

# Valutazione di processo, valutazione d'esito

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# Cosa sono gli indicatori

- Gli **indicatori** sono strumenti in grado di mostrare (misurare) l'andamento di un fenomeno che si ritiene rappresentativo per l'analisi e sono utilizzati per monitorare o valutare il grado di successo, oppure l'adeguatezza delle attività implementate.

# Requisiti degli indicatori/1

- **validità** - devono misurare effettivamente ciò che si intende misurare
- **controllabilità** - devono riguardare aspetti che sono sotto l'effettivo controllo di chi governa la politica in questione
- **comprensibilità** - devono essere comprensibili a coloro che devono utilizzarli
- **unicità** - ogni indicatore deve rilevare un aspetto che nessun altro indicatore rileva

## Requisiti degli indicatori/2

- **tempestività** - le informazioni necessarie devono essere disponibili in tempo utile
- **comparabilità** - deve essere possibile una comparazione nel tempo (over time) e/o nello spazio (cross section)
- **economicità** - i benefici derivanti dall'indicatore devono essere superiori al costo della rilevazione

## INDICATORI DI PROCESSO

- Misurano l'appropriatezza del processo assistenziale in relazione a standard di riferimento: linee guida, percorsi assistenziali.
- Non forniscono informazioni sui risultati dell'assistenza (esiti),  
Ma sono potenzialmente in grado di prevedere un miglioramento degli esiti assistenziali.
- Tale predittività è strettamente correlata alla forza della raccomandazione clinica su cui viene costruito l'indicatore: tanto più robuste sono le evidenze che documentano l'efficacia di un intervento sanitario, più forte sarà la raccomandazione clinica e più robusto il corrispondente indicatore di processo.

# LA QUALITA' DELLA CURA NEI DISTURBI MENTALI GRAVI IN LOMBARDIA

a cura di  
Antonio LORA e Emiliano MONZANI



RegioneLombardia

## - **INDICATORI CLINICI NEL DISTURBO SCHIZOFRENICO:**

Nel dominio dell'accessibilità dei servizi:

1. L'età di presa in carico dei pazienti con disturbo all'esordio.
2. I tempi di attesa per la prima visita nei CPS.
3. Il 'treatment gap' nella schizofrenia.

Nel dominio della **continuità assistenziale:**

4. Continuità della cura.
5. Continuità della cura nei pazienti con disturbo all'esordio
6. Pazienti che ricevono una visita psichiatrica in CPS entro 14 giorni dalla dimissione in SPDC.
7. Continuità del trattamento territoriale dopo la dimissione dal SPDC
8. Attività domiciliare dopo la dimissione dal SPDC.

Nel dominio dell'**appropriatezza:**

9. Conclusione non concordata del trattamento.
10. Ricoveri in regime di TSO.
11. Riammissioni in SPDC entro 7 e 28 giorni.
12. Degenze ospedaliere superiori ai 30 giorni.
13. Intensità dell'assistenza territoriale rivolta ai familiari.
14. Intensità dell'assistenza territoriale rivolta al paziente.

## INDICATORI CLINICI NEL DISTURBO SCHIZOFRENICO (2)

15. Intensità dell'assistenza territoriale rivolta ai pazienti con disturbo a esordio.
16. Intensità dell'assistenza territoriale per familiari pazienti con dist. esordio
17. Piano di trattamento individuale.
18. Case manager per i disturbi mentali gravi.
19. Attività multiprofessionale erogata nei CPS.
20. Attività multiprofessionale erogata nei CPS per i pazienti con dist. esordio.
21. Trattamenti psicoeducativi.
22. Trattamenti psicoeducativi pazienti con disturbo all'esordio.
23. Pazienti in trattamento psicoterapico.
24. Pazienti con disturbo all'esordio in trattamento psicoterapico.
25. Attività domiciliare rivolta a pazienti con disturbo all'esordio.
26. Attività di risocializzazione, espressive, motorie e pratico manuali.
27. Attività promosse dal DSM in campo lavorativo.
28. Supporto all'abitare.

Nel dominio dell'appropriatezza dei **trattamenti psicofarmacologici**:

29. Dosaggio dei farmaci antipsicotici durante il ricovero in SPDC.
30. Trattamento continuativo con farmaci antipsicotici nel periodo successivo all'episodio acuto.
31. Terapia di mantenimento con farmaci antipsicotici.
32. Prescrizione di un unico farmaco antipsicotico



## INDICATORI CLINICI NEL DISTURBO SCHIZOFRENICO (3)

33. Frequenza e dosaggio dei farmaci antipsicotici long-acting.
34. Monitoraggio della terapia nei pazienti trattati con farmaci antipsicotici long-acting.
35. Clozapina nella schizofrenia resistente al trattamento.
36. Visita psichiatrica in CPS entro 90 giorni dall'interruzione di un farmaco antipsicotico.
37. Controllo della glicemia e dell'iperlipidemia in pazienti all'inizio del trattamento con farmaci antipsicotici di seconda generazione.
38. Monitoraggio periodico della glicemia e dell'iperlipidemia in pazienti in trattamento continuativo con farmaci antipsicotici di seconda generazione.

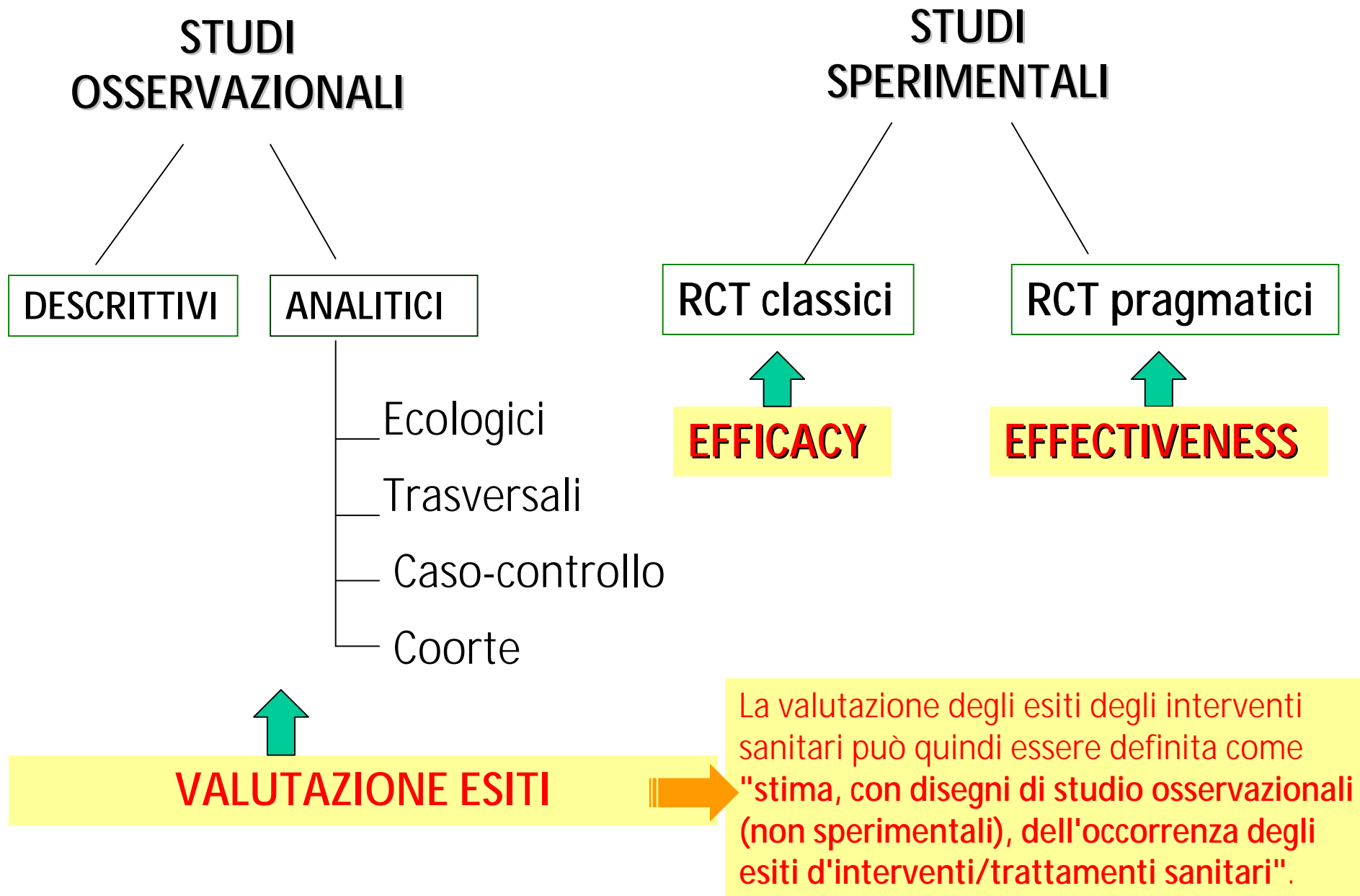
Nel dominio della **sicurezza e degli eventi sentinella:**

39. Mortalità nei disturbi mentali gravi.
40. Contenzione fisica in SPDC.
41. Pazienti in trattamento presso il DSM che hanno commesso suicidio.

## INDICATORI DI ESITO

- Documentano una modifica di esiti assistenziali: clinici (mortalità, morbilità), economici (costi diretti e indiretti) e umanistici (qualità di vita, soddisfazione dell'utente).
- Considerato che gli esiti clinici, oltre che dalla qualità dell'assistenza, sono influenzati da numerose determinanti (patrimonio genetico, fattori ambientali, condizioni socio-economiche), il principale elemento che condiziona la loro robustezza è il tempo trascorso dall'erogazione del processo. Ad esempio, nell'assistenza ospedaliera, gli indicatori di esito sono molto robusti se misurati entro la dimissione, moderatamente robusti sino a 4 settimane: quindi si "indeboliscono" progressivamente in misura variabile, anche in relazione al numero di potenziali determinanti.

# Valutazione d'efficacia, di efficacia nella pratica, di esito



## **La maggior parte dei RCT sono studi sperimentali di efficacia:**

- I ricercatori arruolano pazienti accuratamente selezionati (+++omogenei)
- definiscono dettagliatamente il regime terapeutico (intervento specifico)
- il setting è controllatissimo e ideale (artificiale)
- esiti di breve termine

**Il trattamento di questi pazienti non riflette la complessità e la variabilità del mondo reale. Per questi motivi e per i dubbi sulla applicabilità dei risultati dei RCT nella pratica corrente (pazienti multiproblematici ed eterogenei), i trials pragmatici sono visti con molto favore.**

## **I trials pragmatici confrontano 2 o più interventi sanitari e valutano l'effectiveness nella real life:**

- i criteri di ammissione e di elegibilità sono molto ampi, i pazienti possono essere reclutati da differenti setting di cura
- il management è simile a quello della 'usual care'
- la durata del trattamento e del follow-up deve essere sufficientemente protratta per valutare rischi e benefici.

## Limiti dei trials pragmatici :

- la non aderenza al trattamento – o il crossover tra terapie - rappresenta un problema per interpretare correttamente i risultati
- la perdita di pazienti arruolati durante il follow-up può annullare il significato dello studio
- per rilevare piccole differenze nel trattamento di 2 popolazioni tra loro disomogenee occorrono ampi campioni di soggetti arruolati
- una terapia non impostata in cieco può esporre a bias potenziali, specialmente se
- gli outcomes non sono rilevati mediante misure oggettive.



La 'validità interna' viene ad essere sacrificata per poter generalizzare i risultati...  
**la sfida è raggiungere un equilibrio tra correttezza dei risultati e applicabilità nella pratica clinica.**

Comunque **quando mancano RCT** su un certo argomento, ci si orienta di necessità **alla ricerca osservazionale** ed alle opinioni degli esperti per poter elaborare raccomandazioni utili per la pratica clinica.

In questo senso **i trials pragmatici**, con i loro vantaggi ed i loro limiti, rappresentano uno strumento importante per migliorare la gestione clinica e l'assistenza al malato.

# STUDI DI ESITO:

I principali obiettivi:

**valutazione osservazionale dell'efficacia "teorica" (efficacy) di interventi sanitari per i quali non sono possibili/disponibili valutazioni sperimentali (RCT)**

**valutazione osservazionale dell'efficacia "operativa" (effectiveness) di interventi sanitari per i quali sono disponibili valutazioni sperimentali di efficacia**

**valutazione comparativa tra soggetti erogatori e/o tra professionisti e tra ASL**

applicazioni possibili in termini di accreditamento, remunerazione, informazione dei cittadini/utenti e delle loro associazioni per la scelta dei servizi

**valutazione comparativa tra gruppi di popolazione (per livello socioeconomico, residenza, etc)** applicazioni in programmi di valutazione e promozione dell'equità

**individuazione dei fattori dei processi assistenziali che determinano esiti**

stimare quali volumi minimi di attività sono associati ad esiti migliori delle cure e usare i volumi minimi come criterio di accreditamento

**auditing interno ed esterno**

# I limiti degli studi osservazionali di esito

**BIAS!**  
(pregiudizi)

- selezione del campione
- performance (mancanza di cecità)
- recall
- disomogeneità criteri diagnostici

... per questi motivi gli studi osservazionali vanno interpretati con cautela... mostrano le associazioni tra fenomeni, non le relazioni causali.

