



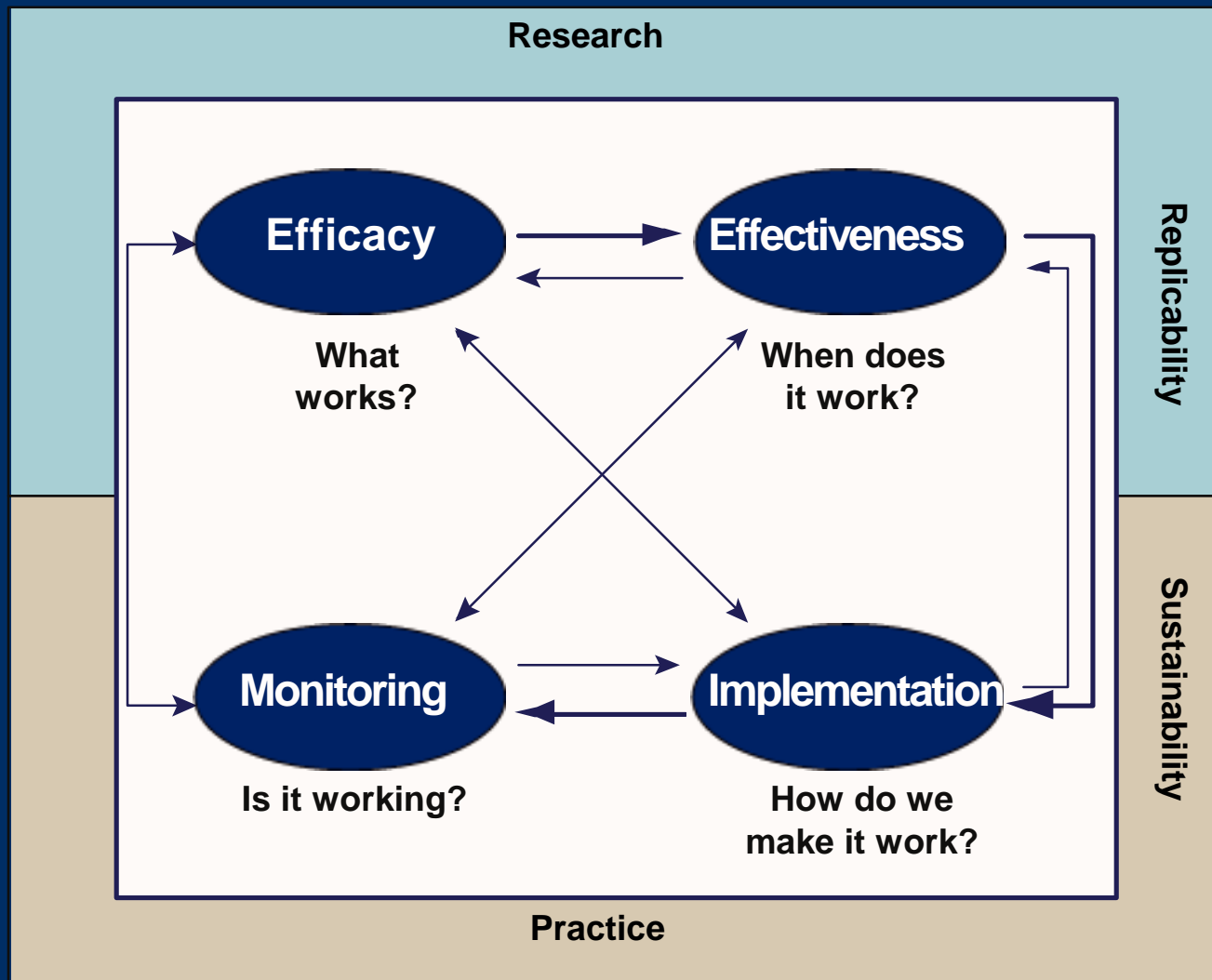
LA VALUTAZIONE DI ESITO IN SALUTE MENTALE

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Research-Practice Loop



Cosa vuol dire in pratica efficacia ?

