paul Bebbington**
- **Laura Bislenghi**
- **Tiziana Bolis**
- **Davide Dettore**
- **David Fowler**
- **Chris Jackson**
- **Susan Jolley**
- **Elisabeth Kuipers**
- **Paolo Michielin**
- **Giovanni Patelli**
- **Antonio Pinto**

Metodi (3): il Programma del Corso

Le componenti essenziali del corso sono state:

- Valutazione regolare e costante delle abilità apprese
- Valutazioni periodiche e feedback regolari da parte dei supervisori della formazione
- Esame finale al termine del corso: soglia per ottenere la qualificazione di terapeuta GET UP=35/50

Metodi (4): I partecipanti

Il corso di formazione è stato eseguito su:

96 membri dello staff dei Centri di Salute Mentale (CSM), psichiatri e psicologi, appartenenti ai CSM assegnati tramite randomizzazione_al braccio di intervento del programma GET UP

24 psicologi cognitivo-comportamentisti, reclutati nello studio per supportare lo staff dei Centri di Salute Mentale - questo gruppo, grazie alle competenze personali precedentemente acquisite, costituiva lo "standard di riferimento" per la valutazione dello sviluppo delle abilità

- 124 partecipanti
- Tutti tranne 4 hanno concluso il Corso
- All’Esame finale, tutti tranne 5 hanno ottenuto un punteggio inferiore alla soglia predefinita (35/50) e hanno dovuto fare ulteriore training

Metodo utilizzato per le valutazioni

Competenze di base:

Curriculum Vitae, esperienze lavorative precedenti e background

Valutazione continua:

- Questionari a risposta multipla sulle conoscenze teoriche in merito agli argomenti di CBT presentati durante i vari moduli del corso;
- Analisi di casi clinici (saggi sulla formulazioni dei casi e le strategie di trattamento);
- Questionari autosomministrati “ad hoc” per valutare la soddisfazione dei partecipanti;

Giudizio dei formatori (sullo sviluppo delle capacità effettuato alla fine delle sessioni di supervisione e durante la fase di attuazione dello studio):

Partecipazione, atteggiamento nei confronti del corso, stile terapeutico e attinenza ai concetti della CBT.

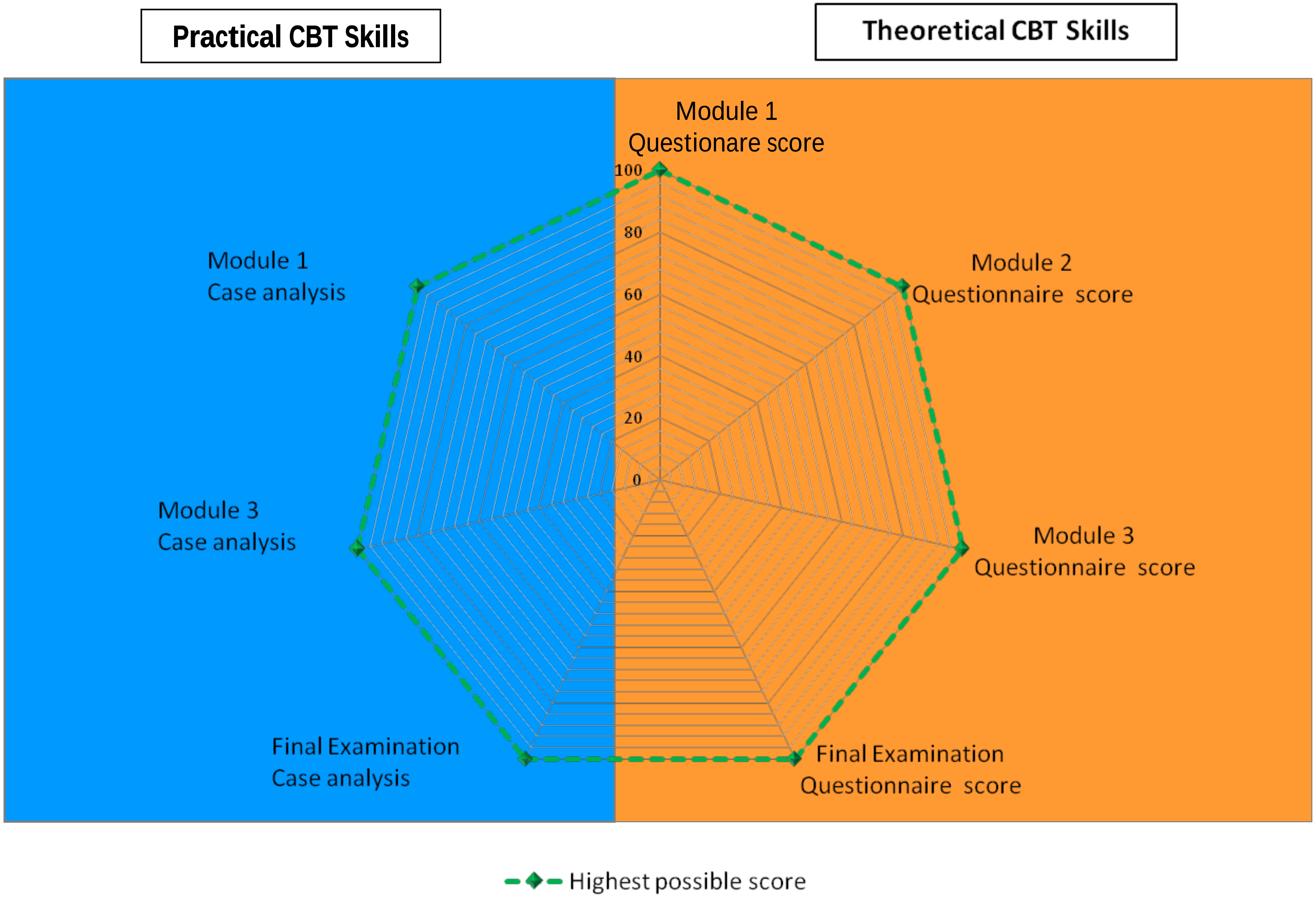
Risultati (1): caratteristiche dei partecipanti

Characteristics	Categories	[redacted]	CBT Expert Psychologists (n=24)	P-value T-test
Age mean (sd)		[redacted]	33.21 (3.43)	.000*
Gender	M n (%) F n (%)	[redacted]	4 (16.7) 20 (83.3)	.090
Professional background	Psychiatrist n (%) Psychologist n (%)	[redacted]	0 (0) 24 (100)	.000*
Years from graduation dichotomized	<10 n (%) • 10 n (%)	[redacted]	21 (48.3) 3 (12.5)	.000*
Theoretical orientation[a]	No CBT n (%) Yes CBT n (%)	[redacted]	3 (12.5) 21 (87.5)	.000*
Years of work dichotomized	<10 n (%) • 10 n (%)	[redacted]	23 (95.8) 1 (4.2)	.000*