# ROA - La valutazione degli esiti nella routine clinica (1)

## Criticità della misurazione nei servizi di salute mentale:

1. L'effetto del trattamento può rallentare/evitare il peggioramento, così che il punteggio può diminuire o rimanere uguale nonostante l'ottima qualità delle cure.

2. Le evidenze in UK indicano che le variabili cliniche e sociali non predicano più del 30% della varianza della Qualità della vita (UK700 Group, 1999).

3. I differenti tipi di outcome non sono sincronizzati, modificandosi in momenti diversi durante il trattamento.

4. Può non esserci accordo tra stakeholders su ciò che è un cambiamento positivo.

5. Si possono distinguere tre livelli di servizio salute mentale:

- di trattamento (specifici interventi);

- di programma (combinazione di differenti trattamenti);

- di sistema (tutti i programmi per un definito gruppo di pazienti in una data area).

I dati di outcome necessari per valutare ogni livello possono essere molto differenti.



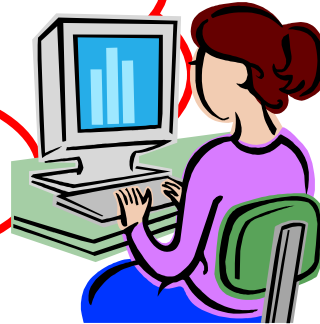
## ROA - La valutazione degli esiti nella routine clinica (2)

**A parte questi limiti, è necessario:**

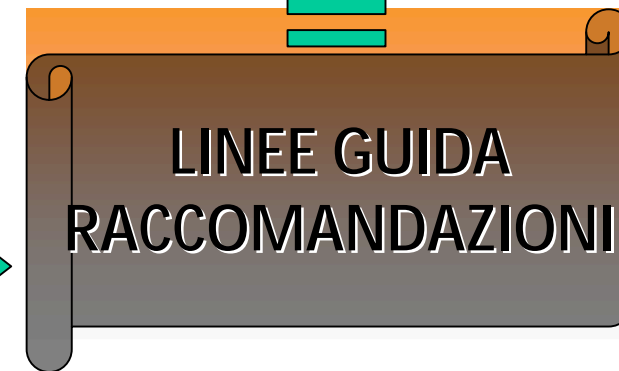
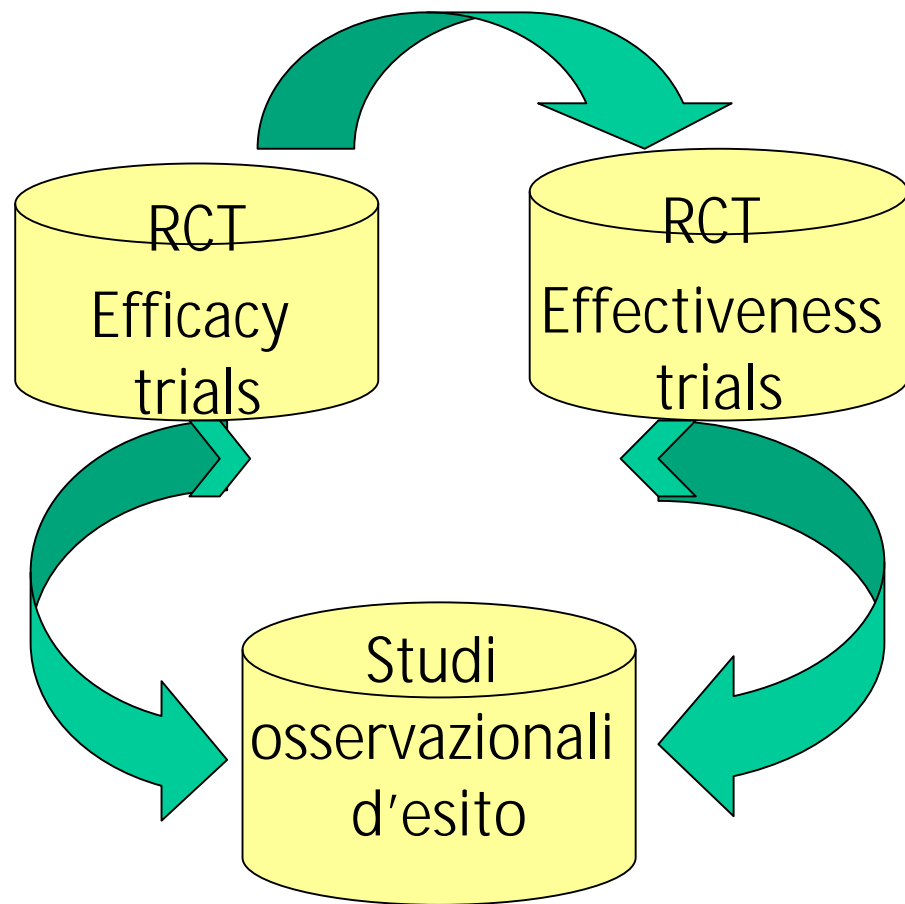
- 1. Usare misure standardizzate e validate** (training valutatori)
- 2. Organizzare una raccolta dati semplice ed economica**
- 3. Fornire un feedback rapido, comprensibile e significativo**
- 4. Prevedere un'indagine longitudinale.**

(M. Slade, 2002)

...che ruolo hanno i sistemi informativi per fare ROA in salute mentale?

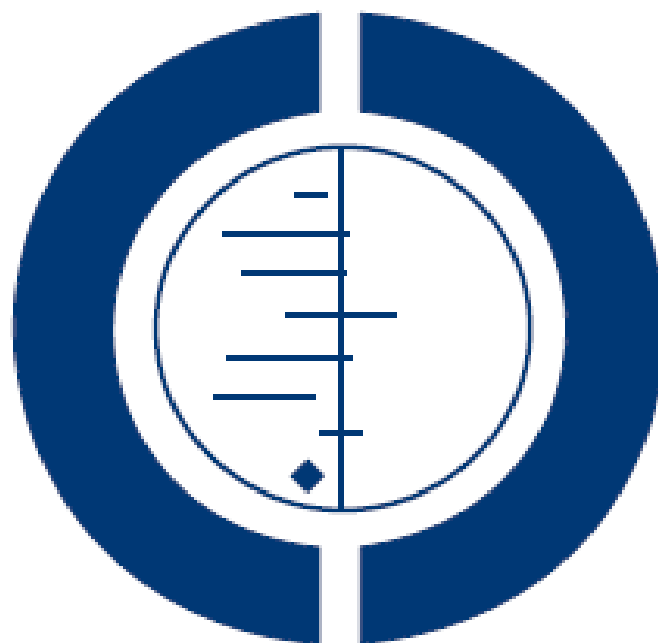


- forniscono la base indispensabile di dati sui pazienti e i trattamenti
- forniscono indicatori di esito basati sull'utilizzo dei servizi
- Linkando flussi dati di tipo diverso si possono espandere le informazioni e ottenere database clinicamente orientati



# Implementation of treatment guidelines for specialist mental health care (Review)

Barbui C, Girlanda F, Ay E, Cipriani A, Becker T, Koesters M



**THE COCHRANE  
COLLABORATION®**

2014, Issue 1

## PLAIN LANGUAGE SUMMARY

### Implementation of treatment guidelines in mental health care

During the past few decades, a wide range of therapies and interventions for mental health have been developed that have been supported by research and randomised evidence. This includes research evidence on the effectiveness of pharmacological treatments (such as antipsychotic drugs) and psychological therapies (such as cognitive behavioural therapy, family therapy and psychoeducation). However, research evidence is not easily translated into practice and the everyday working of healthcare services. A huge gap exists between the production of research evidence (what is known) and its uptake in healthcare settings (what is done). Better uptake of research evidence can be achieved by increasing awareness that such evidence exists.

One method of encouraging better uptake is the use of treatment guidelines based on assessments of research evidence. Treatment guidelines are now commonly employed in healthcare settings, including those providing treatment for schizophrenia. It remains unclear, however, whether treatment guidelines have any positive impact on the performance of mental health services or whether they improve outcomes for patients (such as better quality of life, improved mental state, employment and fewer admissions to hospital).

This review is based on a search carried out in March 2012 and includes five studies. The review examines the effectiveness of guideline implementation strategies in improving healthcare services and outcomes for people with mental illness. However, with such a small number of studies, and with all main results graded by review authors as providing very low quality evidence, it is not possible to arrive at concrete and definite conclusions. Although single studies provided initial evidence that implementation of treatment guidelines may achieve small changes in mental health practice, a gap in knowledge still exists about how this might improve patient outcomes and health services. This leaves scant information for people with mental health problems, health professionals and policy makers. More large-scale, well-designed and well-conducted studies are necessary to fill this gap in knowledge.

Qualche studio  
sperimentale di  
efficacy e effectiveness  
in salute mentale...



# **Cognitive behavioural therapy (brief versus standard duration) for schizophrenia (Review)**

Naeem F, Farooq S, Kingdon D



**THE COCHRANE  
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## Plain language summary

# Brief versus standard cognitive behavioural therapy for schizophrenia

People with schizophrenia often hear voices or see things (hallucinations) and have strange beliefs (delusions). Characteristics of the illness are disordered thoughts, feelings, beliefs and perceptions. People with schizophrenia may also find it difficult to find employment, make friends and socialise with other people.

Cognitive behavioural therapy (CBT) works by focusing on people's thoughts, emotions and behaviours and by challenging strange or dysfunctional thoughts. CBT was originally developed to help people with psychological disorders such as Obsessive Compulsive Disorder. More recently it has been used to help people with psychosis (CBTp). Working with a therapist, people establish links between their thoughts, feelings or actions. They are encouraged to re-evaluate their beliefs, perceptions and reasoning as well as to monitor their own thoughts, feelings, behaviours and symptoms. CBTp is suggested to provide alternative ways of coping with strange thoughts and the symptoms of schizophrenia, which should reduce distress and improve people's functioning.

Standard CBTp tends to involve around 16 sessions (12 to 20 sessions) over 4 to 6 months, while brief CBTp involves around 6 to 10 sessions, in less than 4 months.

The aim of this review was to compare two types of CBTp, brief CBTp and standard CBTp for people with schizophrenia. A search was run for relevant randomised studies in 2013. Only seven potentially-relevant studies were found. However, although all of them randomised people with schizophrenia, none of these studies compared brief CBTp with standard CBTp. In the main they compared brief CBTp with standard care or other therapies. There is, therefore, no information or literature available to compare brief with standard CBTp for schizophrenia and psychosis.

There is a need for large scale research and trials that compare brief CBTp with standard CBTp. This research needs to evaluate costs, have clear definitions of standard and brief CBTp and focus on the time period or number of sessions, i.e. the 'effective dose' of CBTp.

**This plain language summary has been written by a consumer, Ben Gray, Service User Expert, Rethink Mental Illness.**



# The National Institute of Mental Health Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) Project: Schizophrenia Trial Design and Protocol Development

*Schizophrenia Bulletin*, 29(1):15–31, 2003.

by T. Scott Stroup, Joseph P. McEvoy, Marvin S. Swartz, Matthew J. Byerly,  
Ira D. Glick, Jose M. Canive, Mark F. McGee, George M. Simpson,  
Michael C. Stevens, and Jeffrey A. Lieberman\*

The National Institute of Mental Health initiated the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) program to evaluate the effectiveness of antipsychotic drugs in typical settings and populations so that the study results will be maximally useful in routine clinical situations. The CATIE schizophrenia trial blends features of efficacy studies and large, simple trials to create a pragmatic trial that will provide extensive information about antipsychotic drug effectiveness over at least 18 months.

The protocol allows for subjects who receive a study drug that is not effective to receive subsequent treatments within the context of the study. Medication dosages are adjusted within a defined range according to clinical judgment. The primary outcome is all-cause treatment discontinuation because it represents an important clinical endpoint that reflects both clinician and patient judgments about efficacy and tolerability. Secondary outcomes include symptoms, side effects, neurocognitive functioning, and cost-effectiveness.