Esempio 1

Terapia dello stato maniacale acuto
Tasso di remissione sintomatica dopo 3-12 settimane
13 studi clinici controllati

Farmaci antipsicotici e/o stabilizzanti		Placebo	
N	%	N	%
868/1713	51% (45-56%)	506/1716	29% (21-36%)
Aumento relativo dell'efficacia 75% Aumento assoluto dell'efficacia 22% NNT 5			

Cosa vuol dire in pratica efficacia ?

Esempio 2

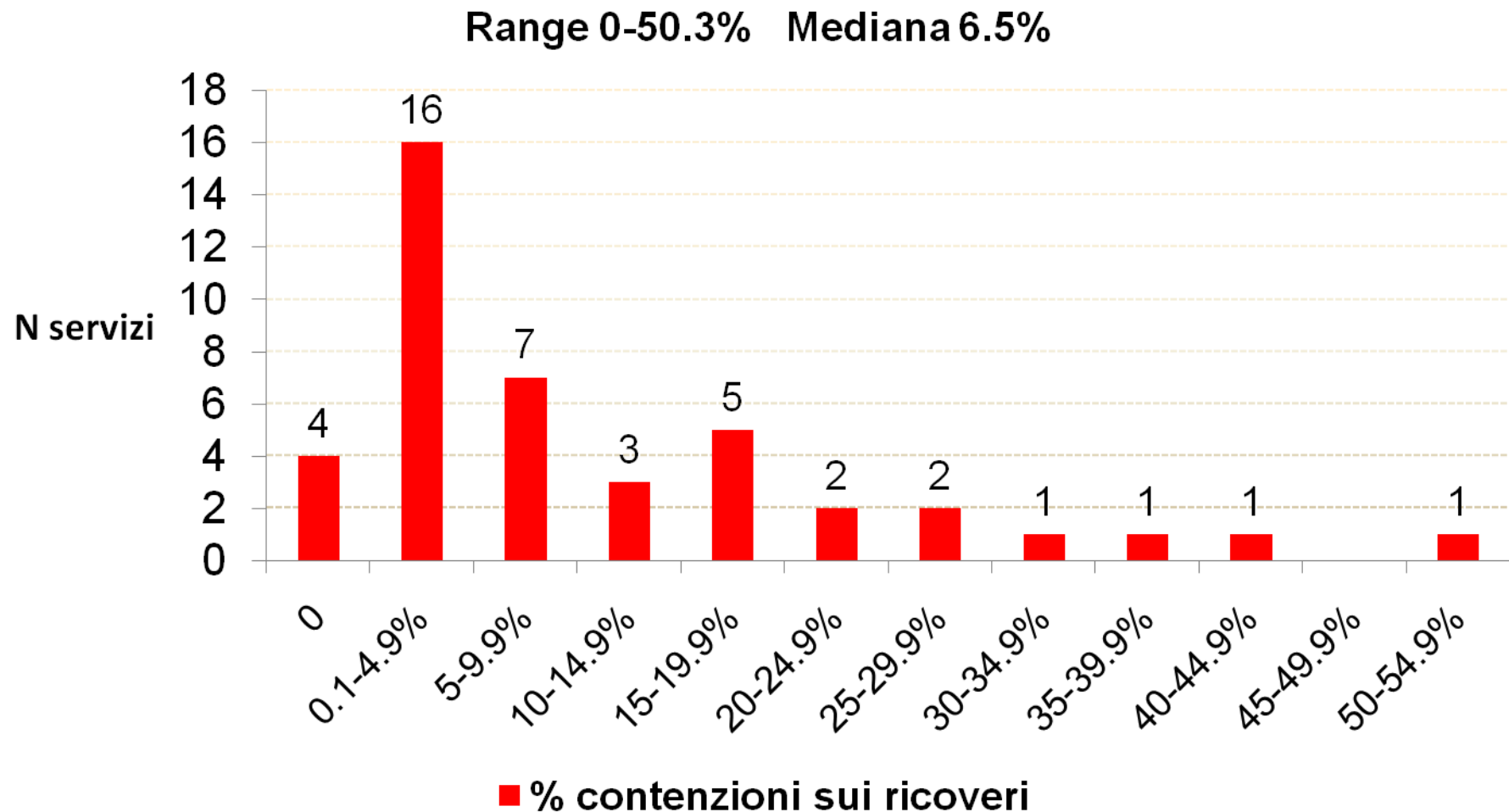
Terapia dei disturbi schizofrenici

Tasso di miglioramento clinicamente significativo dopo 3-12 mesi

14 studi clinici controllati

Farmaci antipsicotici		Placebo	
N	%	N	%
266/880	30% (18-80%)	75/644	12% (0-33%)
Aumento relativo dell'efficacia 150% Aumento assoluto dell'efficacia 18% NNT 6			