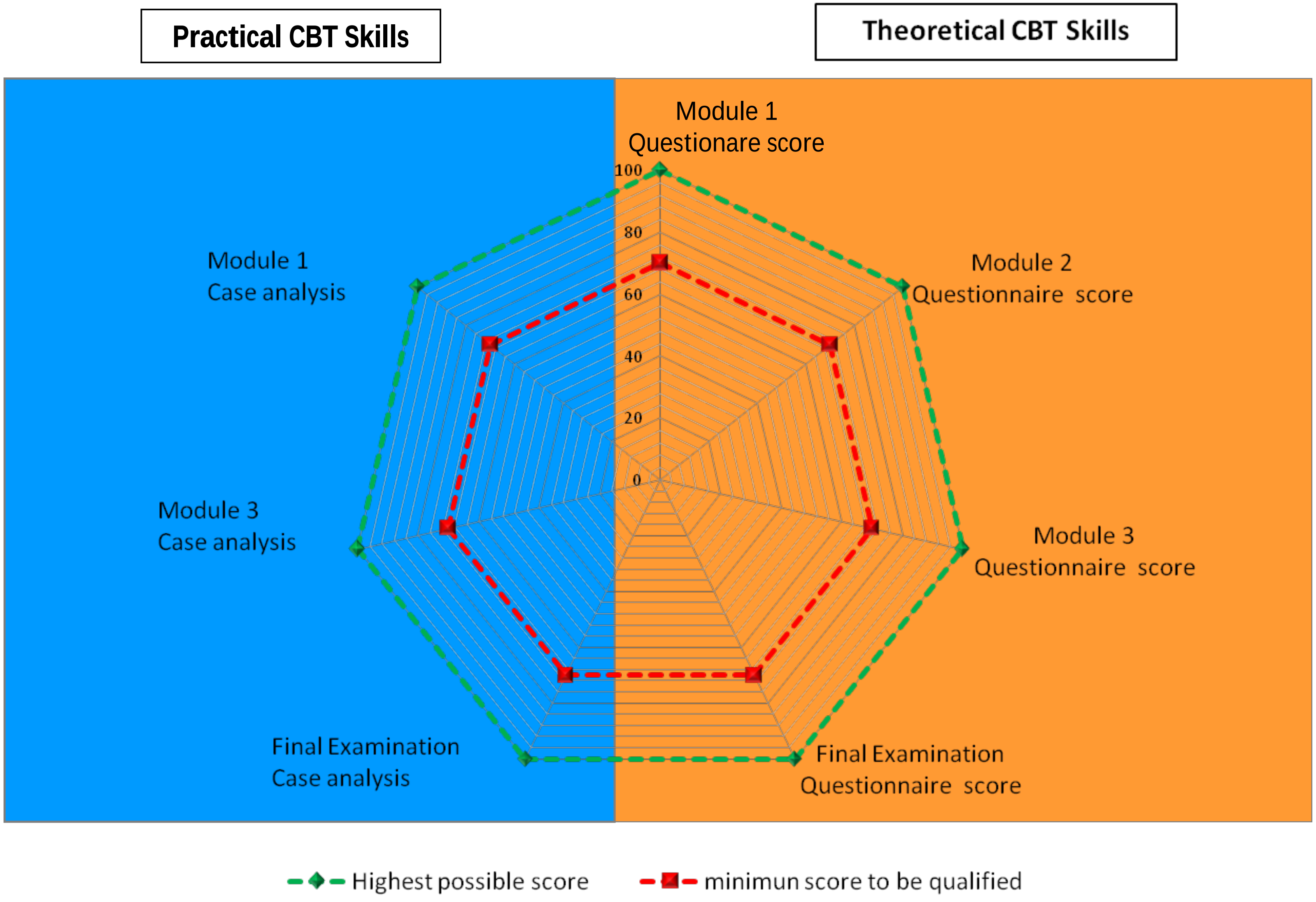
[a] Previous formal course in CBT

* p < .0001

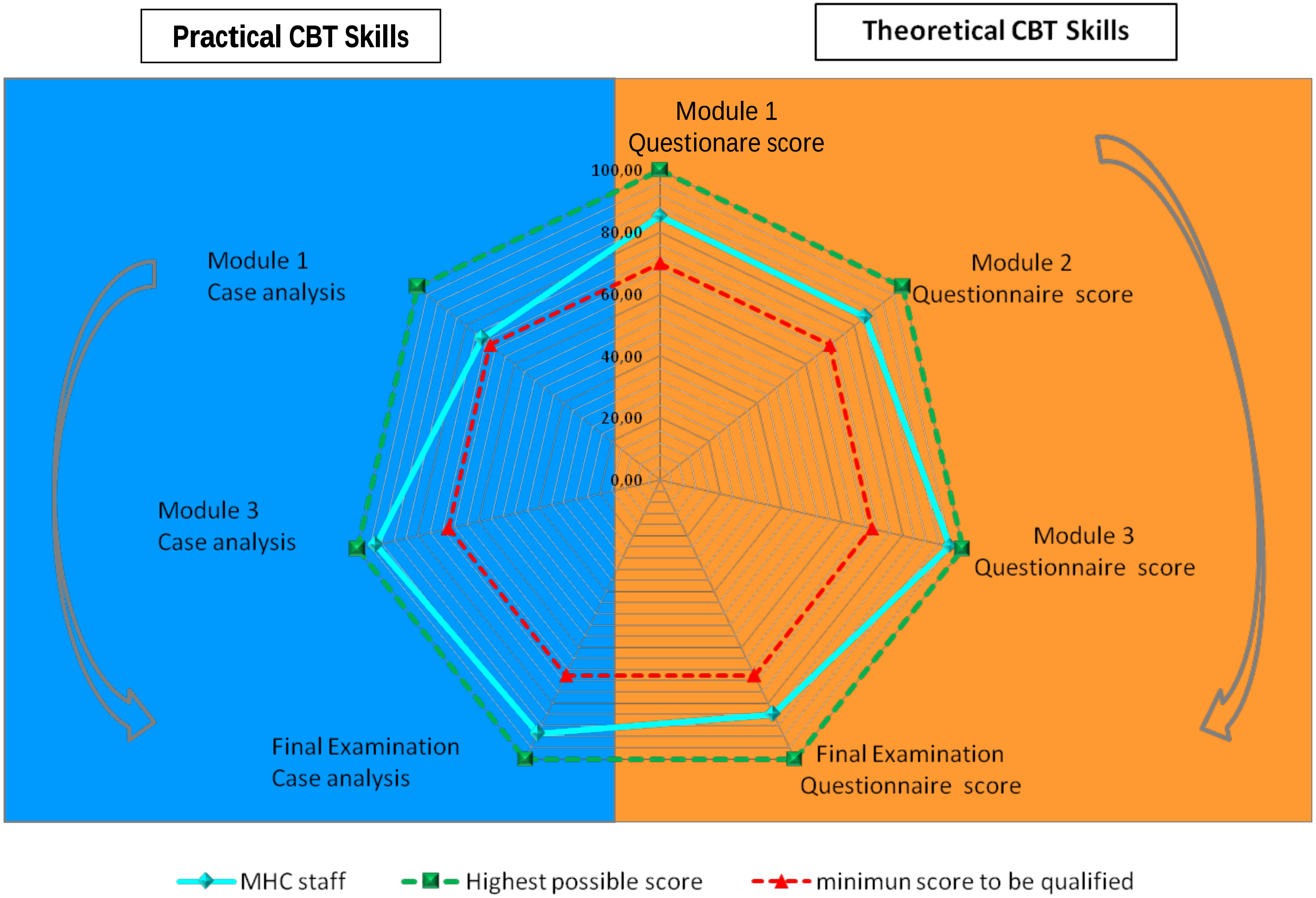
Risultati (2): punteggi ottenuti alle valutazioni (medie)



Risultati (2): punteggi ottenuti alle valutazioni (medie)



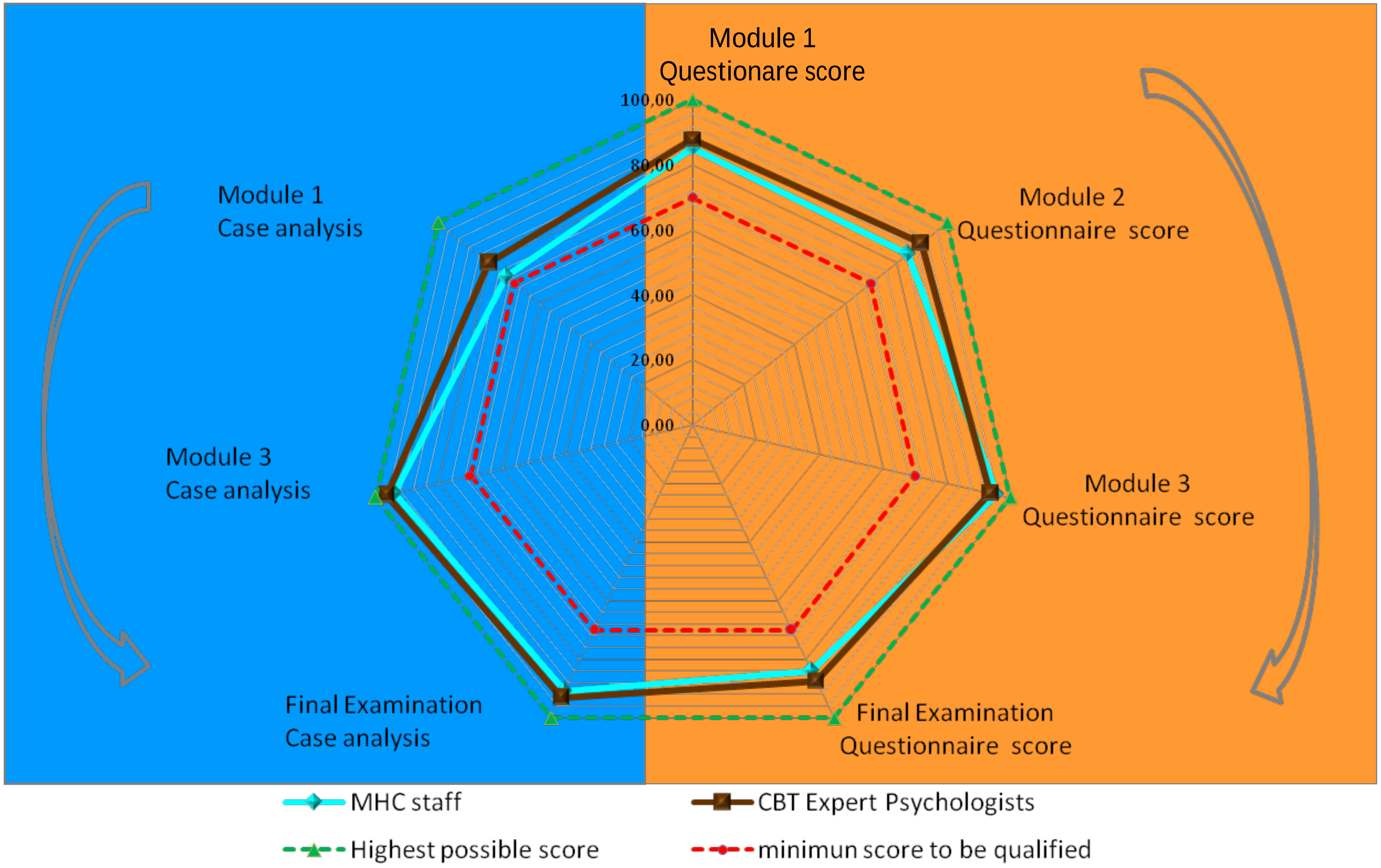
Risultati (2): punteggi ottenuti alle valutazioni (medie)