Approximately 50 clinical sites across the United States are seeking to enroll a total of 1,500 persons with schizophrenia. Phase 1 is a double-blinded randomized clinical trial comparing treatment with the second generation antipsychotics olanzapine, quetiapine, risperidone, and ziprasidone to perphenazine, a midpotency first generation antipsychotic. If the initially assigned medication is not effective, subjects may choose one of the following phase 2 trials: (1) randomization to open-label clozapine or a double-blinded second generation drug that was available but not assigned in phase 1; or (2) double-blinded randomization to ziprasidone or another second generation drug that was available but not assigned in phase 1. If the phase 2 study drug is discontinued, subjects may enter

phase 3, in which clinicians help subjects select an open-label treatment based on individuals' experiences in phases 1 and 2.

Keywords: Randomized clinical trial, schizophrenia, antipsychotic drugs, effectiveness, longitudinal.

STUDY PROTOCOL

Open Access

# Depression in Primary care: Interpersonal Counseling vs Selective serotonin reuptake inhibitors. The DEPICS Study. A multicenter randomized controlled trial. Rationale and design

Marco Menchetti<sup>1\*</sup>, Blancamaria Bortolotti<sup>1</sup>, Paola Rucci<sup>2,3</sup>, Paolo Scocco<sup>4,5</sup>, Annarosa Bombi<sup>1</sup>, Domenico Berardi<sup>1</sup>, DEPICS Study Group

## Abstract

**Background:** Depression is a frequently observed and disabling condition in primary care, mainly treated by Primary Care Physicians with antidepressant drugs. Psychological interventions are recommended as first-line treatment by the most authoritative international guidelines but few evidences are available on their efficacy and effectiveness for mild depression.

**Methods/Design:** This multi-center randomized controlled trial was conducted in 9 Italian centres with the aim to compare the efficacy of Inter-Personal Counseling, a brief structured psychological intervention, to that of Selective Serotonin Reuptake Inhibitors. Patients with depressive symptoms referred by Primary Care Physicians to psychiatric consultation-liaison services were eligible for the study if they met the DSM-IV criteria for major depression, had a score  $\geq 13$  on the 21-item Hamilton Depression Rating Scale, and were at their first or second depressive episode. The primary outcome was remission of depressive symptoms at 2-months, defined as a HDRS score  $\leq 7$ . Secondary outcome measures were improvement in global functioning and recurrence of depressive symptoms at 12-months. Patients who did not respond to Inter-Personal Counseling or Selective Serotonin Reuptake Inhibitors at 2-months received augmentation with the other treatment.

**Discussion:** This trial addresses some of the shortcomings of existing trials targeting major depression in primary care by evaluating the comparative efficacy of a brief psychological intervention that could be easily disseminated, by including a sample of patients with mild/moderate depression and by using different outcome measures.

**Trial registration:** Australian New Zealand Clinical Trials Registry ACTRN12608000479803

# Moderators of remission with interpersonal counselling or drug treatment in primary care patients with depression: randomised controlled trial

Marco Menchetti, Paola Rucci, Biancamaria Bortolotti, Annarosa Bombi, Paolo Scocco, Helena Chmura Kraemer, Domenico Berardi and the DEPICS group

## Background

Despite depressive disorders being very common there has been little research to guide primary care physicians on the choice of treatment for patients with mild to moderate depression.

## Aims

To evaluate the efficacy of interpersonal counselling compared with selective serotonin reuptake inhibitors (SSRIs), in primary care attenders with major depression and to identify moderators of treatment outcome.

## Method

A randomised controlled trial in nine centres (DEPICS, Australian New Zealand Clinical Trials Registry number ACTRN12608000479303). The primary outcome was remission of the depressive episode (defined as a Hamilton Rating Scale for Depression score  $\leq 7$  at 2 months). Daily functioning was assessed using the Work and Social Adjustment Scale. Logistic regression models were used to identify moderators of treatment outcome.

## Results

The percentage of patients who achieved remission at 2 months was significantly higher in the interpersonal counselling group compared with the SSRI group (58.7% v. 45.1%,  $P=0.021$ ). Five moderators of treatment outcome were found: depression severity, functional impairment, anxiety comorbidity, previous depressive episodes and smoking habit.

## Conclusions

We identified some patient characteristics predicting a differential outcome with pharmacological and psychological interventions. Should our results be confirmed in future studies, these characteristics will help clinicians to define criteria for first-line treatment of depression targeted to patients' characteristics.

## Declaration of interest

None.

# Individual Placement and Support (IPS)

## Riabilitazione

- *'Train and place'* – programmazione
  - Superamento dei deficit
  - Training skills
  - Occupazioni e formazione in ambito protetto
- *'Place and train'* – ricerca del lavoro nel libero mercato
  - Trovare un lavoro e poi sostenere il paziente, formarlo sul campo
  - *'Supported employment'*
  - *'Individual Placement and Support'* IPS

## Efficacia dei programmi di riabilitazione e inserimento lavorativo

Review di Lehman (1995):

Nessun effetto sull'occupazione a lungo termine sino agli anni 1970

Nessun miglioramento nei lavori *competitivi* sino all'introduzione del supported employment negli anni 1990

Dopo il 1990:

Lavoro ordinario:

Meta-analisi di 11 studi (Crowther 2001)

Supported employment : 34%

Riab. lavorativa standard : 12%


Analisi di 13 studi (Bond 2004)

Supported employment : 40-60%

Riab. lavorativa standard : 20%





## IPS – Individual Placement and Support

- Novità nel campo della riabilitazione lavorativa
  - Primo format di intervento sul lavoro codificato come trattamento psicosociale
  - Primo format manualizzato
  - Primo format sottoposto a verifica empirica mediante studi randomizzati
- 



## Principi dell'IPS (Angelozzi PdC 07)

- Processo guidato dalle scelte della persona
  - Supporto integrato nel trattamento
  - Obiettivo occupazione competitiva
  - Rapida ricerca
  - Basata sulle preferenze della persona
  - Supporto a tempo indeterminato
- 
- 

# Il Progetto EQOLISE

Enhancing  
Quality  
Of  
Life  
Implementing  
Supported  
Employment









**MODELLI A CONFRONTO**






# EQOLISE

 6 centri:

-  Londra (UK)
  -  Rimini (I)
  -  Ulm (D)
  -  Zurich (CH)
  -  Groeningen (NL)
  -  Sofia (BUL)
- 



# EQOLISE

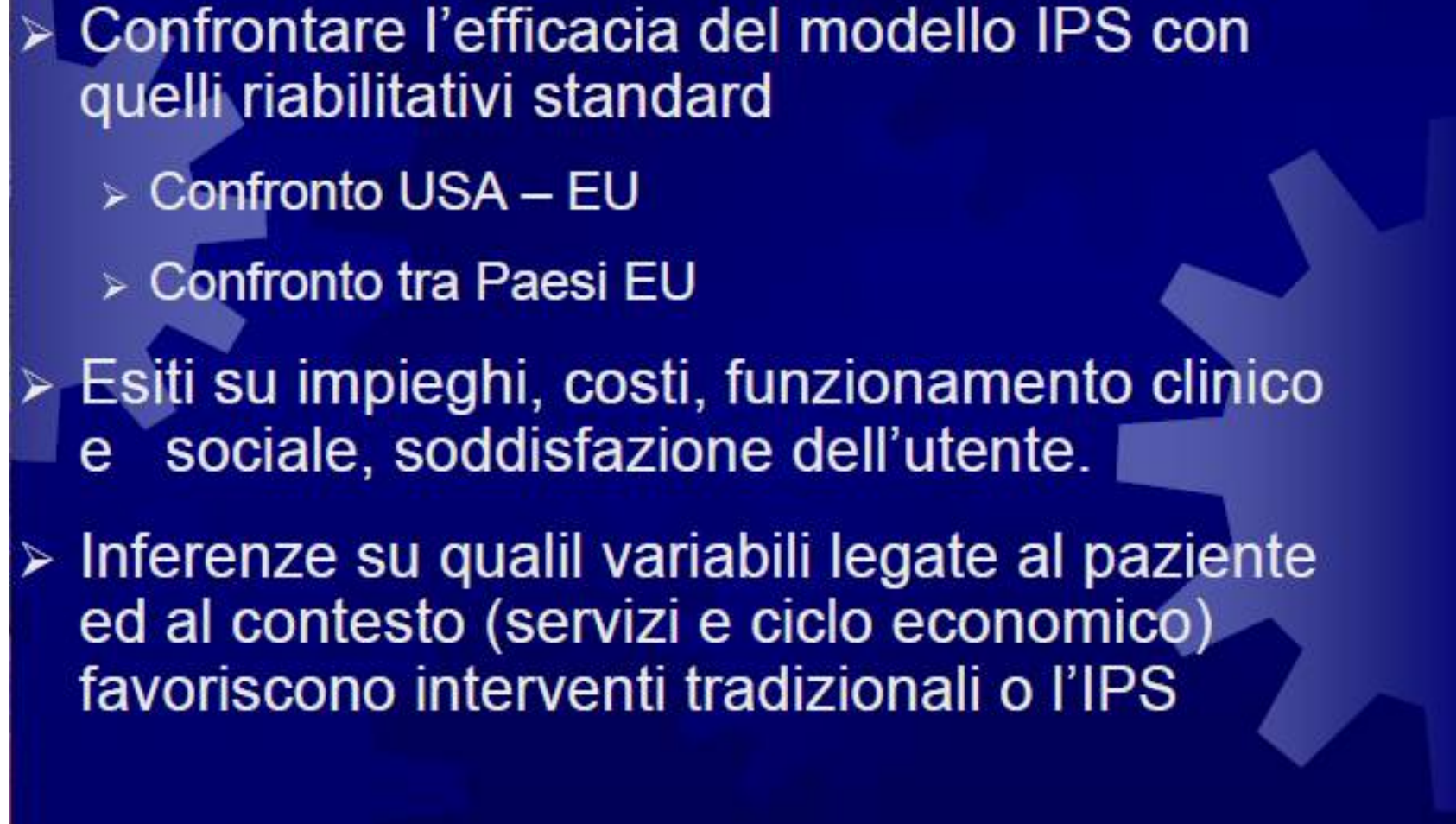
- 50 pazienti per ogni centro
  - Diagnosi di schizofrenia o disturbo bipolare
  - Età 19-45 anni
  - Non inseriti nel mercato del lavoro negli ultimi due anni
  - Desiderano lavorare
- 

# EQOLISE






## Scopo del progetto

- Confrontare l'efficacia del modello IPS con quelli riabilitativi standard
    - Confronto USA – EU
    - Confronto tra Paesi EU
  - Esiti su impieghi, costi, funzionamento clinico e sociale, soddisfazione dell'utente.
  - Inferenze su quali variabili legate al paziente ed al contesto (servizi e ciclo economico) favoriscono interventi tradizionali o l'IPS
- 




## Valutazione degli esiti

- ☀️ Persone entrate nel mondo del lavoro regolare
  - ☀️ Giornate di lavoro svolte nel mondo del lavoro regolare
  - ☀️ Psicopatologia
  - ☀️ Soddisfazione e QOL
  - ☀️ Disabilità
  - ☀️ Uso dei servizi di ricovero
- 



# Strumenti

- OPCRIT
- PANSS
- CSSRI-EU
- GROENINGEN SOCIAL DISABILITY SCH.
- LANCASHIRE QUALITY OF LIFE PROFILE

- CAN
  - HADS
  - HELPING ALLIANCE SCALE
  - JOB PREFERENCES INTERVIEW
  - INDIANA JOB SATISFACTION SCALE
- 

## The effectiveness of supported employment for people with severe mental illness: a randomised controlled trial

Tom Burns, Jocelyn Catty, Thomas Becker, Robert E Drake, Angelo Fioritti, Martin Knapp, Christoph Lauber, Wulf Rössler, Toma Tomov, Joeske van Busschbach, Sarah White, Durk Wiersma, for the EQOLISE Group\*

### Summary

**Background** The value of the individual placement and support (IPS) programme in helping people with severe mental illness gain open employment is unknown in Europe. Our aim was to assess the effectiveness of IPS, and to examine whether its effect is modified by local labour markets and welfare systems.

**Methods** 312 patients with severe mental illness were randomly assigned in six European centres to receive IPS (n=156) or vocational services (n=156). Patients were followed up for 18 months. The primary outcome was the difference between the proportions of people entering competitive employment in the two groups. The heterogeneity of IP effectiveness was explored with prospective meta-analyses to establish the effect of local welfare systems and labour markets. Analysis was by intention to treat. This study is registered with ClinicalTrials.gov, with the number NCT00461318.