Distribuzione degli SPDC in Lombardia per tasso di contenzioni sui ricoveri (n=43)



Discontinuation of antidepressant drug therapy in real world practice

Author	Country	Design	N cases	Period	% Discontinuation	
Cantrell, 2008	USA	Retrospective Analysis of administrative database	22.947	6 months	SSRIs	57
Olfson, 2006	USA	Observational Prospective	829	1 month	Any	42
Tournier, 2007	Canada	Prospective Analysis of administrative database	12.825	6 month	Any	56
Meijer, 2004	Netherlands	Prospective Analysis of administrative database	9.857	2 month	SSRIs	30

Disturbi mentali gravi

Indicatori di esito più importanti

Priorità dei differenti attori

Attori	Indicatori
Utenti	Benessere soggettivo
Familiari	Carico familiare
Clinici	Sintomi
Amministratori	Efficienza
Finanziatori	Costi
Pubblico	Disturbo sociale

What is outcome ?

Outcome is the end result of a healthcare intervention for a target population, measured through an **indicator** whose **variations**, according to the theory and goals of the intervention, can reasonably represent the result itself

Outcome categories

- **Patient status indicators**

Clinical

Functional

- **Care process indicators**

- **Satisfaction indicators**

- **Ecological indicators**

- **Cost indicators**

Levels of outcome assessment

- **Single intervention**
- **Individual care**
- **Program**
- **Service**
- **Local population**
- **Regional population**
- **Country population**

Source of outcome indicators

- Administrative
- Target population
- Provider
- Significant other
- Independent researcher

Most valued outcome indicators in mental health

Views of different stakeholders

Stakeholders	Indicator
Consumers	Subjective wellbeing/Quality of life
Relatives	Family burden
Clinicians	Symptoms
Managers	Efficiency
Sponsors	Costs
Public	Social disturbance

Research strategies

- Prospective vs. retrospective vs. cross-sectional
- Continuous vs. categorical variables
- Hard vs. soft indicators
- Group vs. individual level
- Statistical vs. clinical significance
- Observational vs. experimental

Statistical significance

To what extent can the difference between two measurements be due to chance ?

Effect size

How large is the difference ?

Clinical significance

To what extent is the difference relevant ?

Clinical significance

Reliable change index

Reliable change

When a difference between two measurements falls beyond the range attributable to the measurement error of the instrument itself.

Clinically significant change

When the patient 's score moves away from the dysfunctional population range and comes closer to the functional population range.

Do patients improve after short psychiatric admission ?

A cohort study in Italy

Total BPRS score					
Diagnosis	N	Admission	Discharge	ES	p*
Substance abuse	22	49.8 (13.7)	37.7 (10.1)	0.99 (0.4/1.6)	0.00
Schizophrenic disorder	72	57.1 (19.7)	43 (14.2)	0.81 (0.5/1.1)	0.00
Bipolar disorder	33	53.9 (18.1)	41 (12.4)	0.83 (0.3/1.3)	0.00
Depressive disorder	19	46.5 (13.1)	38.6 (10)	0.67 (0.0/1.3)	0.00
Neurotic disorder	11	45.7 (11.1)	36 (9.4)	0.94 (0.1/1.8)	0.01
Personality disorder	36	49.5 (12.5)	40.3 (9.7)	0.81 (0.3/1.3)	0.00
Other	13	62 (16.3)	54.1 (16.5)	0.46 (-0.3/1.2)	0.05
TOTAL	206	53.2 (17)	41.5 (12.9)	0.80 (0.6/1)	0.00