Risultati (2): punteggi ottenuti alle valutazioni (medie)

Practical CBT Skills

Theoretical CBT Skills



Risultati (3):

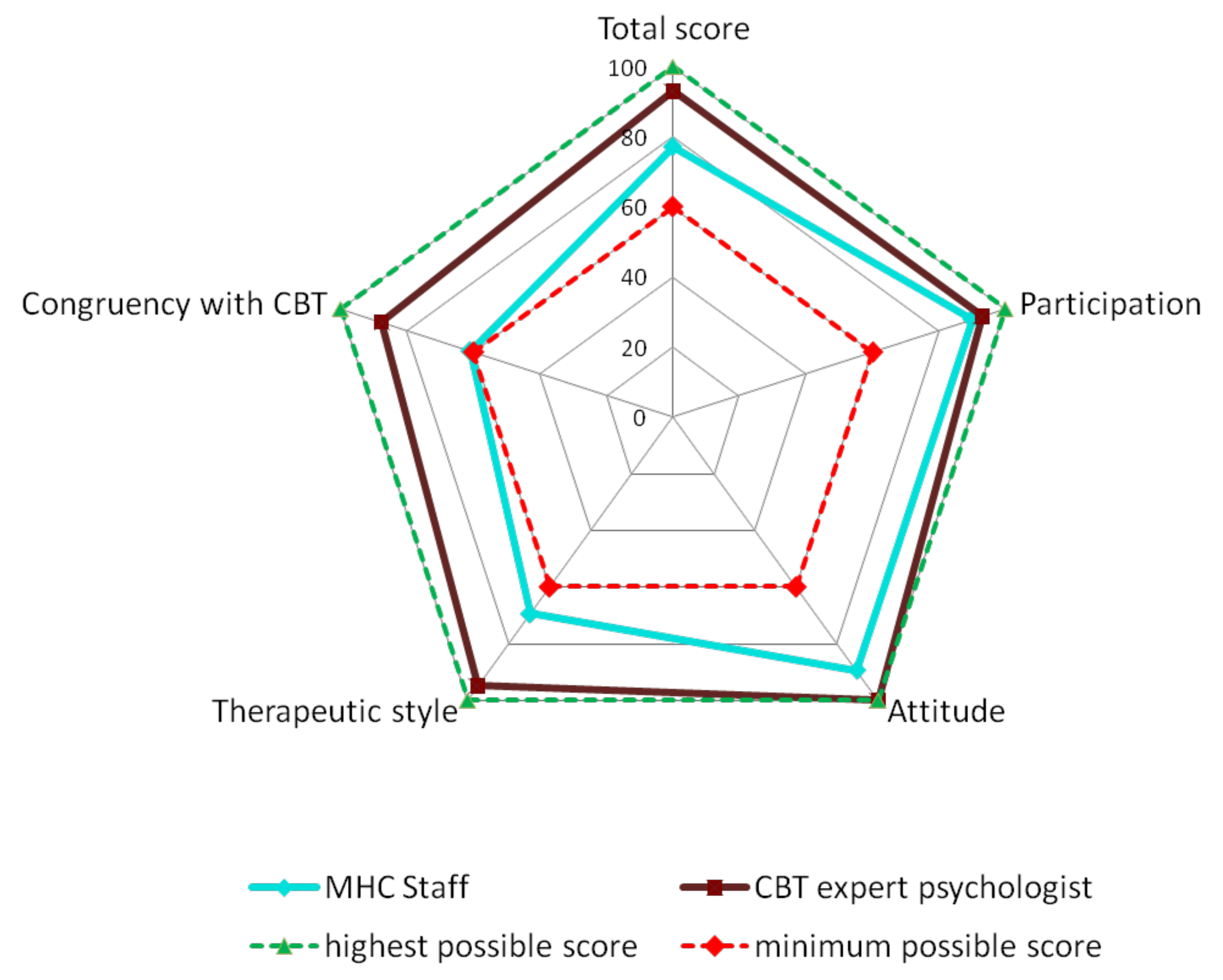
Caratteristiche dello Staff dei CSM e acquisizione di competenze

Examination scores	**Age mean (sd)**		**Years from graduation** mean (sd)		**Years of work mean (sd)**		**Theor. Orient. mean (sd)**		**Professional Background mean (sd)**	
	(<40)	**(•40)**	**(<10)**	**(•10)**	**(<10)**	**(•10)**	**No CBT**	**Yes CBT**	**Psychiat.**	**Psychol.**
Module 1 Quest. (Range 0-30)										25.69 (2.93)
Module 2 Quest. (Range 0-20)										17.00 (1.64)
Module 3-4 Quest. (Range 0-30)										25.62* (2.44)
Final Exam. Quest. (Range 0-20)										17.71* (1.20)
Module 1 Case analysis (Range 0-20)										15.21 (3.39)
Module 3-4 Case analysis (Range 0-20)										18.96 (0.98)
Final Exam. Case analysis (Range 0-20)	18.22 (1.31)	18.13 (1.30)	18.13 (1.31)	18.19 (1.29)	18,35 (1.31)	18,03 (1.28)	18.19 (1.27)	18.08 (1.38)	18.14 (1.20)	18.25 (1.58)

No differences in competence acquisition in MHC staff referring to age, years from graduation, years of work, theoretical orientation and professional background

* p < .0001

Risultati (4): Valutazioni dei supervisori (medie)



Risultati (4): Esame finale

All participants successfully passed the final examination, obtaining a Global Score higher than 35/50 (minimum score required to be qualified)

Global Score (Final Examination total score + Trainer judgment total score)	MHC staff (n=96)	CBT Psychologists (n= 24)
Sufficient score (36-40)	19.79 %	4.35 %
Medium – High score (41-50)	80.21 %	95.65 %

Risultati (5): Soddisfazione dei partecipanti

Satisfaction	MHC staff Mean (SD) (n=96)	CBT Psychologists Mean (SD) (n= 24)
Theorical and practical teaching	7.42 (1.03)	7.45 (0.93)
Overall impact of the course on capacity building	7.91 (1.26)	7.36 (1.04)
Methods used for assessing capacity building	7.38 (1.33)	7.32 (1.33)
Total	7.81 (1.14)	7.52 (1.10)

satisfaction range: 0=awful 10= excellent

if you can talk, you can sing;
if you can walk, you can dance

(african proverb)

KEY STEPS FOR USING MENTAL HEALTH SERVICE RESEARCH TO IDENTIFYING THE MOST APPROPRIATE STRATEGIES TO TRANSLATING KNOWLEDGE INTO CLINICAL PRACTICE

- Assess services' representativeness
- Assess capacity building among MH professionals
- Assess patients' representativeness

PSYCHOSIS: EARLY INTERVENTION AND ASSESSMENT OF NEEDS AND OUTCOME

Popolazione nell'area territoriale di riferimento:
9.951.306 abitanti
Assistiti da 126 Servizi di Salute Mentale

117 Servizi di Salute Mentale coinvolti
(8.700.093 abitanti)

Randomizzazione SSM

GRUPPO DI CONTROLLO
52 SSM – 4.126.110 abitanti

Identificati: 264 Pazienti

GRUPPO SPE
65 SSM – 4.57

Identificati: 3

Supponendo che il 75% dei casi si rivolga a un SSM, circa 700 nuovi casi/anno erano attesi nel bacino di utenza GET UP

Numero totale di pazienti eleggibili: 626

ELEGGIBILI: 262 (94.5%)

VALUTATI AL BASELINE:
172 Pazienti (74.7%)

VALUTATI AL 9 ° MESE DI FOLLOW-UP:
154 Pazienti (87.9%)

ELEGGIBILI: 364 (99.2%)

VALUTATI AL BASELINE:
272 Pazienti (65.6%)

VALUTATI AL 9 ° MESE DI FOLLOW-UP:
242 Pazienti (88.9%)

Caratteristiche socio-demografiche dei pazienti valutati al BL (dopo stabilizzazione clinica) e confermati tali tramite SCAN al 9° mese di follow up (1)