**Findings** IPS was more effective than vocational services for every vocational outcome, with 85 (55%) patients assigned to IPS working for at least 1 day compared with 43 (28%) patients assigned to vocational services (difference 26.9% 95% CI 16.4–37.4). Patients assigned to vocational services were significantly more likely to drop out of the service and to be readmitted to hospital than were those assigned to IPS (drop-out 70 [45%] vs 20 [13%]; difference –32.1% [95% CI –41.5 to –22.7]; readmission 42 [31%] vs 28 [20%]; difference –11.2% [–21.5 to –0.90]). Local unemployment rates accounted for a substantial amount of the heterogeneity in IPS effectiveness.

**Interpretation** Our demonstration of the effectiveness of IPS in widely differing labour market and welfare context confirms this service to be an effective approach for vocational rehabilitation in mental health that deserves investment and further investigation.

Lancet 2007; 370: 1146–52  
See Comment page 1108  
\*Collaborators listed in full at end of Article  
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## Predictors of employment for people with severe mental illness: results of an international six-centre randomised controlled trial

Jocelyn Catty, Pascale Lissouba, Sarah White, Thomas Becker, Robert E. Drake, Angelo Fioritti, Martin Knapp, Christoph Lauber, Wulf Rössler, Toma Tomov, Joeske van Busschbach, Durk Wiersma and Tom Burns, on behalf of the EQOLISE Group

### Background

An international six-centre randomised controlled trial comparing individual placement and support (IPS) with usual vocational rehabilitation for people with serious mental illness found IPS to be more effective for all vocational outcomes.

### Aims

To determine which patients with severe mental illness do well in vocational services and which process and service factors are associated with better outcomes.

### Method

Patient characteristics and early process variables were tested as predictors of employment outcomes. Service characteristics were explored as predictors of the effectiveness of IPS.

### Results

Patients with previous work history, fewer met social needs

and better relationships with their vocational workers were more likely to obtain employment and work for longer. Remission and swifter service uptake were associated with working more. Having an IPS service closer to the original IPS model was the only service characteristic associated with greater effectiveness.

### Conclusions

The IPS service was found to be more effective for all vocational outcomes. In addition, maintaining high IPS fidelity and targeting relational skills would be a valuable focus for all vocational interventions, leading to improved employment outcomes. Motivation to find work may be decreased by satisfaction with current life circumstances.

### Declaration of interest

None. Funding detailed in Acknowledgements.

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## The Impact of Supported Employment and Working on Clinical and Social Functioning: Results of an International Study of Individual Placement and Support

Tom Burns<sup>1,2</sup>, Jocelyn Catty<sup>3</sup>, Sarah White<sup>3</sup>, Thomas Becker<sup>4</sup>, Marsha Koletsis<sup>3</sup>, Angelo Fioritti<sup>5</sup>, Wulf Rössler<sup>6</sup>, Toma Tomov<sup>7</sup>, Joeske van Busschbach<sup>8</sup>, Durk Wiersma<sup>8</sup>, Christoph Lauber<sup>6</sup> for the EQOLISE Group

there is sufficient evidence of work having beneficial effects on clinical and social functioning to merit further exploration.

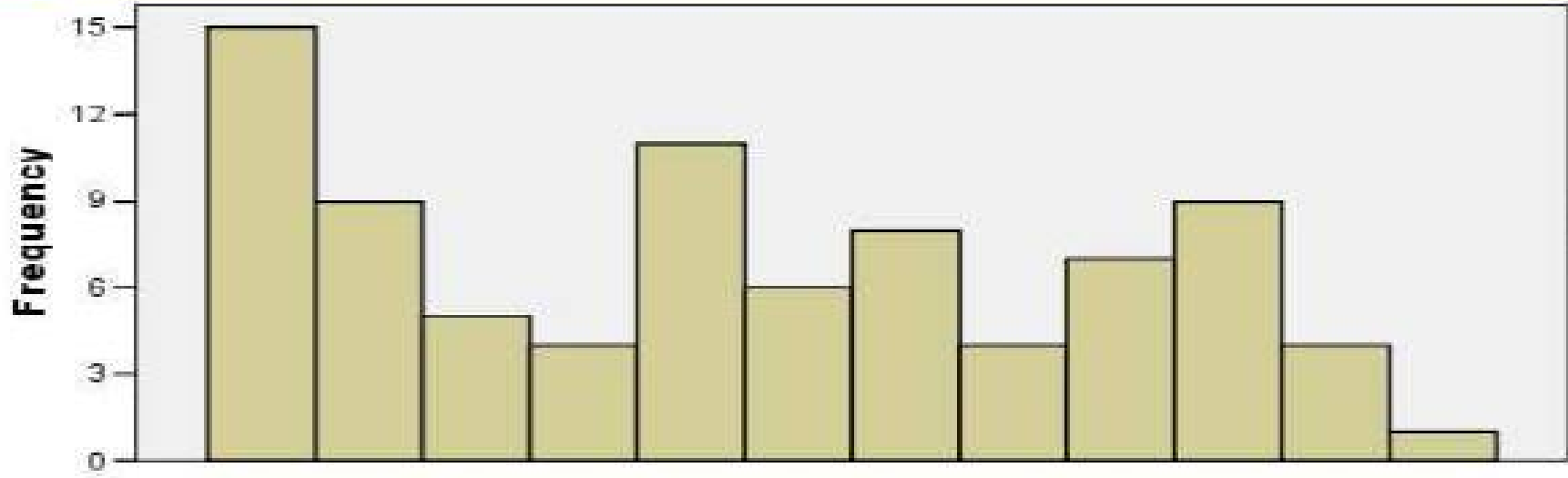
*Key words:* vocational rehabilitation/psychosis/outcomes

	IPS	n	Vocational service	n	Difference (95% CI)
Worked for at least 1 day	85 (55%)	156	43 (28%)	156	26.9% (16.4 to 37.4)
Number of hours worked*	428.8 (706.77)	143	119.1 (311.94)	138	308.7 (189.22 to 434.17)
Number of days employed*	130.3 (174.12)	154	30.5 (80.07)	152	99.8 (70.71 to 129.27)
Job tenure (days)*	213.6 (159.42)	83	108.4 (111.95)	39	104.9 (56.03 to 155.04)
Drop-out from service	20 (13%)	156	70 (45%)	156	-32.1% (-41.5 to -22.7)
Admission	28 (20%)	148	42 (31%)	141	-11.2% (-21.5 to -0.90)
Percentage of time spent in hospital*	4.6 (13.56)	148	8.9 (20.08)	141	-4.3 (-8.40 to -0.59)

Data are number (%) or mean (SD). \*Data for hours worked were not available for all patients, since not all patients completed follow-up interviews or were able to supply this information. Data for days employed were collected outside interview. Job tenure data were only calculated for the subgroup of patients who worked. Data for hospital use were missing for 23 patients. †Bootstrapped estimates of difference between means and bias corrected and accelerated 95% CIs presented.

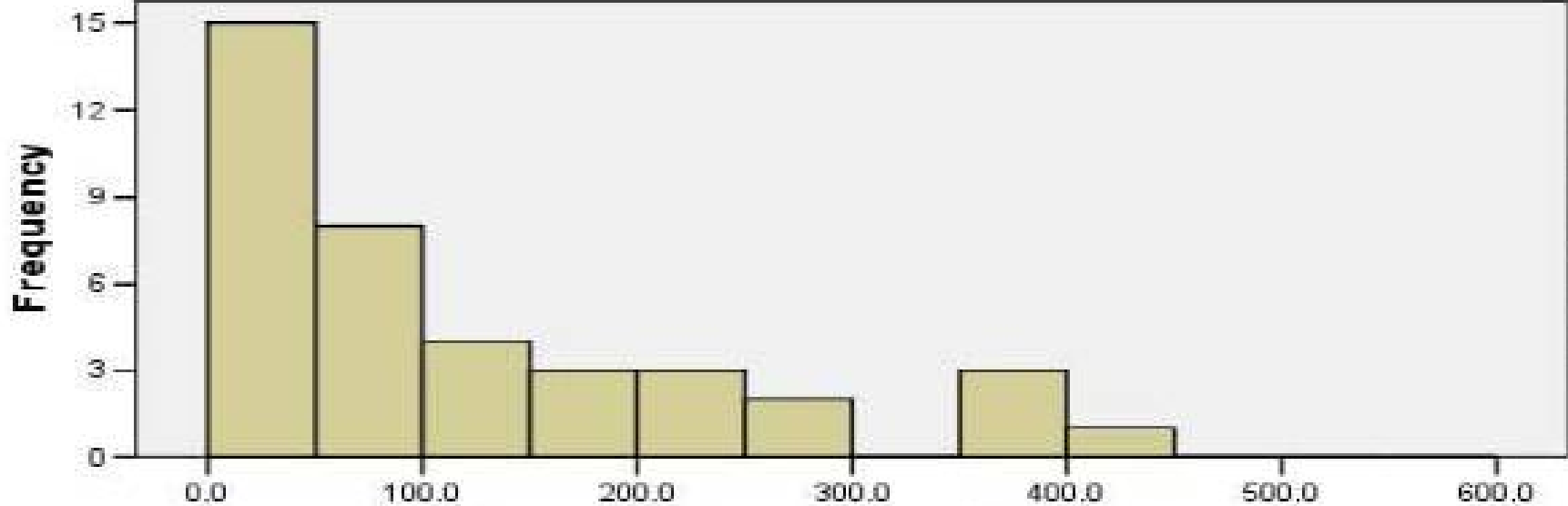
**Table 2: Vocational, admission, and drop-out outcomes†**





IPS

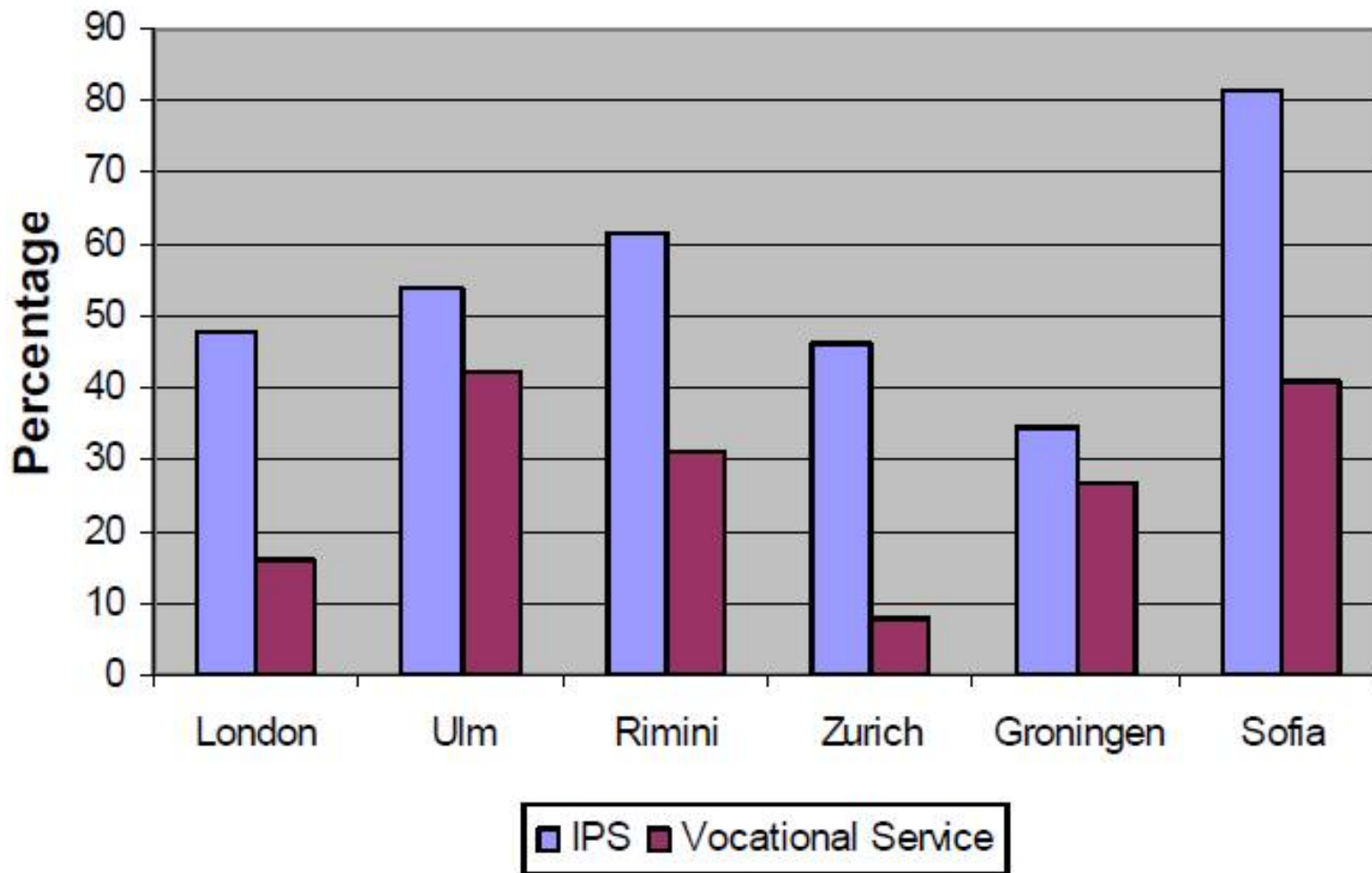
Service



Vocational service

Number of days employed in 18 months

# Hanno lavorato almeno un giorno



STUDY PROTOCOL

Open Access

# A multi-element psychosocial intervention for early psychosis (GET UP PIANO TRIAL) conducted in a catchment area of 10 million inhabitants: study protocol for a pragmatic cluster randomized controlled trial

Mirella Ruggeri<sup>1,15\*</sup>, Chiara Bonetto<sup>1</sup>, Antonio Lasalvia<sup>1</sup>, Giovanni De Girolamo<sup>2,3</sup>, Angelo Fioritti<sup>2,4</sup>, Paola Rucci<sup>2</sup>,

**Background:** Multi-element interventions for first-episode psychosis (FEP) are promising, but have mostly been conducted in non-epidemiologically representative samples, thereby raising the risk of underestimating the complexities involved in treating FEP in 'real-world' services.