Do patients improve after short psychiatric admission ? A cohort study in Italy

BPRS total score

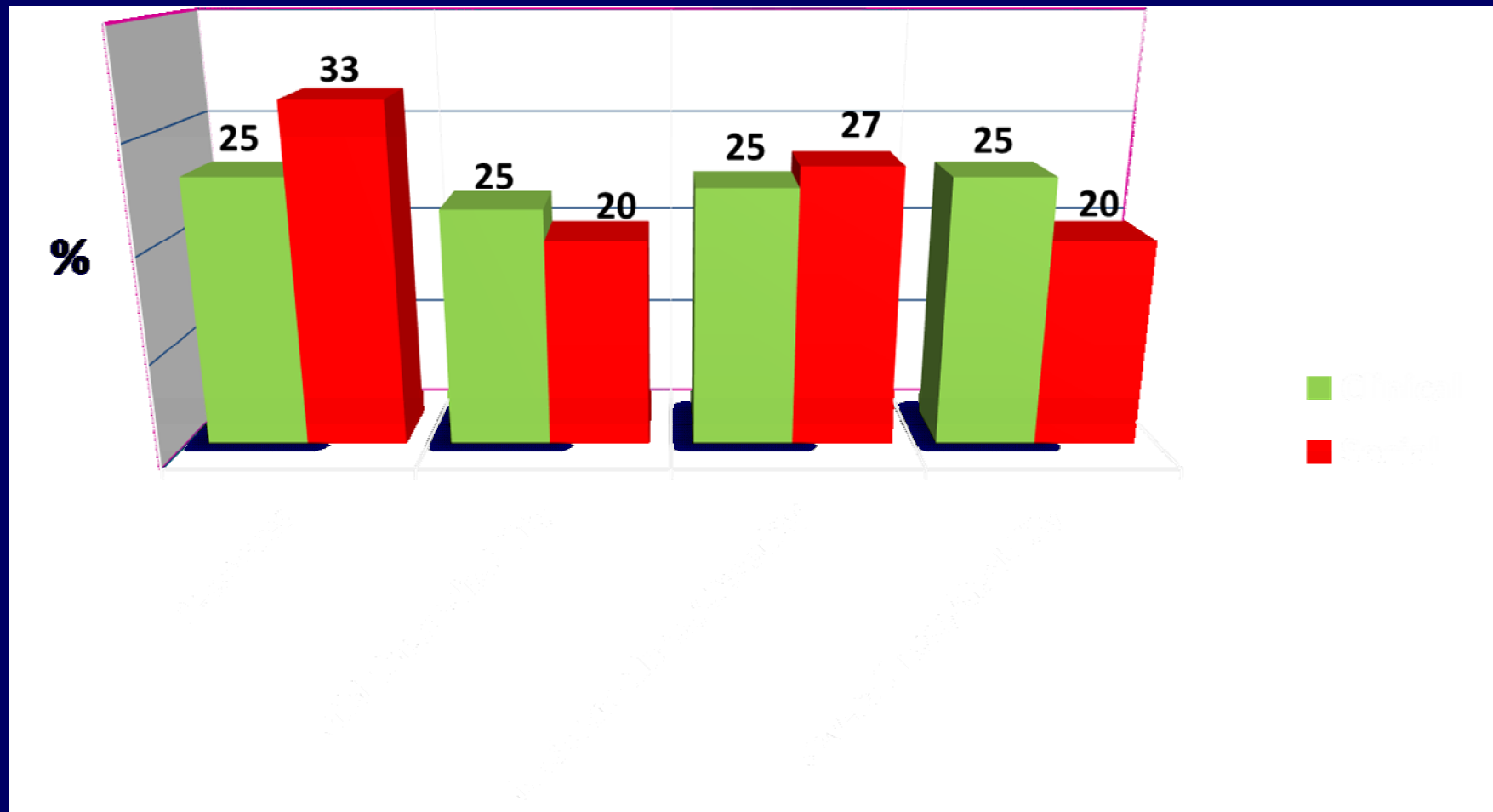
Reliable Change Index *18 points*

Threshold of clinically significant change *38 points*