	GRUPPO DI CONTROLLO (n=172)	GRUPPO SPERIMENTALE (n=272)
GENERE, N (%)		
Maschi	94 (54.7)	166 (61.0)
ETA' AL PRIMO CONTATTO CON I SERVIZI, media (ds)	31.5 (9.2)	29.3 (9.8)
SCOLARIZZAZIONE, N (%)	(13 mancanti)	(9 mancanti)
Bassa (medie inferiori)	68 (42.8)	95 (36.1)
Alta (medie superiori, università)	91 (57.2)	168 (63.9)
STATO CIVILE, N (%)	(12 mancanti)	(12 mancanti)
Celibe/nubile	118 (73.8)	195 (75.0)
Coniugato	27 (16.9)	53 (20.4)
Vedovo, separato, divorziato	15 (9.3)	12 (4.6)
SITUAZ ABITATIVA, N (%)	(14 mancanti)	(12 mancanti)
Solo	9 (5.7)	14 (5.4)
Con il partner e/o i figli	39 (24.7)	60 (23.0)
Con altri parenti	105 (66.5)	182 (70.0)
Altro	5 (3.1)	4 (1.6)

Caratteristiche socio-demografiche dei pazienti valutati al BL (dopo stabilizzazione clinica) e confermati tali tramite SCAN al 9° mese di follow up (2)

	GRUPPO DI CONTROLLO (N=172)	GRUPPO SPERIMENTALE (N=272)
CONDIZ LAVORATIVA, N(%)	(4 mancanti)	(11 mancanti)
Occupato	64 (38.1)	95 (36.4)
Disoccupato	61 (36.3)	83 (31.8)
Casalinga, studente, pensionato	38 (22.6)	76 (29.1)
Altro	5 (3.0)	7 (2.7)
NAZIONALITA', N (%)		
Italiana	149 (86.6)	241 (88.6)
Est-Europea	11 (6.4)	17 (6.2)
Africana	10 (5.8)	6 (2.2)
Sud-Americana	1 (0.6)	6 (2.2)
Asiatica	0 (0.0)	2 (0.8)
Altro	1 (0.6)	0 (0.0)
DIAGNOSI, N (%)		
Psicosi non affettiva	132 (76.7)	214 (78.7)
Psicosi affettiva	40 (23.3)	58 (21.3)

GET UP

Terapia fornita al gruppo sperimentale (1)

GRUPPO SPERIMENTALE (N=272)		
SESSIONI DI CBT, N (%) **0** 1-4 5-9 10-19 **20+**	**24 (8.8%)** 15 (5.5%) 25 (9.2%) 70 (25.8%) **138 (50.7%)**	**CBT -** **STANDARD OTTIMALE PREDEFINITO:** **> 15 SESSIONI /9 MESI**
NUMERO DI SESSIONI DI CBT, media (ds), min-max	**17.8 (10.3), 0-44**	
SESSIONI DI TERAPIA FAMILIARE, N (%) **0** 1-4 5-9 **10-19** 20+	**52 (19.2%)** 24 (8.8%) 56 (20.6%) **120 (44.1%)** 20 (7.3%)	**TERAPIA FAMILIARE -** **STANDARD OTTIMALE PREDEFINITO:** **> 9 SESSIONI / 9MESI**
NUMERO DI SESSIONI TF, media (ds), min-max	**9.3 (7.0), 0-36**	

Terapia fornita
al gruppo sperimentale (2)

GRUPPO SPERIMENTALE (N=272)		
		SOTTOGRUPPO CON 0 SESSIONI: MOTIVI, N (%)
		N=24
SESSIONI DI CBT, N (%) **0** 1-4 5-9 10-19 **20+**	 **24 (8.8%)** 15 (5.5%) 25 (9.2%) 70 (25.8%) **138 (50.7%)**	**Rifiuto del paziente alla CBT 13 (54.2%)** Early drop out 4 (16.7%) Spostati in ambito privato 2 (8.4%) Trasferiti 3 (12.5%) Gravidanza ad alto rischio 1 (4.1%) Orari lavorativi incompatibili con gli appuntamenti 1 (4.1%)
NUMERO DI SESSIONI DI CBT, media (ds), min-max	**17.8 (10.3), 0-44**	**N=52**
SESSIONI DI TERAPIA FAMILIARE, N (%) **0** 1-4 5-9 **10-19** 20+	 **52 (19.2%)** 24 (8.8%) 56 (20.6%) **120 (44.1%)** 20 (7.3%)	**Familiari non disponibili 16 (30.8%)** Rifiuto del pz a contattare i familiari 6 (11.5) **Rifiuto dei familiari alla TF 13 (25.0%) *** Rifiuto dei familiari alla TF 7 (13.5%) Early drop out 4 (7.7%) Trasferiti 3 (5.8%) Spostati in ambito privato 2 (3.8%) Orari lavorativi incompatibili 1 (1.9%)
NUMERO DI SESSIONI TF, media (ds), min-max	**9.3 (7.0), 0-36**	-

Terapia fornita al gruppo sperimentale (3)

GRUPPO SPERIMENTALE (N=272)	
CONTATTI DI CASE MANAGEMENT, N (%)	
0	0 (0,0%)
1-4	**96 (35.3)**
5-9	40 (14,7)
10-19	59 (21,7)
20+	**77 (28,3)**
NUMERO DI SESSIONI DI CM, media (ds), min-max	**21,7 (24,4), 1-120**

CASE MANAGEMENT - STANDARD OTTIMALE PREDEFINITO:

> 20 SESSIONI / 9 MESI

Statistical analyses (1)

v Intention to treat (**ITT**) and **CONSORT** guidelines for cluster randomized trials

Estimates of the intervention effect at FU:

•quantitative outcomes: **random effects linear regression models** (‘xtreg’, Stata 11.0) with CMHC as a random effect and the corresponding baseline score and the treatment assignment as fixed effects

•qualitative outcomes (being admitted to psychiatric inpatient unit, etc.): **random effects logistic regression models** (‘xtlogit’, Stata 11.0)

Statistical analyses (2)

- **Robustness** of the results with respect to **violation of Normality** guaranteed by estimating CIs and p-values from 1.000 bootstrap samples, using the non-parametric method (‘bootstrap’, Stata 11.0)

- **Stratification variables** (affiliation to the same Participating Unit, CMHC catchment area size and type of area) accounted for in analysis by including them as covariates in the random effects regression models

GENETIC ENDOPHENOTYPES TREATMENT: UNDERSTANDING EARLY PSYCHOSIS

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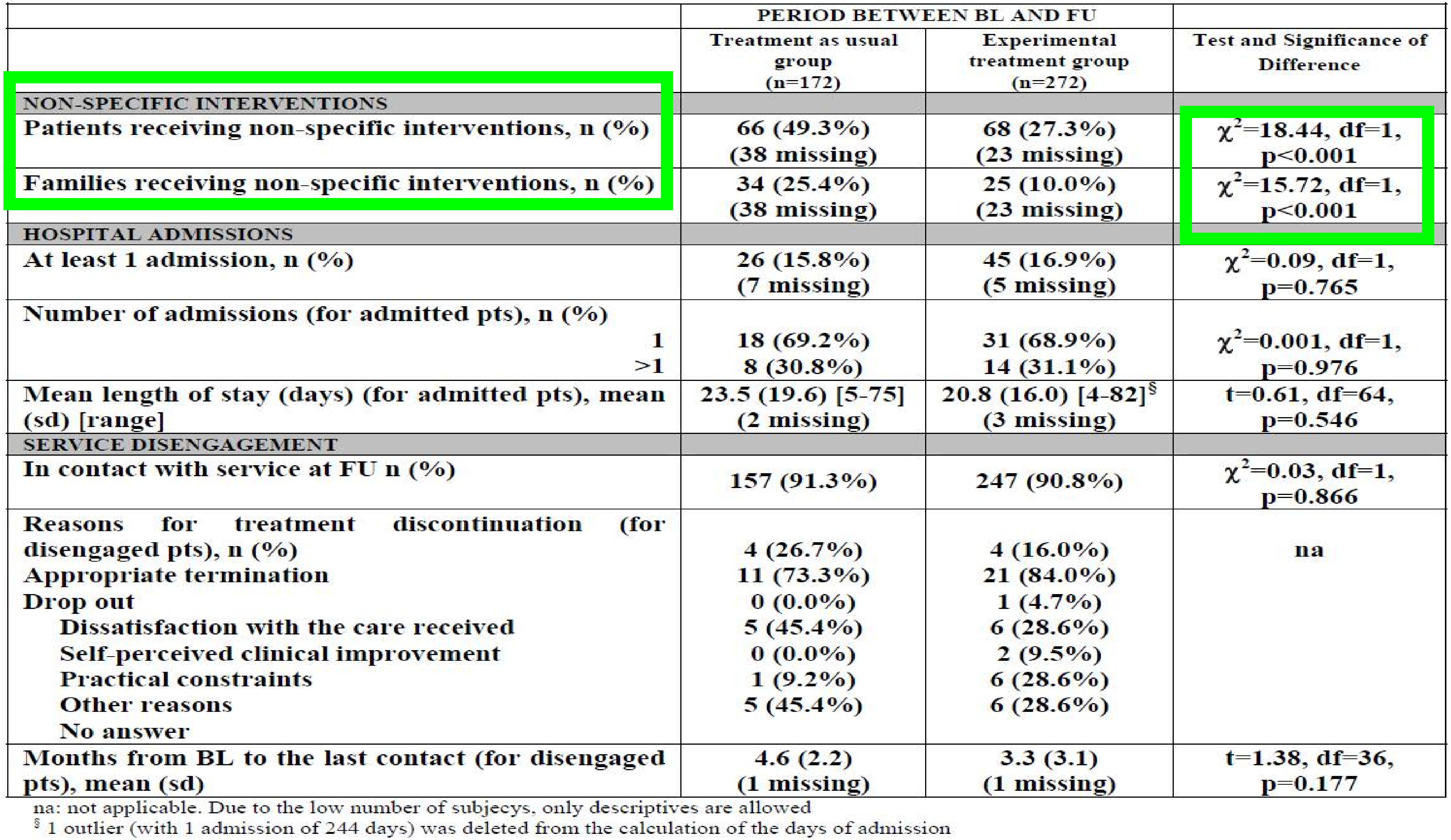
Non-specific interventions, admissions and service disengagement during the period between baseline (after clinical stabilization) and 9-month follow-up.