**Methods/Design:** The Psychosis early Intervention and Assessment of Needs and Outcome (PIANO) trial is part of a larger research program (Genetics, Endophenotypes and Treatment: Understanding early Psychosis - GET UP) which aims to compare, at 9 months, the effectiveness of a multi-component psychosocial intervention versus treatment as usual (TAU) in a large epidemiologically based cohort of patients with FEP and their family members recruited from all public community mental health centers (CMHCs) located in two entire regions of Italy (Veneto and Emilia Romagna), and in the cities of Florence, Milan and Bolzano. The GET UP PIANO trial has a pragmatic cluster randomized controlled design. The randomized units (clusters) are the CMHCs, and the units of observation are the centers' patients and their family members. Patients in the experimental group will receive TAU plus: 1) cognitive behavioral therapy sessions, 2) psycho-educational sessions for family members, and 3) case management. Patient enrolment will take place over a 1-year period. Several psychopathological, psychological, functioning, and service use variables will be assessed at baseline and follow-up. The primary outcomes are: 1) change from baseline to follow-up in positive and negative symptoms' severity and subjective appraisal; 2) relapse occurrences between baseline and follow-up, that is, episodes resulting in admission and/or any case-note records of re-emergence of positive psychotic symptoms. The expected number of recruited patients is about 400, and that of relatives about 300.

Owing to the implementation of the intervention at the CMHC level, the blinding of patients, clinicians, and raters is not possible, but every effort will be made to preserve the independency of the raters. We expect that this study will generate evidence on the best treatments for FEP, and will identify barriers that may hinder its feasibility in 'real-world' clinical settings, patient/family conditions that may render this intervention ineffective or inappropriate, and clinical, psychological, environmental, and service organization predictors of treatment effectiveness, compliance, and service satisfaction.

Qualche studio  
osservazionale per  
la valutazione  
d'esito  
in salute mentale



# Lo studio PERDOVE. Uno studio osservazionale prospettico di coorte in quattro strutture residenziali della Provincia Lombardo Veneta.

Giovanni de Girolamo

**Introduzione:** L'approvazione della Legge 180 ha prodotto una modificazione dello scenario dell'assistenza psichiatrica in Italia. Uno degli aspetti più rilevanti è la creazione di una rete di Strutture Residenziali (SR), mirate ad assistere in maniera intensiva i pazienti con disturbi mentali gravi. Un aspetto cruciale per la valutazione degli esiti dell'intervento attuato nelle SR è rappresentato dalla possibilità di dimissione.

**Obiettivi:** Lo studio PERDOVE è volto a indagare le caratteristiche demografiche, cliniche e psicosociali dei pazienti in quattro strutture residenziali della Provincia Lombardo Veneta. E' stata posta particolare attenzione alla valutazione della qualità della vita e della soddisfazione dei bisogni spirituali. Alcune di queste variabili sono state valutate al baseline e al follow-up a un anno. Ciò ha permesso di identificare variabili correlate alla dimissione e di monitorare il decorso delle condizioni cliniche dei pazienti.

**Metodo:** Sono stati coinvolti tutti i pazienti ricoverati nel mese-indice di Settembre 2010 in comunità di medio-lunga degenza. Criteri di inclusione erano avere una diagnosi psichiatrica primaria e un'età inferiore a 64 anni. Per ciascun ospite sono stati rilevati dati socio-demografici, clinici e assistenziali, oltre all'utilizzo di strumenti standardizzati di valutazione. Dopo un anno sono stati rivalutati tutti i pazienti, sia quelli dimessi sia quelli ancora ricoverati, al fine di valutare i cambiamenti avvenuti nelle condizioni cliniche e sociali.

**Risultati:** Lo studio ha coinvolto 403 pazienti. La maggioranza è di sesso maschile (67%); l'età media è di 49 anni (sd= ±10). Il 70% è celibe/nubile. La diagnosi prevalente è la schizofrenia (67.5%). La durata media di malattia è di 23 anni (± 11.3). I pazienti si collocano su punteggi che riflettono una sintomatologia lieve. Più compromesso è il funzionamento psicosociale. Il 77% dei clinici sostiene che il paziente è appropriatamente collocato nella struttura e, rispetto alla predizione di dimissione a un anno, il 51% predice un esito positivo. Il fattore principale identificato come ostacolo alla dimissione è la gravità psicopatologica (56%). Al follow-up il 26% dei pazienti è stato dimesso.

**Discussione:** I risultati mostrano che solo un esiguo numero di pazienti è dimesso dopo un anno. Rispetto alla gravità psicopatologica come fattore ostacolante non vi è coerenza con la valutazione clinica fornita dai medici. C'è quindi da interrogarsi se la permanenza in queste strutture sia dovuta alla gravità della malattia, piuttosto che ad altri fattori di natura sociale, economica, ecc. E' possibile ipotizzare che la mancanza di supporto fornito dai servizi territoriali, l'assenza di supporto alle famiglie e lo stigma siano fattori che si frappongono alla dimissione di tali pazienti e al loro reinserimento nella comunità.

## Valutare gli esiti dei ricoveri nei servizi psichiatrici di diagnosi e cura: uno studio osservazionale

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### ABSTRACT

**Background.** Vi è la necessità di migliorare il ricovero nei Servizi Psichiatrici di Diagnosi e Cura (SPDC), sia in termini di appropriatezza che in termini della qualità delle cure erogate durante il ricovero. In Italia solo il 45 % dei posti letto si trova in strutture pubbliche (SPDC e Cliniche Psichiatriche Universitarie), il resto in case di cura private sia convenzionate che non. Il Dipartimento Interaziendale di Siena ha predisposto un protocollo di valutazione degli esiti dei ricoveri in SPDC per migliorare la qualità del ricovero nell'ambito dell'assistenza sanitaria pubblica.

**Obiettivi.** Valutare se il ricovero ospedaliero produce un miglioramento psicopatologico e di funzionamento sociale e relazionale dei pazienti, utilizzando dei semplici strumenti clinici adatti alla pratica clinica quotidiana: la scala HoNOS-Roma in una versione modificata a 13 item, la scala BPRS 4.0 e una scheda Buona Salute, appositamente predisposta per valutare parametri clinici di salute. Tali strumenti fanno parte del protocollo operativo per la valutazione degli esiti adottato dal Dipartimento.

**Metodi.** Le schede di valutazione sono state somministrate a tutti i pazienti ricoverati nei SPDC della provincia e nella Clinica Psichiatrica e dimessi dal 01.01.2012 al 30.04.2013 per un totale di 406 ricoveri. Viene considerata la diagnosi principale di dimissione utilizzando ICD-9-CM 24<sup>a</sup> edizione.

somministrata almeno una scala, vi è una marcata significatività del miglioramento psicopatologico e del funzionamento sociale. Non raggiungono la significatività statistica la scala HoNOS-Roma per la diagnosi stato psicotico organico e per i disturbi da abuso di sostanze: entrambe non evidenziano un significativo miglioramento per le diagnosi inserite nel gruppo "altre diagnosi". Particolarmente significativi i miglioramenti nei gruppi diagnostici di psicosi e altre psicosi e per i disturbi dell'umore. La degenza media è stata di 11.7 giorni.

**Limiti.** Nonostante la supervisione del coordinatore infermieristico e del responsabile medico del reparto è presente e non eliminabile un certo grado di valutazione soggettiva dei rilevatori.

**Conclusioni.** Lo studio, condotto su 381 ricoveri negli SPDC della Provincia di Siena, documenta un significativo beneficio per i pazienti ricoverati, soprattutto per le diagnosi di psicosi e disturbi dell'umore, sia in termini psicopatologici che di recupero del funzionamento sociale. Sicuramente il ricovero ospedaliero rappresenta solo il punto di partenza per costruire un progetto terapeutico individualizzato da parte del team assistenziale, utilizzando metodologie di lavoro come il case management territoriale che la letteratura ha già dimostrato efficace nel trattamento dei disturbi mentali gravi.

## La valutazione di routine dell'esito nei Dipartimenti di Salute Mentale

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LA VALUTAZIONE DELL'ESITO DEI  
TRATTAMENTI IN PSICHIATRIA

NÓOς  
3:2003; 205-220

### RIASSUNTO

Per ben pochi interventi psichiatrici esistono, allo stato attuale delle conoscenze, dei dati relativi alla loro efficacia nella pratica che siano affidabili, completi e raccolti su campioni rappresentativi. Il *Progetto Outcome*, uno studio naturalistico e longitudinale avviato nel 1994 presso il Servizio Psichiatrico Territoriale (SPT) di Verona-Sud, rappresenta il primo organico tentativo mai realizzato sia in campo nazionale sia internazionale di ricavare dati utili per la valutazione dell'efficacia degli interventi forniti dai Servizi di Salute Mentale. Tale progetto ha l'obiettivo di: a) valutare l'esito dell'assistenza fornita privilegiando lo studio dei fenomeni che avvengono nel "mondo reale"; b) studiare l'esito dell'assistenza psichiatrica dal punto di vista clinico, sociale e dell'interazione degli utenti con il servizio; c) promuovere l'utilizzazione di metodi per la raccolta standardizzata delle informazioni come parte integrante dell'attività clinica di routine. Le valutazioni vengono effettuate, dopo un breve training, dai clinici del Servizio nel corso dei colloqui che avvengono di routine ed includono il funzionamento globale, la psicopatologia, la disabilità nei ruoli sociali, i bisogni di cura; altre valutazioni sono effettuate dai pazienti in prima persona e comprendono la qualità della vita e la soddisfazione nei confronti del servizio. La compilazione degli strumenti viene effettuata due volte l'anno e riguarda tutti i pazienti che entrano in contatto con il SPT di Verona-Sud, ed include sia i nuovi casi sia i pazienti già in carico. Mediante gli strumenti utilizzati sono stati valutati oltre 2000 pazienti. La banca-dati così ottenuta consente di: a) descrivere le condizioni dei pazienti psichiatrici di Verona-Sud rispetto ai vari indicatori di esito considerati; b) studiare i fattori predittivi di esito favorevole o sfavorevole per ciascuno degli indicatori presi in considerazione. Il disegno del progetto si è dimostrato utile nel consentire un'utilizzazione ottimale del personale già esistente nei Servizi di Salute Mentale ai fini della valutazione dell'esito e si è rivelato idoneo per una valutazione dettagliata e di routine dei pazienti psichiatrici.

# Valutazione degli esiti in salute mentale

## UN MODELLO DI ECCELLENZA:

**Multiassiale:** valutazioni di operatori, utenti, familiari

**Multidimensionale:** esiti clinici, assistenziali, funzionamento sociale, qualità della vita, bisogni di cura, soddisfazione del servizio

**Longitudinale:** protratta nel tempo



## **Il Progetto Outcome di VeronaSud:**

1. Psicopatologia, disabilità e funzionamento globale al baseline sono in grado di predire i successivi livelli: i soggetti con i maggiori livelli di gravità tendono a manifestare un miglioramento più marcato nelle stesse dimensioni.

2. Il trattamento di pazienti con elevati livelli di psicopatologia e scarso funzionamento è gravato da costi assistenziali più alti, senza che ciò corrisponda a un successivo incremento di funzionamento.

3. Le variabili cliniche (psicopatologia, funzionamento globale e disabilità) tendono a essere strettamente correlate tra loro.