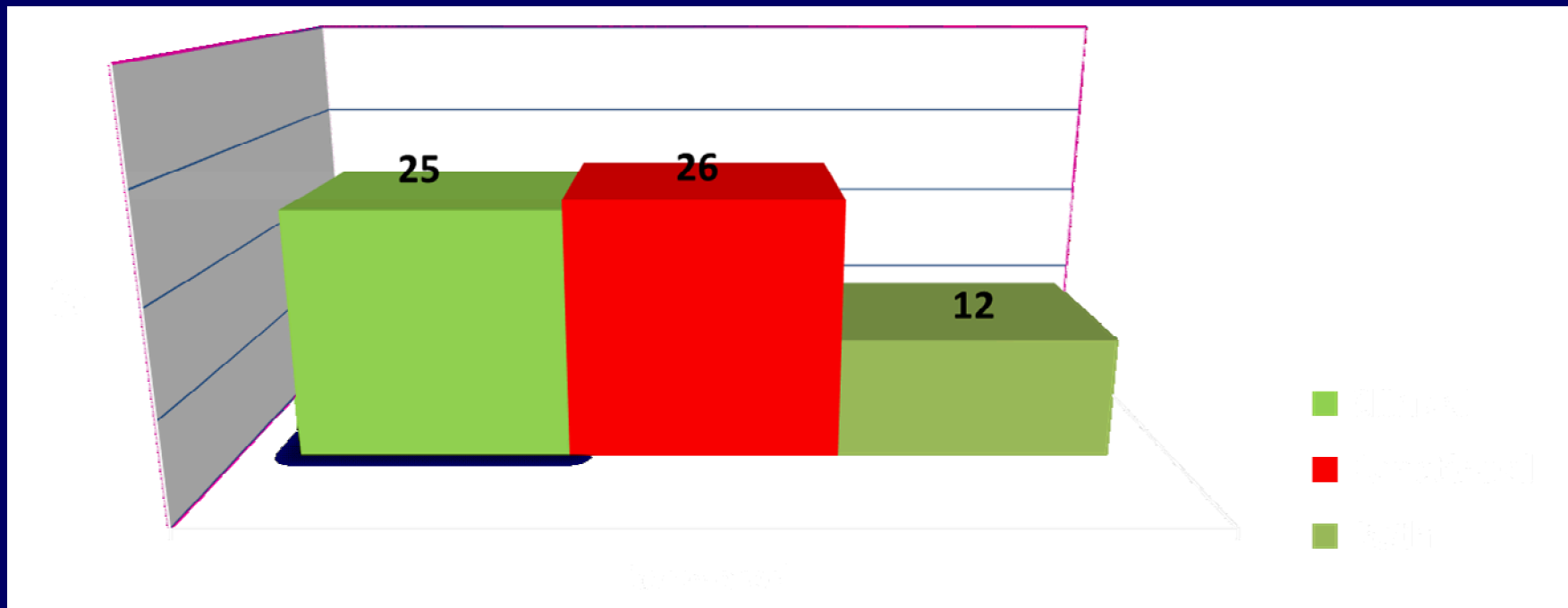
Clinically significant change in patients (n=206)		
	N	%
Reliable deterioration	3	1.5
No reliable change	73.8	152
Reliable change	23	10.1
Clinically significant change	28	13.6