	PERIOD BETWEEN BL AND FU		
	Treatment as usual group (n=172)	Experimental treatment group (n=272)	Test and Significance of Difference
NON-SPECIFIC INTERVENTIONS			
Patients receiving non-specific interventions, n (%)	66 (49.3%) (38 missing)	68 (27.3%) (23 missing)	χ^2=18.44, df=1, p<0.001
Families receiving non-specific interventions, n (%)	34 (25.4%) (38 missing)	25 (10.0%) (23 missing)	χ^2=15.72, df=1, p<0.001
HOSPITAL ADMISSIONS			
At least 1 admission, n (%)	26 (15.8%) (7 missing)	45 (16.9%) (5 missing)	χ^2=0.09, df=1, p=0.765
Number of admissions (for admitted pts), n (%)			
1	18 (69.2%)	31 (68.9%)	χ^2=0.001, df=1, p=0.976
>1	8 (30.8%)	14 (31.1%)	
Mean length of stay (days) (for admitted pts), mean (sd) [range]	23.5 (19.6) [5-75] (2 missing)	20.8 (16.0) [4-82][§] (3 missing)	t=0.61, df=64, p=0.546
SERVICE DISENGAGEMENT			
In contact with service at FU n (%)	157 (91.3%)	247 (90.8%)	χ^2=0.03, df=1, p=0.866
Reasons for treatment discontinuation (for disengaged pts), n (%)	4 (26.7%)	4 (16.0%)	na
Appropriate termination	11 (73.3%)	21 (84.0%)	
Drop out	0 (0.0%)	1 (4.7%)	
Dissatisfaction with the care received	5 (45.4%)	6 (28.6%)	
Self-perceived clinical improvement	0 (0.0%)	2 (9.5%)	
Practical constraints	1 (9.2%)	6 (28.6%)	
Other reasons	5 (45.4%)	6 (28.6%)	
No answer			
Months from BL to the last contact (for disengaged pts), mean (sd)	4.6 (2.2) (1 missing)	3.3 (3.1) (1 missing)	t=1.38, df=36, p=0.177

na: not applicable. Due to the low number of subjecys, only descriptives are allowed

[§] 1 outlier (with 1 admission of 244 days) was deleted from the calculation of the days of admission

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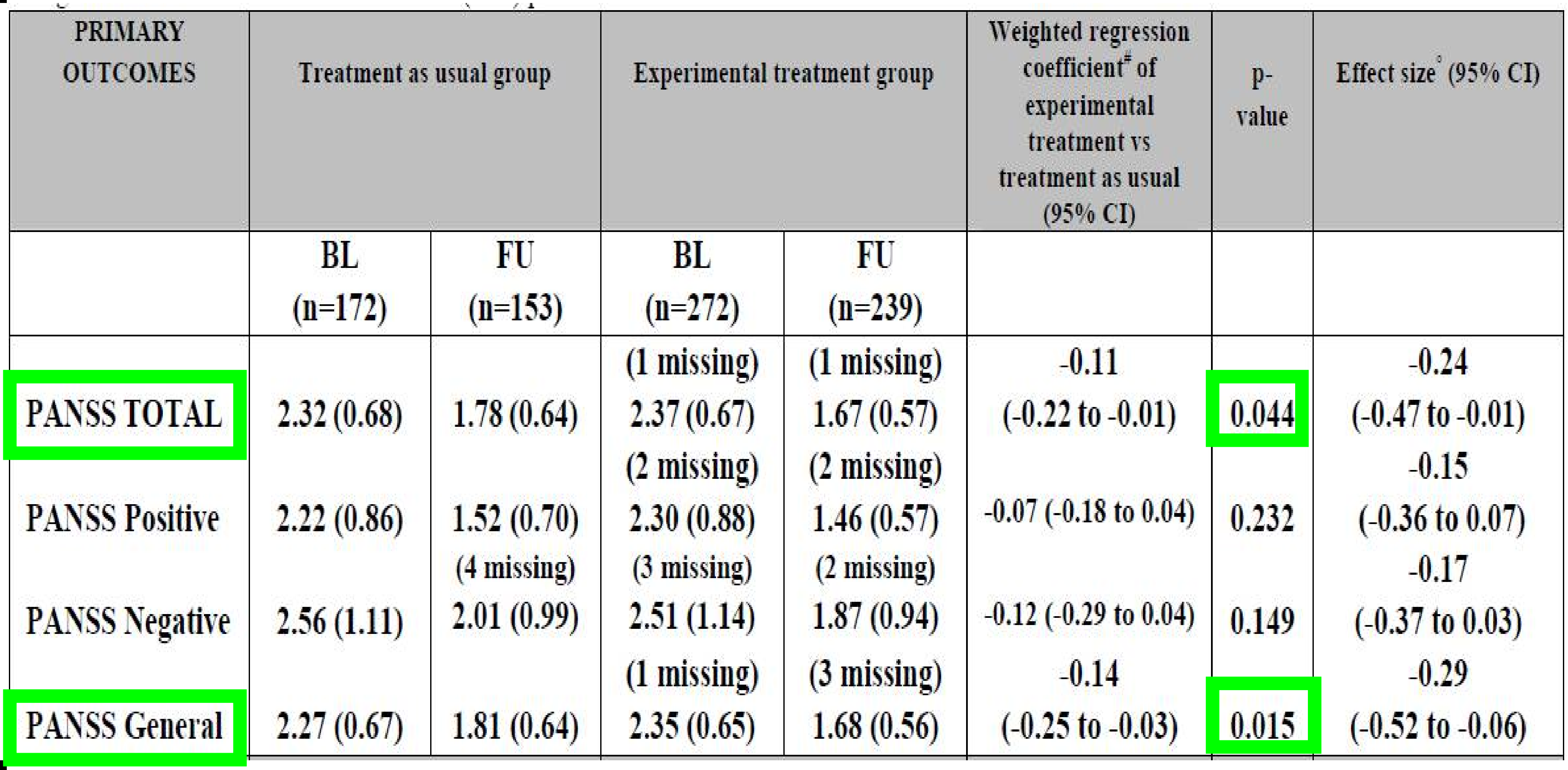
PRIMARY OUTCOMES AT 9-month follow-up



PRIMARY OUTCOMES	Treatment as usual group		Experimental treatment group		Weighted regression coefficient$^{\#}$ of experimental treatment vs treatment as usual (95% CI)	p-value	Effect size$^{\circ}$ (95% CI)
	BL (n=172)	FU (n=153)	BL (n=272)	FU (n=239)			
PANSS TOTAL	2.32 (0.68)	1.78 (0.64)	(1 missing) 2.37 (0.67)	(1 missing) 1.67 (0.57)	-0.11 (-0.22 to -0.01)	0.044	-0.24 (-0.47 to -0.01)
PANSS Positive	2.22 (0.86)	1.52 (0.70)	(2 missing) 2.30 (0.88)	(2 missing) 1.46 (0.57)	-0.07 (-0.18 to 0.04)	0.232	-0.15 (-0.36 to 0.07)
PANSS Negative	2.56 (1.11)	(4 missing) 2.01 (0.99)	(3 missing) 2.51 (1.14)	(2 missing) 1.87 (0.94)	-0.12 (-0.29 to 0.04)	0.149	-0.17 (-0.37 to 0.03)
PANSS General	2.27 (0.67)	1.81 (0.64)	(1 missing) 2.35 (0.65)	(3 missing) 1.68 (0.56)	-0.14 (-0.25 to -0.03)	0.015	-0.29 (-0.52 to -0.06)

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SECONDARY OUTCOMES AT 9-month follow-up