4. Analogamente le variabili che esplorano l'esperienza soggettiva dei pazienti (QoL, soddisfazione servizio) sono tra loro correlate

5. Invece le correlazioni tra i due gruppi di variabili appaiono molto deboli.

6. Solo la soddisfazione dei servizi predice la QoL. La soddisfazione verso servizi è predetta da bassa disabilità iniziale e da miglioramento funzionamento globale.

## Le principali evidenze del Progetto Outcome Verona Sud:

- i) clinical and social dimensions of outcome display different patterns of exacerbation and remission over time and are influenced by different sets of predictors and may be susceptible to specific interventions (27);
- ii) a comprehensive system of care provided within a community-based context may help long-term patients to reduce the likelihood of deterioration in their clinical and social needs over time (28);
- iii) community-based mental health services seem to be more tailored for people with psychotic disorders, compared with other types of patients (as psychotics tend to remain stable in their contact with services over time), whereas the vast majority of the patients who interrupt their contacts suffer from non-psychotic disorders (29), and are in a relevant percentage dissatisfied with care received;
- iv) repeated, routine assessments of service satisfaction, if performed with appropriate instruments and correct methodology, can provide a clear view of a service's strengths and weaknesses. However, this is a highly service-specific exercise, that might greatly increase the capacity of the professionals working in CMHS to understand the individual user's requests and needs, and to adapt treatment provision accordingly (30);
- v) the majority of informal caregivers experience considerable levels of family burden and emotional distress, due to their close day-to-day relationship with mentally ill relatives; however, well-integrated programmes of community care seem to contribute to a small but significant improvement in their condition, as a reduction in both global burden and emotional distress during the follow-up period was detected (31).

# Predictors of changes in needs for care in patients receiving community psychiatric treatment: a 4-year follow-up study

| Lasalvia A, Bonetto C, Salvi G, Bissoli S, Tansella M, Ruggeri M. | A. Lasalvia, C. Bonetto, G. Salvi,

## Significant outcomes

- Community-based mental health services may be effective in helping long-term patients prevent deterioration in needs for care over time.
- Changes in needs for care over time follow a specific pattern according to the perspective of subjects being assessed, with staff more focused on symptoms and patients on practical and social issues.
- Staff-rated and patient-rated needs for care recognize specific and different patterns of predictors.

## Limitations

- The study was conducted on a treated prevalence cohort composed of both long-term patients and patients at their initial contact with the Service.
- The study was performed with a naturalistic design.
- The study design did not allow to disentangle which specific components of care had more impact on meeting needs.

# Predicting clinical and social outcome of patients attending ‘real world’ mental health services: a 6-year multi-wave follow-up study

| Lasalvia A, Bonetto C, Cristofalo D, Tansella M, Ruggeri M. Predicting | **A. Lasalvia, C. Bonetto,**

## Significant outcomes

- The long-term outcome of psychiatric patients treated in community services (including those with psychosis) is a dynamic and evolving process of emergence and disappearance of clinical and social needs, with frequent chances of functional amelioration over time.
- After adjustment for other variables, diagnosis had no effect on both the clinical and social outcomes, thus confirming well-known limitations of the traditional categorical approach in prioritizing service interventions.
- Clinical and social dimensions of outcome display different patterns of exacerbation and remission over time, are influenced by different set of predictors and may be susceptible to specific interventions.

## Limitations

- The study was conducted on a treated prevalence cohort composed of both long-term patients and patients at their initial contact with the service.
- The naturalistic design did not allow to identify which specific components of care played a more effective role in reducing symptom levels or social disability.
- Not all potentially relevant predictors were included in the multivariate analyses.

## Applications and usefulness of routine measurement of patients' satisfaction with community-based mental health care

| Ruggeri M, Lasalvia A, Salvi G, Cristofalo D, Bonetto C, Tansella M. | **M. Ruggeri, A. Lasalvia, G. Salvi**

### Significant outcomes

- The highest scores were found for overall satisfaction and satisfaction with professionals' skills and behaviour, whereas the lowest for access, relative's involvement and information.
- Long-term and more disabled patients are more likely to be dissatisfied with the care they received.
- Perceived strengths and weaknesses in the provision of care represent precious information for implementing a continuous quality improvement process.

### Limitations

- Results found here are generalizable only to those mental health services which share a similar community-based approach to the South Verona service.
- The research assessed the satisfaction with the overall care provided by the service, and not with specific interventions.
- Many analyses, and thus many tests, have been performed on the same data set with the risk of inflation of type I error.

## Predictors of changes in caregiving burden in people with schizophrenia: a 3-year follow-up study in a community mental health service

| Parabiaghi A, Lasalvia A, Bonetto C, Cristofalo D, Marrella G, ... | **A. Parabiaghi<sup>1</sup>, A. Lasalvia<sup>2</sup>,**

### Significant outcomes

- Well-integrated programmes of community care may contribute for a small but significant improvement in family burden and emotional distress over 3 years.
- Caregivers experiencing high levels of burden may have worse outcomes.
- Caregivers' coping skills should be assessed regularly in patients with schizophrenia and family interventions should be planned.

### Limitations

- The sample size is relatively small.
- The association between family burden outcome and its predictors is not clearly demonstrated.
- This is a naturalistic study and most of its analyses are more likely to generate hypothesis than to draw conclusions.

## Heterogeneity of outcomes in schizophrenia

3-year follow-up of treated prevalent cases

MIRELLA RUGGERI, ANTONIO LASALVIA, MICHELE TANSELLA,  
CHIARA BONETTO, MARIA ABATE, GRAHAM THORNICROFT,  
LILIANA ALLEVI and PAOLA OGNIBENE

### Epsilon Study

**Background** Care for people with schizophrenia should address a wide range of outcomes, including professional and consumer perspectives.

**Aims** To measure changes in psychopathology, functioning, needs for care and quality of life; to develop predictive models for each outcome domain; and to assess the frequency of 'good' and 'poor' outcomes, as defined in a series of different definitions that use combinations of the four domains measured.

**Method** Three-year follow-up of a 1-year-treated prevalence cohort of 107 patients with an ICD–10 diagnosis of schizophrenia attending the South Verona community-based mental health service.

**Results** Mean symptom severity and some types of needs for care worsen, but quality of life shows no change. Functioning shows a non-significant trend to deteriorate. Between 32% and 42% of the variance in the four key outcomes was explained by our model. Different definitions of 'good' and 'poor' outcome included 0–31% of patients, depending on the definition used.

**Conclusions** The 3-year outcome for schizophrenia depends on the domain of outcome used, whether staff or patient ratings are used and the stringency of the definitions used for good and poor outcome.

# 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<sup>1\*</sup>, S. Tosato<sup>1</sup>, P. Brambilla<sup>2</sup>, M. Bertani<sup>1</sup>, C. Bonetto<sup>1</sup>, D. Cristofalo<sup>1</sup>, S. Bissoli<sup>1</sup>,

**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.

**Conclusions.** Both strengths and limitations of PICOS are discussed in the light of issues not addressed in the current literature on FEP. This study aims at making a substantial contribution to research on FEP patients. It is hoped that the research strategies adopted in PICOS will enhance the convergence of methodologies in ongoing and future studies on FEP.



# Valutazione degli esiti in salute mentale

## UN MODELLO DI ECCELLENZA:

**Multiassiale:** valutazioni di operatori, utenti, familiari

**Multidimensionale:** esiti clinici, assistenziali, funzionamento sociale, qualità della vita, bisogni di cura, soddisfazione del servizio

**Longitudinale:** protratta nel tempo

...ma:

È sostenibile nel nostro contesto?

Come interpretare/usare i risultati?



# **Progetto “Farmaci-Famiglie”**

**I rapporti tra medici, pazienti e familiari nella scelta delle terapie farmacologiche dei disturbi psichici:  
un’indagine presso il Dipartimento di Salute Mentale della AziendaUSL di Bologna  
focalizzata sull’impatto delle reazioni avverse ai farmaci**

## **CENTRI PARTECIPANTI:**

- **Dipartimento di Salute Mentale e Dipendenze Patologiche della AUSL di Bologna (centro coordinatore)**
  - **Unità di Psichiatria e Unità di Farmacologia – Dipartimento di Scienze Mediche e Chirurgiche dell’Università di Bologna**
  - **5 Centri di Salute Mentale AUSL Bologna (somministrazione dei questionari):**
    - CSM Scalo**
    - CSM Zanolini**
    - CSM Mazzacorati**
    - CSM San Lazzaro**
    - CSM Casalecchio di Reno**
- **Associazioni di familiari e gruppi di Auto Mutuo Aiuto di Bologna**

**Il progetto è stato svolto dal 2012 al 2014.**

## **INDICATORI PER LA VALUTAZIONE DELL'ESITO:**

**1) livello di condivisione della scelta terapeutica tra medico, paziente e familiare o amico stretto.**

**2) percentuale di concordanza tra medico, paziente e familiare o amico stretto nella percezione dei benefici e degli effetti collaterali della terapia farmacologica.**

Sono stati valutati complessivamente 212 pazienti, 113 familiari o amici stretti. I medici psichiatri hanno finora compilato le schede relative a 190 pazienti intervistati.

### **I RISULTATI HANNO EVIDENZIATO CHE:**

**I. il grado di condivisione delle scelte terapeutiche tra medici e pazienti, dal punto di vista dei pazienti, è elevato (oltre il 70%).**

**La condivisione delle scelte del trattamento farmacologico è avvenuta in modo totale secondo il 66% dei medici.**

**II. Per quanto riguarda la condivisione degli effetti collaterali, il 56% dei pazienti intervistati ritiene che sia stata totale. La stessa opinione è riportata dal 63% dei medici.**

**III. Vi è anche una sostanziale concordanza tra medici, pazienti e familiari-amici stretti:**

**a) sul livello dei benefici percepiti**

--> tra medico e paziente la concordanza sui benefici è stata “massima” nel 47% dei casi e “buona” in un ulteriore 48% dei casi

**b) sui rischi della terapia**

--> tra medico e paziente la concordanza sugli effetti collaterali è stata “massima” nel 35% dei casi e “buona” nel 48% dei casi.

**Nella maggior parte dei casi gli effetti collaterali della terapia farmacologica sono stati definiti come “pochi e sopportabili”, specialmente confrontando le opinioni di pazienti e medici.**

Solo nel 4% dei casi si è osservata una forte discrepanza tra medici e pazienti nella percezione degli effetti avversi (il paziente riferiva effetti avversi “insopportabili”, mentre il medico li riteneva “accettabili” o viceversa).

Anche **alcuni familiari o amici stretti** hanno definito gli effetti collaterali come “troppi e insopportabili”, manifestando disaccordo con le opinioni dei clinici e talvolta con quelle dei pazienti.

**IV. Alla ricerca hanno preso parte circa la metà dei familiari o amici stretti dei pazienti partecipanti.**

Si è evidenziata la difficoltà che spesso i pazienti hanno avuto nel proporre lo studio ai propri congiunti, per via della sofferenza dei familiari associata all'esperienza della malattia, alle importanti ricadute sul clima familiare ed anche alle possibili criticità nel rapporto paziente-familiare.

**V. L'analisi di regressione logistica multipla ha permesso di valutare quali caratteristiche cliniche dei pazienti possono essere associate ad una maggiore concordanza su benefici ed effetti avversi percepiti.**

**La consapevolezza di malattia è risultata essere un fattore che favorisce una maggiore concordanza medico-paziente rispetto ai benefici della terapia farmacologica,**

**la presenza di una patologia cardio-metabolica costituisce un elemento predittivo di disaccordo nelle percezioni dei benefici tra le due figure (medico e paziente)**

# New tasks and methods in mental health service research

Prof. Stefan Priebe  
Queen Mary University of London



## More care is better

- Studies on assertive community treatment in the US showed that community treatment is better than no treatment
- Specific early intervention teams (with pharmacological, psychological and social interventions) are better than usual care
- The advantage disappears when patients are referred to usual care

.....but not always

- In the UK 700 study, no difference between staff-patient ratio of 1:15 and 1:30-50
- In the UK, no difference between Assertive Outreach and usual care



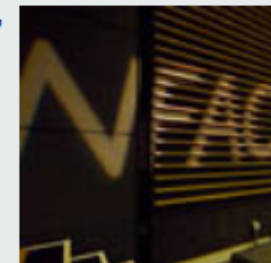
## For AO and flexible (FACT) models

# About AO

### What is Assertive Outreach?

Known as Assertive Community Treatment (ACT) in the United States, a huge, and largely US, literature and research base underpins this model. Assertive Outreach is not a treatment but a way of organising and delivering care via a specialised team to provide intensive, highly coordinated and flexible support and treatment for clients with longer term needs living in the community.