A Barbato et al Nordic Journal of Psychiatry 2011, in press

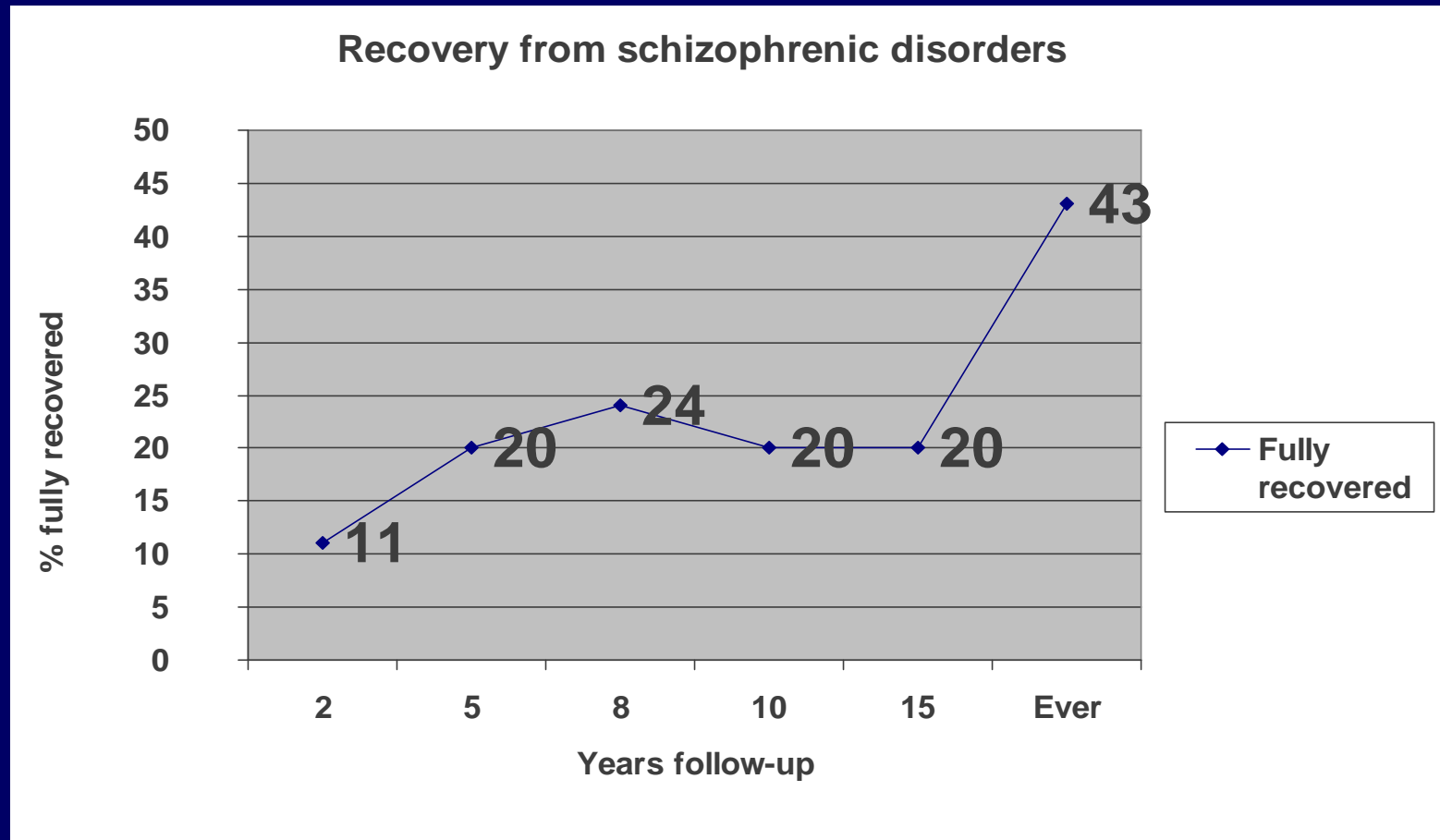
Outcome of schizophrenic disorders 5-year Bali follow-up study



Outcome of schizophrenic disorders 7-year Melbourne follow-up study



Outcome of schizophrenic disorders Chicago follow-up study



Harrow et al Schizophrenia Bulletin 2005

Outcome of long-stay patients after closure of a mental hospital

Question

Can long-stay patients with severe mental disorders live successfully in the community after discharge from mental hospital ?

Design

Prospective observational cohort study with pre-post patients' assessment and postdischarge monitoring of adverse events