SECONDARY OUTCOMES	Treatment as usual group		Experimental treatment group		Weighted regression coefficient[#] of experimental treatment vs treatment as usual (95% CI)	p-value	Effect size° (95% CI)
	BL (n=172)	FU (n=153)	BL (n=272)	FU (n=239)			
GAF Score	(1 missing) 45.69 (12.96)	(1 missing) 60.11 (16.63)	(1 missing) 44.46 (13.81)	63.15 (16.94)	3.98 (1.15 to 6.82)	0.006	0.35 (0.06 to 0.64)
HAMILTON SCORE	(2 missing) 16.42 (9.90)	(5 missing) 10.62 (10.17)	(1 missing) 17.29 (8.29)	(3 missing) 8.81 (6.58)	-1.86 (-3.40 to -0.31)	0.019	-0.25 (-0.48 to -0.03)
PSYRAT AUDITORY HALLUCINATION SCALE	N=22[a] 2.03 (1.25)	N=22 0.51 (1.08)	N=29[b] 1.67 (1.34)	N=29 0.41 (0.93)	-0.17 (-0.75 to 0.42)^	0.580	-0.23 (-1.13 to 0.66)
PSY AHS distress	2.13 (1.52)	0.76 (1.48)	1.69 (1.57)	0.48 (1.09)	-0.40 (-1.21 to 0.40) ^	0.328	-0.62 (-1.85 to 0.62)
PSY AHS cognitive	2.38 (1.39)	0.57 (1.08)	1.94 (1.48)	0.42 (0.90)	-0.25 (-0.90 to 0.39) ^	0.443	-0.35 (-1.29 to 0.60)
PSY AHS physical	1.87 (1.19)	0.45 (0.97)	1.56 (1.27)	0.40 (0.94)	-0.09 (-0.61 to 0.45) ^	0.772	-0.07 (-0.82 to 0.68)
PSYRAT DELUSION SCALE	N=31[c] 2.78 (1.15)	N=31 1.59 (1.38)	N=50[d] 3.12 (0.73)	N=50 0.76 (1.11)	-0.96 (-1.52 to -0.39) ^	0.001	-0.82 (-1.29 to -0.35)
PSY DS distress	2.62 (1.38)	1.60 (1.53)	3.05 (0.97)	0.75 (1.12)	-0.93 (-1.59 to -0.28) ^	0.005	-0.78 (-1.32 to -0.23)
PSY DS cognitive	2.84 (1.14)	1.65 (1.45)	3.15 (0.77)	0.77 (1.12)	-1.01 (-1.56 to -0.46) ^	0.000	-0.86 (-1.32 to -0.39)

OBIETTIVI DELLO STUDIO

GET UP

1. testare l'ipotesi che il trattamento sperimentale … nella pratica clinica "ultra-reale" dei Servizi di Salute Mentali territoriali …

OUTCOMES PRIMARI

a) **Riduzione dei sintomi positivi e negativi – ALCUNI MIGLIORAMENTI SIGNIFICATIVI, CON UN TREND GENERALE E GLOBALE FAVOREVOLE**

b) **Riduzione dei tassi di ricaduta – RIDUZIONE DEI GIORNI DI RICOVERO (ma solo per gli ospedalizzati)**

c) **Miglioramento nella percezione soggettiva dei sintomi e del loro impatto sulla vita quotidiana – SI' SOPRATTUTTO PER IL DELIRIO**

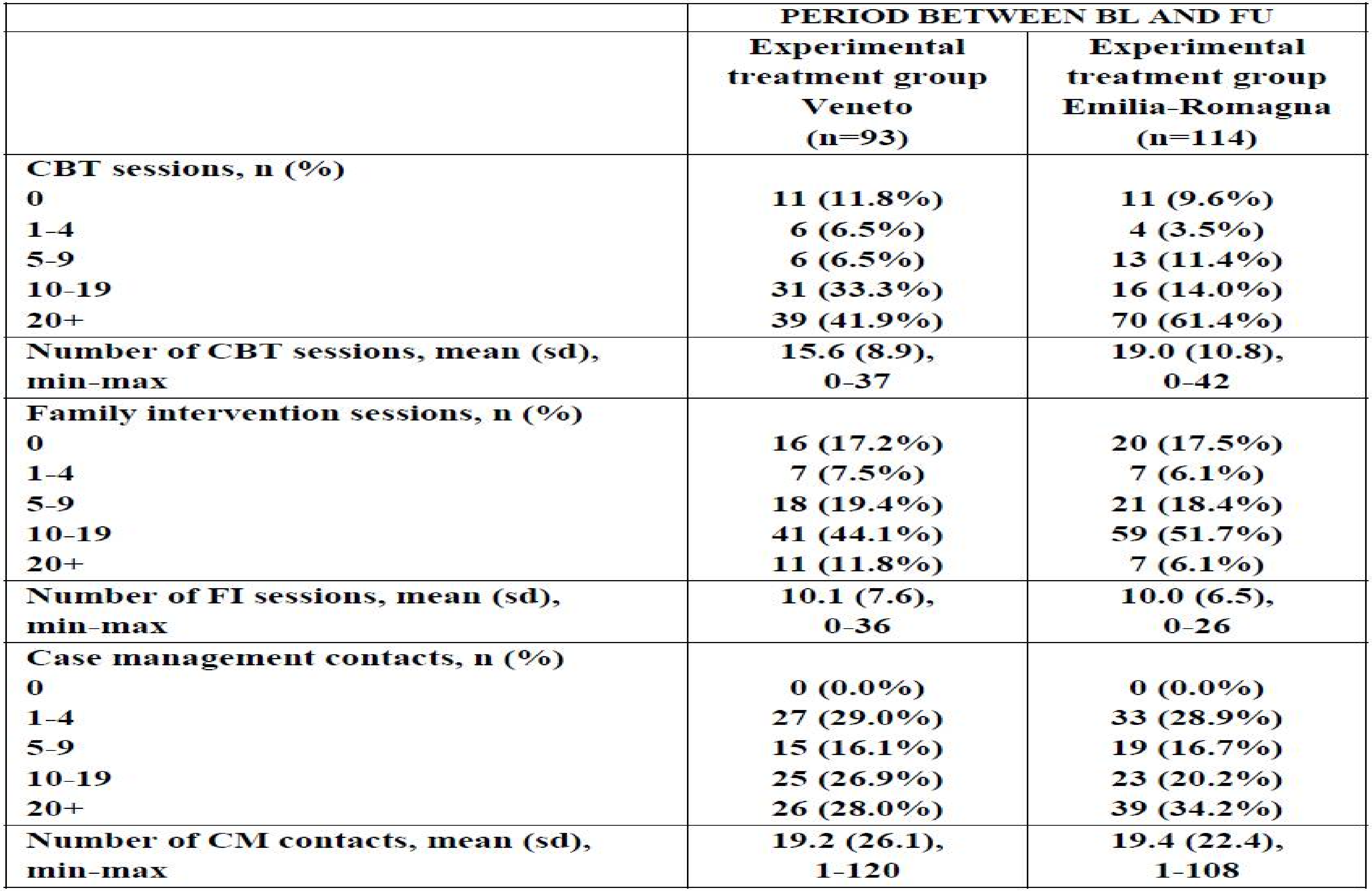
d) **Miglioramento dell'atteggiamento emotivo e del funzionamento sociale – SI'**

e) **Perdita dell'aggancio con il Servizio – NO – L'AGGANCIO E' ALTO PER ENTRAMBI I BRACCI**