Specifically those referred to Assertive Outreach are people with whom mainstream mental health services have found it difficult to engage, and with histories including a severe and enduring mental illness, social chaos, high use of inpatient beds, and with multiple complex needs. To be effective teams must deliver a mix of evidence based psychosocial intervention and intensive practical support from multi-skilled and multi-disciplinary practitioners. The focus of the work must be on engagement and rapport, building up, often over the long-term, strong relationships. Effective teams aim to replicate the findings of numerous international randomised controlled trial studies comparing ACT with standard care. These outcomes for ACT are summarised as:



#### Large impact on:

- Engagement
- Housing
- Bed use (not replicated in UK)

#### Moderate impact on:

- Symptoms
- Quality of life

#### Weak impact on:

- Employment
- Substance use
- Jail and legal problems
- Social adjustment

# Assertive Community Treatment for People with Severe Mental Illness

Developed by

Gary R. Bond

Indiana University-Purdue University Indianapolis

Indianapolis, IN

March 17, 2002

Ma in UK:

RESEARCH REPORT

## The UK700 trial of Intensive Case Management: an overview and discussion

TOM BURNS *World Psychiatry* 1:3 - October 2002

5. Killaspy H, Kingett S, Bebbington P, Blizard R, Johnson S, Nolan F, Pilling S, King M (2009) Randomised evaluation of assertive community treatment: 3-year outcomes. *Br J Psychiatry* 195:81–82

6. Bond GR, Drake RE, Marder DR, Marder SR, Marder DR (2005) Risperidone in the treatment of schizophrenia: a meta-analysis of randomized controlled trials. *Am J Psychiatry* 162:1005–1012

... tuttavia:

8. Brugha TS, Taub N, Smith J, Morgan T, Hill T, Meltzer H, Wright C, Burns T, Priebe S, Evans J, Fryers T (2012) Predicting outcome of assertive outreach across England. *Soc Psychiatry Psychiatr Epidemiol* 47(2):313–322

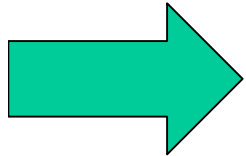
“... Le équipe AO si sono dimostrate efficaci nel prendere in cura pazienti caotici, che altri servizi non sono riusciti ad agganciare...”

... gli olandesi variano il modello e propongono il FACT (Flexible Assertive Community Treatment):

**1. Van Veldhuizen JR (2007) FACT: a Dutch version of ACT. Commun Ment Health J 43(4):421–433**

**Table 1** Comparison of model elements in the two clinical team types

Team/model characteristics	Assertive outreach team	CMHT with FACT
Shared caseload with multiple staff visiting same patient	Yes for all patients	Yes for FACT patients (11 %) only. Remaining patients individually case managed
Daily coordination meeting	Yes for all patients	Yes for FACT patients (11 %) only
Patient to clinical staff ratios	12:1	>25:1
Team case load	75	260 of which average of 29 (11 %) on FACT per team
Duration of assertive outreach	Long terms. Once referred to AO patients typically stay for several years	Assertive outreach flexible and titrated according to need. A few weeks, months or longer
Serves severely mentally ill population only	Yes, psychosis service	No, generic team with two levels of care. Individual case management/ care coordination and FACT higher level of care. Access to higher level of care according to need not diagnosis or tertiary referral
Service level	Tertiary specialist service requiring formal referral to a separate team	Secondary service, team can move patients internally between two levels of care on a daily basis if required. The same team staff responsible for both levels



## A dismantling study of assertive outreach services: comparing activity and outcomes following replacement with the FACT model

Mike Firn · Keelyjo Hindhaugh · Dieneke Hubbeling ·  
Gwyn Davies · Ben Jones · Sarah Jane White

Received: 31 August 2012 / Accepted: 28 September 2012  
© Springer-Verlag Berlin Heidelberg 2012

### Abstract

**Purpose** Financial constraints and some disappointing research evaluations have seen English assertive outreach (AO) teams subject to remodelling, decommissioning and integration into standard care. We tested a specific alternative model of integrating the AO function from two AO teams into six standard community mental health teams (CMHT). The Flexible Assertive Community Treatment model (FACT) was adopted from the Netherlands (Van Veldhuizen, *Commun Mental Health J* 43(4):421–433, 2007; Bond and Drake, *Commun Mental Health J* 43(4): 435–438, 2007). We aimed to demonstrate non-inferiority in clinical effectiveness and thereby show cost efficiencies associated with FACT.

**Methods** Outcomes were compared in a mirror-image study of the 12 months periods pre- and post-service change with eligible individuals from the AO teams' caseloads ( $n = 112$ ) acting as their own controls. We also conducted a cost-consequence analysis of the changes. Outcome data regarding admissions, use of crisis and home treatment, frequency of contact and DNA rate were extracted from the electronic patient record.

**Results** The results show AO patients ( $n = 112$ ) transferred to standard CMHTs with FACT had significantly fewer admissions and a halving of bed use (21 fewer admission and 2,394 fewer occupied bed days) whilst being in receipt of a less intensive service (2,979 fewer contacts). This was offset by significantly poorer engagement but not by increased use of crisis and home treatment services.

**Conclusions** Enhancing multi-disciplinary CMHTs with FACT provides a clinically effective alternative to AO teams. FACT offers a cost-effective model compared to AO.

**Keywords** Assertive · Outreach · Community · Treatment · Schizophrenia

### Background

Academic and clinical opinion is moving away from supporting stand alone, specialised assertive outreach (AO) teams in England [3]. English RCT outcome trials have failed to demonstrate effectiveness of AO teams in reducing bed use or clinical outcomes [4, 5]. English studies,

# Compulsory community and involuntary outpatient treatment for people with severe mental disorders (Review)

Kisely SR, Campbell LA



**THE COCHRANE  
COLLABORATION®**

2014, Issue 12

## PLAIN LANGUAGE SUMMARY

### Compulsory community and involuntary outpatient treatment for people with severe mental disorders

Compulsory community treatment (CCT) for people with severe mental health problems is used in many countries, including Australia, Israel, New Zealand, the United Kingdom, and the United States. Supporters of this approach suggest that it is less restrictive and better to compulsorily treat someone in the community than to subject them to repeated hospital admissions. They also argue that it is effective in bringing stability to the lives of people with severe mental illness. Opponents of CCT fear treatment and support will be replaced by a greater emphasis on control, restraint, and threat. CCT may also undermine the relationship between healthcare professionals and patients, leading to feelings of mistrust and being controlled, which may drive people with severe mental illnesses away from services.

Given the widespread use of such powers, which effectively force people in the community to compulsorily undergo treatment, it is important to assess the benefits, effectiveness or possible hazards of compulsory treatment.

Update searches for randomised trials were run in 2012 and 2013 and this review now includes three trials with a total of 752 people. Two of these trials compared a form of CCT called 'Outpatient Commitment' (OPC) versus standard care and the third trial compared a form of CCT called Community Treatment Order to supervised discharge. The review authors rated the quality of evidence for the main outcomes to be low to medium grade. Results from the trials showed overall CCT was no more likely to result in better service use, social functioning, mental state or quality of life compared with standard 'voluntary' care. People receiving CCT were less likely to be victims of violent or non-violent crime. It is unclear whether this benefit is due to the intensity of treatment or its compulsory nature. Other than feelings of coercion or being controlled, there were no other negative outcomes. Short periods of conditional leave may be as effective (or non-effective) as compulsory treatment in the community. However, there is very limited information available, all results are based on three relatively small trials of low to medium quality, making it difficult to draw firm conclusions, so further research into the effects of different types of compulsory community treatment is much needed.

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# Community treatment orders for patients with psychosis (OCTET): a randomised controlled trial



Tom Burns, Jorun Rugkåsa, Andrew Molodynski, John Dawson, Ksenija Yeeles, Maria Vazquez-Montes, Merryn Voysey, Julia Sinclair, Stefan Priebe

## Summary

**Background** Compulsory supervision outside hospital has been developed internationally for the treatment of mentally ill people following widespread deinstitutionalisation but its efficacy has not yet been proven. Community treatment orders (CTOs) for psychiatric patients became available in England and Wales in 2008. We tested whether CTOs reduce admissions compared with use of Section 17 leave when patients in both groups receive equivalent levels of clinical contact but different lengths of compulsory supervision.

*Lancet* 2013; 381: 1627–33

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50140-6736(13)60107-5

**Interpretation** In well coordinated mental health services the imposition of compulsory supervision does not reduce the rate of readmission of psychotic patients. We found no support in terms of any reduction in overall hospital admission to justify the significant curtailment of patients' personal liberty.



# Use of community treatment orders in an inner-London assertive outreach service

Muffazal Rawala,<sup>1</sup> Susham Gupta<sup>2</sup>

Psychiatric Bulletin (2014), 38, 13–18, doi: 10.1192/pb.bp.112.042184

<sup>1</sup>South London and Maudsley NHS Foundation Trust, London; <sup>2</sup>East London NHS Foundation Trust, London  
Correspondence to Muffazal Rawala (muffazal.rawala@kcl.ac.uk)

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**Aims and method** To compare admission rates and bed occupancy before and after the introduction of community treatment orders (CTOs) in 37 assertive outreach service patients. The effect of CTOs on treatment adherence and illicit drug use were also evaluated. The views of patients and care coordinators were obtained through a focus group.

**Results** When CTOs were introduced, admission rates fell from 3.3 to 0.3 per year and average bed occupancy declined from 133.2 to 10.8 days per year. Treatment adherence improved from 4 (10.8%) to 31 (83.7%) patients, and an objective reduction in substance misuse was observed in 25 (67.5%) patients. Whereas patients expressed ambivalence towards CTOs, their care coordinators generally had a more positive view.

**Clinical implications** The decline in hospital usage following the introduction of CTOs is encouraging and could reflect improved adherence and engagement through intensive case management, leading to a reduction in readmissions. However, further studies need to look at quality of life, cost-effectiveness and the impact on patients.

# Complex interventions

- Most treatments in mental health care are complex interventions
- Different components
- Components are specific and non-specific
- They can occur sequentially and/or at the same time
- They can often be combined in different ways

# What makes an intervention complex?

*Craig et Al. BMJ 2008; 337: 979-983*

- » Numero delle componenti e le interazioni tra esse all'interno dell'intervento sperimentale e di controllo
- » Il numero e la difficoltà dei comportamenti richiesti a coloro che erogano o ricevono l'intervento
- » Numero dei gruppi o livelli organizzativi coinvolti nell'intervento
- » Numero e variabilità degli outcomes
- » Grado di flessibilità o di "tailoring" dell'intervento consentito

**FRANCESCO CARDINI**

**Agenzia Sanitaria e Sociale Regionale - Emilia Romagna  
Università di Verona – Corso di Laurea in Ostetricia**

## ***How to research a complex intervention?***

*(again BMJ 2008; 337: 979-983)*

- » Il processo di sviluppo e valutazione di un intervento complesso passa per **parecchie fasi, non necessariamente in sequenza lineare**
- » I disegni sperimentali sono da preferire a quelli osservazionali nella maggior parte dei casi, **ma non sempre sono praticabili**
- » Comprendere i processi è importante, **ma non sostituisce la valutazione degli outcomes**
- » I reports degli studi dovrebbero includere una **descrizione dettagliata** dell'intervento, che ne consenta la replicazione, la sintesi delle evidenze, e la più ampia implementazione

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## Per riassumere (3)

- Nel valutare l'efficacia di interventi complessi, oltre agli outcomes di tipo quantitativo, vanno indagati **preferenze, aspettative, significati, outcomes qualitativi, compliance, soddisfazione**
- Servono **disegni di studio quali-quantitativi e strategie di ricerca adeguate per interventi complessi**
- Individuare metodi, strumenti e indicatori, **innovare!**

*FRANCESCO CARDINI*

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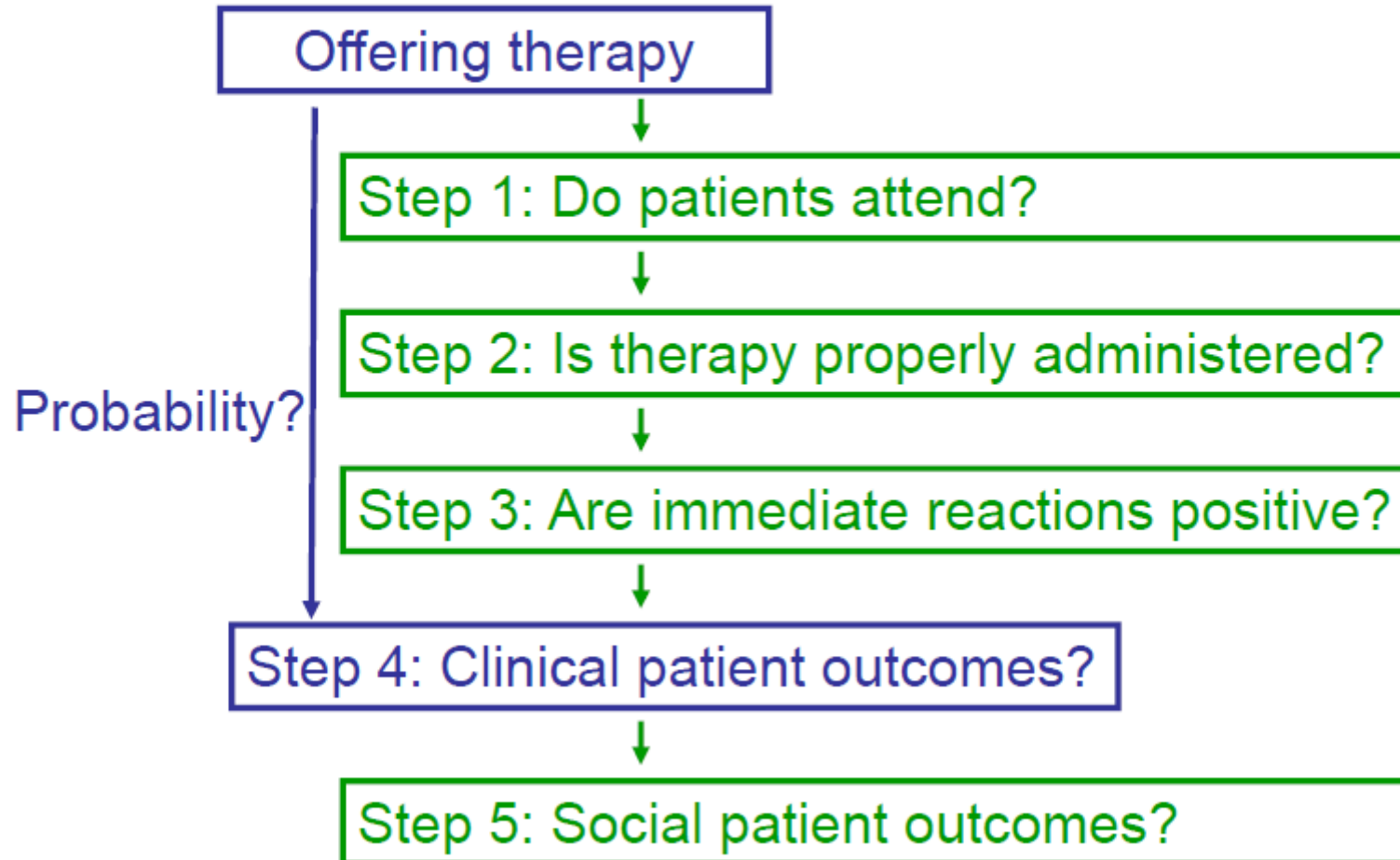
# Evaluation of complex interventions

- A model of the sequence of events
- A theory of the mechanisms of the intervention
- Definition of steps and intermediate outcomes (in line with theory)
- Quantitative and qualitative methods to
  - a) evaluate steps and outcomes and
  - b) optimise the model and intervention

## Non-specific processes

- Throughout health care non-specific processes explain 60% of variance of outcomes in trials (e.g. placebo)
- Expectations and therapeutic relationships as central factors
- How can such processes be understood and improved?
- What is the role of modern information technologies?

# Example: Group therapy






# Cluster randomisation

- Randomisation of clusters instead of individual patients
- Clusters can be clinicians, services, areas
- Specifically relevant for service research
- Plus: More realistic scenario, testing of implementation, no contamination
- Minus: larger sample size, more complex analysis, more complicated procedure

## Example: FIAT

- Testing the effectiveness of financial incentives to improve adherence to anti-psychotic medication
- Teams are identified
- Patients are identified and recruited
- Then, teams are randomised
- Patient outcomes (primary: adherence) and team experiences after one year

## RESEARCH

**Effectiveness of financial incentives to improve adherence to maintenance treatment with antipsychotics: cluster randomised controlled trial** OPEN ACCESS**Abstract**

**Objective** To test whether offering financial incentives to patients with psychotic disorders is effective in improving adherence to maintenance treatment with antipsychotics.

**Design** Cluster randomised controlled trial.

**Setting** Community mental health teams in secondary psychiatric care in the United Kingdom.

**Participants** Patients with a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder, who were prescribed long acting antipsychotic (depot) injections but had received 75% or less of the prescribed injections. We randomly allocated 73 teams with a total of 141 patients. Primary outcome data were available for 35 intervention teams with 75 patients (96% of randomised) and for 31 control teams with 56 patients (89% of randomised).

**Interventions** Participants in the intervention group were offered £15 (€17; \$22) for each depot injection over a 12 month period. Participants in the control condition received treatment as usual.

**Main outcome measure** The primary outcome was the percentage of prescribed depot injections given during the 12 month intervention period.

**Results** 73 teams with 141 consenting patients were randomised, and outcomes were assessed for 131 patients (93%).<sup>↓</sup> Average baseline adherence was 69% in the intervention group and 67% in the control group. During the 12 month trial period adherence was 85% in the

intervention group and 71% in the control group. The adjusted effect estimate was 11.5% (95% confidence interval 3.9% to 19.0%,  $P=0.003$ ). A secondary outcome was an adherence of  $\geq 95\%$ , which was achieved in 28% of the intervention group and 5% of the control group (adjusted odds ratio 8.21, 95% confidence interval 2.00 to 33.67,  $P=0.003$ ).

Although differences in clinician rated clinical improvement between the groups failed to reach statistical significance, patients in the intervention group had more favourable subjective quality of life ratings ( $\beta=0.71$ , 95% confidence interval 0.26 to 1.15,  $P=0.002$ ). The number of admissions to hospital and adverse events were low in both groups and did not show substantial differences.

**Conclusion** Offering modest financial incentives to patients with psychotic disorders is an effective method for improving adherence to maintenance treatment with antipsychotics.

**Trial registration** Current Controlled Trials ISRCTN77769281.

**Introduction**

Poor adherence to antipsychotic drugs is a major problem in patients with psychotic disorders, linked to increased rates of readmission to hospital and high treatment costs.<sup>1</sup> Between 25% and 80% of patients fail to take their drugs correctly at some point in their treatment.<sup>2</sup> Poor adherence to treatment can treble the costs of external services.<sup>3</sup> Many interventions have been tried to improve adherence to treatment in patients with

# Shared decision making

- Three types of professional-patient relationships: paternalistic, partnership, consumer
- Usually, partnership models are preferred
- Shared decision making can improve outcomes (6 positive trials)

## DIALOG – Intervention

- Key workers ask patients in the session to rate their satisfaction with 8 life domains and 3 treatment aspects and wishes for different help
- Ratings are displayed on a hand-held PC
- Results are intended to influence the dialogue between key worker and patient
- The procedure is repeated every two months

# Trial results

- Cluster RCT in six European countries
- DIALOG leads to
  - better subjective quality of life,
  - fewer needs and higher treatment satisfaction
- Overall small effect size in patients with chronic disorders (medium in patients with more problematic baseline scores)

Priebe et al., Br J Psychiatr, 2007

van den Brink et al., Soc Psychiatry Psychiatr Epidemiol, 2010

# VALUTAZIONE

- Cos'è un buon trattamento?
- Cos'è un outcome positivo?
- Criteri prossimali e distali
- Valutazioni & punteggi auto-assegnati o assegnati da osservatori
- Criteri oggettivi e soggettivi (outcome riferiti da pazienti = PROs)
- Quali costrutti si vogliono valutare?

## Objective social outcomes

- Gli outcome della «real life» sono considerati importanti
- Non determinati dal «modello medico»
- Sono di particolare richiamo per gli stakeholders utenti (e le loro organizzazioni)



# Objective Social Outcomes Index (SIX)

- Employment: none=0; sheltered=1; regular=2
- Accommodation: homeless or 24 hour supervised=0; sheltered=1; independent=2
- Partnership/family: living alone=0; living with a partner or family=1
- Friendship: not meeting a friend within the last week=0; =1
- Range from 0 to 6

## SIX: Limitations

- Scala ordinata, che può richiedere test statistici non parametrici
- Sensibile alle differenze culturali dei settings
- Sebbene sia semplice, la definizione di ogni step individuale può diventare complicata
- Nonostante l'oggettività della valutazione, rimane dipendente da giudizi di valore soggettivi

# Involuntary hospital admissions

- What are the outcomes following involuntary hospital admissions?
- Study in 22 hospitals across England
- 778 patients interviewed in the first week after admission
- Follow ups after 1, 3 and 12 months

# Outcomes

	Global functioning GAF 0-100	Symptoms BPRS 24-168	Treatment satisfaction CAT 0-10	Admission right? Yes %	<b>SIX</b>
Admission	33.6	54.5	5.51	21%	<b>3.11</b>
1 Month	43.8	43.9	5.81	30%	<b>2.97</b>
3 Months	47.9	40.1	6.03	35%	<b>2.96</b>
12 Months	50.2	40.8	5.81	40%	<b>2.94</b>

## Patient reported outcomes (PROs)

- Sono popolari e attrattivi per gli stakeholders
- Riflettono il punto di vista degli utenti
- Comprendono una lunga e crescente lista di costrutti
- I costrutti hanno una base intuitiva, ma non sono fondati su un preciso concetto o consenso
- Sono state sviluppate molte scale, che utilizzano aspetti della teoria dei test psicologici

# Problems of PROs

- Effetto «soffitto»
- Alta sovrapposizione dei punteggi (48% - 69%) che suggerisce un tendenza generale a giudizi positivi
- La tendenza è riscontrata sia nelle rilevazioni trasversali che longitudinali
- La tendenza è associata con l'umore ( $r=0.63-0.71$ )
- Può essere misurata da un piccolo numero di items

# DOMANDE

- La tendenza generale all'apprezzamento è in grado di spiegare tutta la varianza dei PROs?
- C'è una parte di varianza spiegata da costrutti specifici (es., soddisfazione per il trattamento, qualità della vita, bisogni)?
- Se sì, da quali ?

## Findings in UK 700 and DIALOG samples

- Il modello bi-fattoriale si adatta meglio ai dati
- Ci sono: tendenza generale all'apprezzamento + costrutti specifici
- Le scale attuali distinguono di più nello spettro favorevole che in quello sfarevole



# Measuring patient-reported outcomes in psychosis: conceptual and methodological review

Ulrich Reininghaus and Stefan Priebe

BJPsych

The British Journal of Psychiatry (2012)  
201, 262–267. doi: 10.1192/bjp.bp.111.107615

## Background

There are calls to use patient-reported outcomes (PROs) routinely across mental health services. However, the use of PROs in patients with psychosis has been questioned.

## Aims

To examine the concepts and measures of four widely used PROs: treatment satisfaction, subjective quality of life, needs for care and the quality of the therapeutic relationship.

## Method

We conducted a literature search of academic databases of concepts, characteristics and psychometric properties of the four PROs in patients with psychosis.

## Results

Although numerous concepts and measures have been published, evidence on the methodological quality of existing PROs is limited. Measures designed to assess distinct PROs

showed a considerable conceptual, operational and empirical overlap, and some of them also included specific aspects. The impact of symptoms and cognitive deficits appears unlikely to be of clinical significance.

## Conclusions

The popularity of PROs has not been matched with progress in their conceptualisation and measurement. Based on current evidence, some recommendations can be made. Distinct and short measures with clinical relevance and sufficient psychometric properties should be preferred. Future research should optimise the validity and measurement precision of PROs, while reducing assessment burden.

## Declaration of interest

None.

# Conclusions

- Mental health service research is important and can receive funding
- Wide range of tasks around the two main questions:
  - a) What is good and effective mental health care?
  - b) How to improve it?
- Methodological advances required

Thank you, professor  
Priebe!

# Grazie per l'attenzione!

Antonella Piazza

## Review article

# Assessing the outcome of community-based psychiatric care: building a feedback loop from ‘real world’ health services research into clinical practice

| Lasalvia A, Ruggeri M. Assessing the outcome of community-based | **A. Lasalvia, M. Ruggeri**

## Considerations

- The outcome of patients receiving community care is heterogeneous and the relationships among multiple outcome variables are complex; thus, specifically developed methodologies are needed to gain a deeper understanding of their reciprocatory interactions.
- Clinical and social dimensions of outcome display different patterns of exacerbation and remission over time and might be influenced by different sets of predictors and susceptible to specific interventions.
- More evidence should be gained on the effects of routine assessments on treatment outcomes in clinical practice.