PSYCHOSIS: EARLY INTERVENTION AND ASSESSMENT OF NEEDS AND OUTCOME

	Treatment as usual group		Experimental treatment group	
BASELINE (after clinical stabilization)	**Veneto (n=85)**	**Emilia-Romagna (n=71)**	**Veneto (n=93)**	**Emilia Romagna (n=114)**
Gender, n (%)				
Male	45 (52.9%)	42 (59.2%)	57 (61.3%)	66 (57.9%)
Female	40 (47.1%)	29 (40.8%)	36 (38.7%)	48 (42.1%)
Age at first contact with services, mean (sd)	32.5 (9.4)	30.5 (8.9)	30.0 (10.8)	30.1 (9.5)
Educational level, n (%)	(5 missing)	(7 missing)	(1 missing)	(6 missing)
Low (primary-middle school)	35 (43.8%)	25 (39.1%)	39 (42.4%)	31 (28.7%)
High (secondary school, university)	45 (56.2%)	39 (60.9%)	53 (57.6%)	77 (71.3%)
Marital status, n (%)	(3 missing)	(9 missing)	(2 missing)	(4 missing)
Unmarried	60 (73.2%)	45 (72.6%)	67 (73.6%)	78 (70.9%)
Married	16 (19.5%)	10 (16.1%)	19 (20.9%)	27 (24.5%)
Widowed, separated, divorced	6 (7.3%)	7 (11.3%)	5 (5.5%)	5 (4.5%)
Living condition, n (%)	(7 missing)	(7 missing)	(2 missing)	(9 missing)
Alone	2 (2.6%)	6 (9.4%)	7 (7.7%)	2 (1.9%)
With partner and/or children	20 (25.6%)	15 (23.4%)	20 (21.5%)	30 (28.6%)
With other relatives	54 (69.2%)	40 (62.5%)	64 (68.8%)	72 (68.6%)
Other	2 (2.6%)	3 (4.7%)	0 (0.0%)	1 (1.0%)
Working status, n (%)	(2 missing)	(2 missing)	(2 missing)	(6 missing)
Employed	32 (38.6%)	27 (39.1%)	29 (31.9%)	42 (38.9%)
Unemployed	28 (33.7%)	25 (36.2%)	28 (30.8%)	37 (34.3%)
Housewife, student, retired	23 (27.7%)	17 (24.6%)	34 (37.4%)	29 (26.9%)
Nationality, n (%)				
Italy	74 (87.0%)	61 (85.9%)	83 (89.2%)	98 (86.0%)
Other	11 (13.0%)	10 (14.1%)	10 (10.8%)	16 (14.0%)
Diagnosis (SCAN-confirmed at 9 months), n (%)				
Non affective psychosis	66 (77.6%)	55 (77.5%)	78 (83.9%)	88 (77.2%)
Affective psychosis	19 (22.4%)	16 (22.5%)	15 (16.1%)	26 (22.8%)
DUP months, mean (sd), median (range)	(13 missing) 5.2 (8.2), 2.0 (0-49)[a]	(15 missing) 11.5 (27.0), 1.5 (0-140)[c]	(2 missing) 7.0 (19.0), 2.0 (0-123)[b]	(24 missing) 9.2 (19.3), 2.0 (0-131)[d]

	Treatment as usual group		Experimental treatment group	
	Veneto (n=85)	Emilia-Romagna (n=71)	Veneto (n=93)	Emilia Romagna (n=114)
Inviante, n (%)	(1 missing)	(3 missing)		(1 missing)
Familiari	41 (48.8%)	20 (29.4%)	49 (52.7%)	38 (33.6%)
Medico di base	20 (23.8%)	14 (20.6%)	22 (23.7%)	36 (31.9%)
Forze dell'ordine	14 (16.7%)	24 (35.3%)	15 (16.1%)	29 (25.7%)
Amici	1 (1.2%)	1 (1.5%)	1 (1.1%)	0 (0.0%)
Specialista	5 (5.9%)	2 (2.9%)	1 (1.1%)	1 (0.9%)
Auto-invio	0 (0.0%)	1 (1.5%)	2 (2.1%)	1 (0.9%)
Altri reparti o istituzioni	3 (3.6%)	0 (0.0%)	3 (3.2%)	5 (4.4%)
Altro	0 (0.0%)	6 (8.8%)	0 (0.0%)	3 (2.7%)
Modalità di accesso, n (%)		(5 missing)		(1 missing)
PS contatto unico	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)
PS+ricovero	46 (54.1%)	19 (28.8%)	37 (39.8%)	43 (38.1%)
PS+CSM/ambulatori	9 (10.6%)	2 (3.0%)	10 (10.7%)	8 (7.1%)
Accesso diretto al	18 (21.2%)	32 (48.5%)	36 (38.8%)	51 (45.1%)
CSM/ambulatori	8 (9.4%)	9 (13.6%)	5 (5.4%)	8 (7.1%)
Visita domiciliare+ricovero	0 (0.0%)	1 (1.5%)	2 (2.1%)	1 (0.9%)
Altro reparto	4 (4.7%)	2 (3.0%)	3 (3.2%)	2 (1.8%)
Altro				



	PERIOD BETWEEN BL AND FU	
	Experimental treatment group Veneto (n=93)	Experimental treatment group Emilia-Romagna (n=114)
CBT sessions, n (%)		
0	11 (11.8%)	11 (9.6%)
1-4	6 (6.5%)	4 (3.5%)
5-9	6 (6.5%)	13 (11.4%)
10-19	31 (33.3%)	16 (14.0%)
20+	39 (41.9%)	70 (61.4%)
Number of CBT sessions, mean (sd), min-max	15.6 (8.9), 0-37	19.0 (10.8), 0-42
Family intervention sessions, n (%)		
0	16 (17.2%)	20 (17.5%)
1-4	7 (7.5%)	7 (6.1%)
5-9	18 (19.4%)	21 (18.4%)
10-19	41 (44.1%)	59 (51.7%)
20+	11 (11.8%)	7 (6.1%)
Number of FI sessions, mean (sd), min-max	10.1 (7.6), 0-36	10.0 (6.5), 0-26
Case management contacts, n (%)		
0	0 (0.0%)	0 (0.0%)
1-4	27 (29.0%)	33 (28.9%)
5-9	15 (16.1%)	19 (16.7%)
10-19	25 (26.9%)	23 (20.2%)
20+	26 (28.0%)	39 (34.2%)
Number of CM contacts, mean (sd), min-max	19.2 (26.1), 1-120	19.4 (22.4), 1-108

PERIOD BETWEEN BL AND FU	Treatment as usual group		Experimental treatment group	
	Veneto (n=85)	**Emilia-Romagna (n=71)**	**Veneto (n=93)**	**Emilia Romagna (n=114)**
NON-SPECIFIC INTERVENTIONS				
Patients receiving non-specific interventions, n (%)	**31 (42.5%) (12 missing)**	**28 (60.9%) (25 missing)**	**16 (18.4%) (6 missing)**	**36 (35.3%) (12 missing)**
Families receiving non-specific interventions, n (%)	**12 (16.4%) (12 missing)**	**17 (37.0%) (25 missing)**	**2 (2.3%) (6 missing)**	**20 (19.6%) (12 missing)**
HOSPITAL ADMISSIONS				
At least 1 admission, n (%)	**14 (17.3%) (4 missing)**	**12 (17.4%) (2 missing)**	**17 (18.5%) (1 missing)**	**20 (17.7%) (1 missing)**
Number of admissions (for admitted pts), n (%)				
1	**10 (71.4%)**	**8 (66.7%)**	**10 (58.8%)**	**14 (70.0%)**
> 1	**4 (28.6%)**	**4 (33.3%)**	**7 (41.2%)**	**6 (30.0%)**
Mean length of stay (days) (for admitted pts), mean (sd) [range]	**25.1 (19.2) [6-73] (1 missing)**	**21.7 (20.8) [5-75] (1 missing)**	**20.7 (19.0) [5-82]**	**23.8 (14.9) [5-51] (3 missing)**
SERVICE DISENGAGEMENT				
In contact with service at FU n (%)	**74 (87.1%)**	**68 (95.8%)**	**84 (90.3%)**	**103 (90.4%)**
Reasons for treatment discontinuation (for disengaged pts), n (%)				
Appropriate termination	**3 (27.3%)**	**0 (0.0%)**	**1 (11.1%)**	**2 (15.4%)**
Drop out	**8 (72.7%)**	**3 (100.0%)**	**8 (88.9%)**	**9 (84.6%)**
Dissatisfaction with the care received	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)
Self-perceived clinical improvement	3 (37.5%)	2 (66.7%)	2 (25.0%)	3 (33.3%)
Practical constraints	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (11.1%)
Other reasons	1 (12.5%)	0 (0.0%)	1 (12.5%)	4 (44.4%)
No answer	4 (50.0%)	1 (33.3%)	3 (37.5%)	1 (11.1%)
Months from BL to the last contact (for disengaged pts), mean (sd)	**5.1 (2.2)**	**2.5 (0.8) (1 missing)**	**3.9 (2.4)**	**3.2 (3.6) (1 missing)**

PRIMARY OUTCOMES	Treatment as usual group						Experimental treatment group					
	VENETO			EMILIA-ROMAGNA			VENETO			EMILIA-ROMAGNA		
	BL (n=85)	FU (n=73)	Δ (n=73)	BL (n=71)	FU (n=66)	Δ (n=66)	BL (n=93)	FU (n=83)	Δ (n=83)	BL (n=114)	FU (n=98)	Δ (n=98)
PANSS TOTAL	2.25 (0.65)	1.79 (0.64)	-0.48	2.38 (0.61)	1.76 (0.65)	-0.62	2.39 (0.69)	1.71 (0.57)	-0.65	2.42 (0.63)	1.61 (0.58)	-0.81
PANSS Positive	2.16 (0.77)	1.55 (0.67)	-0.65	2.26 (0.92)	1.45 (0.71)	-0.81	2.28 (0.91)	1.53 (0.61)	-0.75	2.39 (0.85)	1.37 (0.45)	-1.02
PANSS Negative	2.51 (1.08)	2.09 (1.02)	-0.41	2.60 (1.07)	1.92 (0.96)	-0.68	2.61 (1.17)	1.92 (0.96)	-0.65	2.49 (1.04)	1.77 (0.92)	-0.72
PANSS General	2.18 (0.61)	1.77 (0.61)	-0.43	2.34 (0.64)	1.85 (0.71)	-0.49	2.34 (0.65)	1.70 (0.52)	-0.61	2.40 (0.64)	1.64 (0.61)	-0.76

SECONDARY OUTCOMES	Treatment as usual group						Experimental treatment group					
	VENETO			EMILIA-ROMAGNA			VENETO			EMILIA-ROMAGNA		
	BL (n=85)	FU (n=73)	Δ (n=73)	BL (n=71)	FU (n=66)	Δ (n=66)	BL (n=93)	FU (n=83)	Δ (n=83)	BL (n=114)	FU (n=98)	Δ (n=98)
GAF SCORE	45.78 (13.62)	59.36 (16.89)	13.71	46.76 (11.95)	63.00 (15.28)	16.24	45.41 (14.60)	63.93 (16.58)	17.92	42.53 (12.35)	64.85 (15.68)	22.32
HAMILTON SCORE	16.80 (11.42)	10.82 (6.97)	-6.61	16.34 (7.95)	11.05 (13.43)	-5.29	17.58 (9.06)	9.50 (6.56)	-7.23	17.84 (8.05)	7.88 (5.95)	-9.96

ENMESH

European Network For Mental Health Service Evaluation

WWW.ENMESH.EU

Malaga, October 1-3 2015

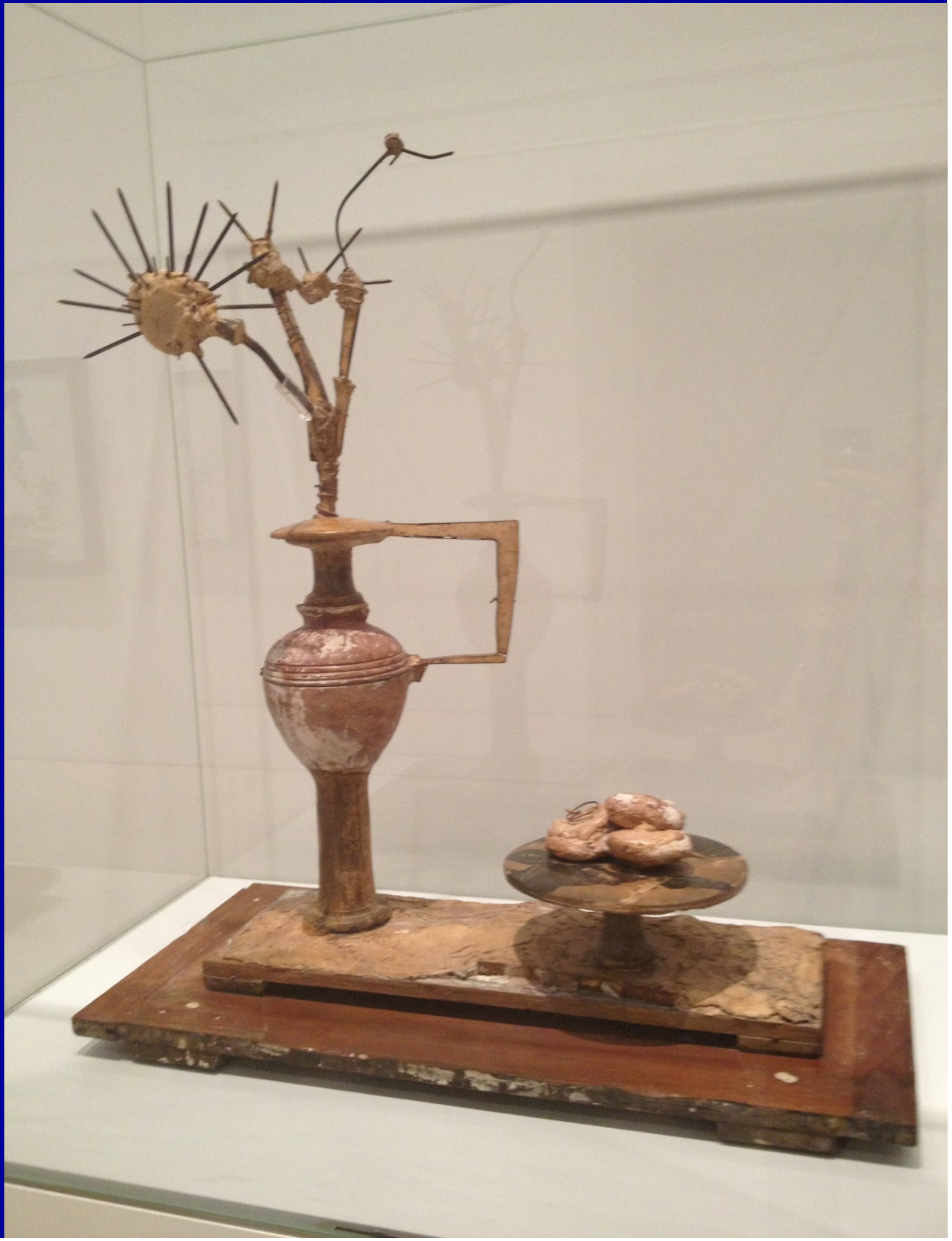
Closing the gap between research and policy in mental health

Pablo Picasso, 1951

Vase with flowers and a plate of cakes

Museo Picasso,
Permanent Collection - Malaga

ENMESH
Eleventh International Conference of the European Network For Mental Health Service Evaluation
Málaga Spain
2015
October 1-3
ENMESH
ENMESH Málaga
2015 October 1-3



GENETIC ENDOPHENOTYPES TREATMENT: UNDERSTANDING EARLY PSYCHOSIS

GET UP

Le 21 tappe principali del Trial di GET UP – PIANO

1. **19 dicembre 2007** - submission Lettera di Intenti al Ministero della Salute -;
2. **5 marzo 2008:** notizia superamento prima fase di selezione e completamento la submission Intero Protocollo sia in italiano che in inglese.
3. **30 settembre 2008** comunicazione ufficile che GET UP ha superato anche la seconda fase di revisione,
4. **10 novembre 2008** Prima riunione Nazionale del Gruppo GET UP
5. **fine Maggio 2009:** completato arruolamento dei CSM;
6. **giugno 2009:** completata identificazione e arruolamento de 24 Psicoterapeuti di supporto ai CSM sperimentali
7. **dicembre 2009:** completato training formativo al centinaio dei professionisti del Gruppo Sperimentale
8. **novembre 2009**: identificazione, arruolamento e training dei 17 valutatori
9. **20 gennaio 2010:** esami finali del Corso sull'Approccio Cognitivo Comportamentale specifico per le psicosi;
10. **1 gennaio - 30 marzo 2010**: Studio Pilota di arruolamento e trattamento pazienti;
11. **1 aprile 2010 - 30 marzo 2011:** arruolamento dei pazienti del trial;
12. **1 aprile 2010 - 31 gennaio 2012:** attuazione interventi sperimentali e di controllo sui pazienti
13. **1 aprile 2010 - 30 aprile 2011**: valutazioni dei pazienti al baseline,
14. **1 gennaio 2011 - 30 marzo 2012:** valutazioni dei pazienti al follow-up
15. **gennaio e febbraio 2012:** completato la submission del protocollo del Trial; subito accettato dalla Rivista Trial,
16. **marzo 2012:** a Verona Congresso internazionale per presentare dati preliminari del trial - 950 partecipanti;
17. **maggio 2012 - maggio 2013:** raccolta dati di processo su interventi sperimentali e di routine e studio di leakage
18. **maggio 2013 - giugno 2014:** verifiche di qualità di tutti i dati ottenuti, con controlli di congruenza caso per caso,
19. **luglio 2014:** completato la predisposizione definitiva del draft del "Main paper" con i risultati del trial, Submission a Schizophrenia Bulletin '8 di agosto 2014.
20. **dicembre 2014** submission a schizophrenia bulletinLa prima resubmission; la seconda resubmission ai primi di marzo 2015. Domenica 5 aprile 2015 richieste modifiche minori e 11 aprile 2015 accettazione finale.
21. **Settembre 2015:** pubblicazione del paper su Schizophrenia Bulletin, n. 4, 2015

THE GET UP MULTI-ELEMENT INTERVENTION PROVED TO BE FEASIBLE AND EFFECTIVE ALSO IN NON-SPECIALISED SERVICES AND IN THE VAST MAJORITY OF INCIDENT CASES OF FEP

but further knowledge on the medium-long term effects of treatments performed in the "real routine world" is needed!

KEY STEPS FOR USING MENTAL HEALTH SERVICE RESEARCH TO IDENTIFYING THE MOST APPROPRIATE STRATEGIES TO TRANSLATING KNOWLEDGE INTO CLINICAL PRACTICE

- **And finally….monitoring the implementation when the research is concluded**

AFTER GET UP

(JUNE 1 2012 - …….

www.psychiatry.univr.it/page_getup

- Papers
- Congress Presentations
- Clinical initiatives derived by GET UP