Outcome dimensions and measures

Dimension

Psychopathology

Social disability

Residential stability

Acute hospital admission

Death

Measure

BPRS score

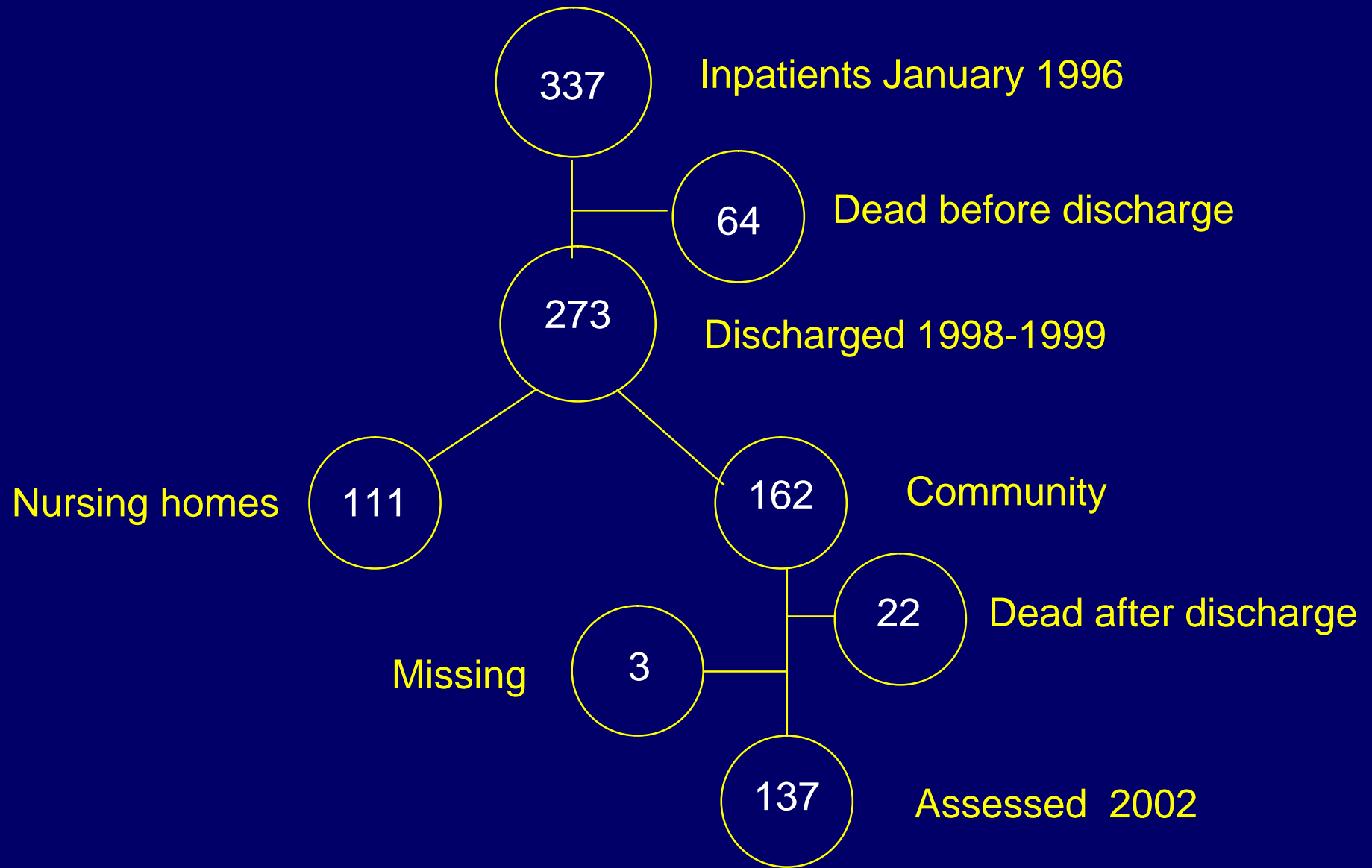
DAS score

Number in community at FU

Admission rate, bed days

Mortality rate

Patients' pathways



Baseline sample characteristics

	All inpatients		Discharged patients	
	N	%	N	%
Gender				
Male	179	53	96	59
Female	158	47	67	41
Age (years)				
<40	4	1	1	1
40-49	53	16	31	19
50-59	81	24	53	33
• 60	199	59	78	47
Mean (SD)	62(12)		58.9(9.3)	
Length of stay (years)				
<20	51	15	36	22
20-29	80	24	51	31
• 30	206	61	76	47
Mean (SD)	32.8 (12.1)		28.3 (9.9)	
Diagnosis				
Schizophrenia and other psychoses	167	49	95	58
Personality disorder	8	2	6	4
Mood disorder	16	5	12	7
Mental retardation	95	28	34	21
Substance abuse	17	5	5	3
Organic mental disorder	35	11	11	7

3-year follow-up of discharged patients: Outcome dimensions (n = 163)

<i>Outcome</i>	<i>Result</i>
Residential stability	79% in the same place 96% in the community
Acute inpatient admission	21% admitted 7% annual admission rate 700 inpatient days 0,7 daily bed occupancy
Mortality	22 deaths 4,4% annual death rate

Symptom severity

Brief Psychiatric Rating Scale scores

(n = 137)

	Baseline		Follow-up	
	N	%	N	%
Low	27	20	24	18
Moderate	80	58	95	69
High	30	22	18	13
Mean (SD)	51.3 (17.6)		49.5(14.7)	
	ES 0.11 (IC 0.37; -0.12)			

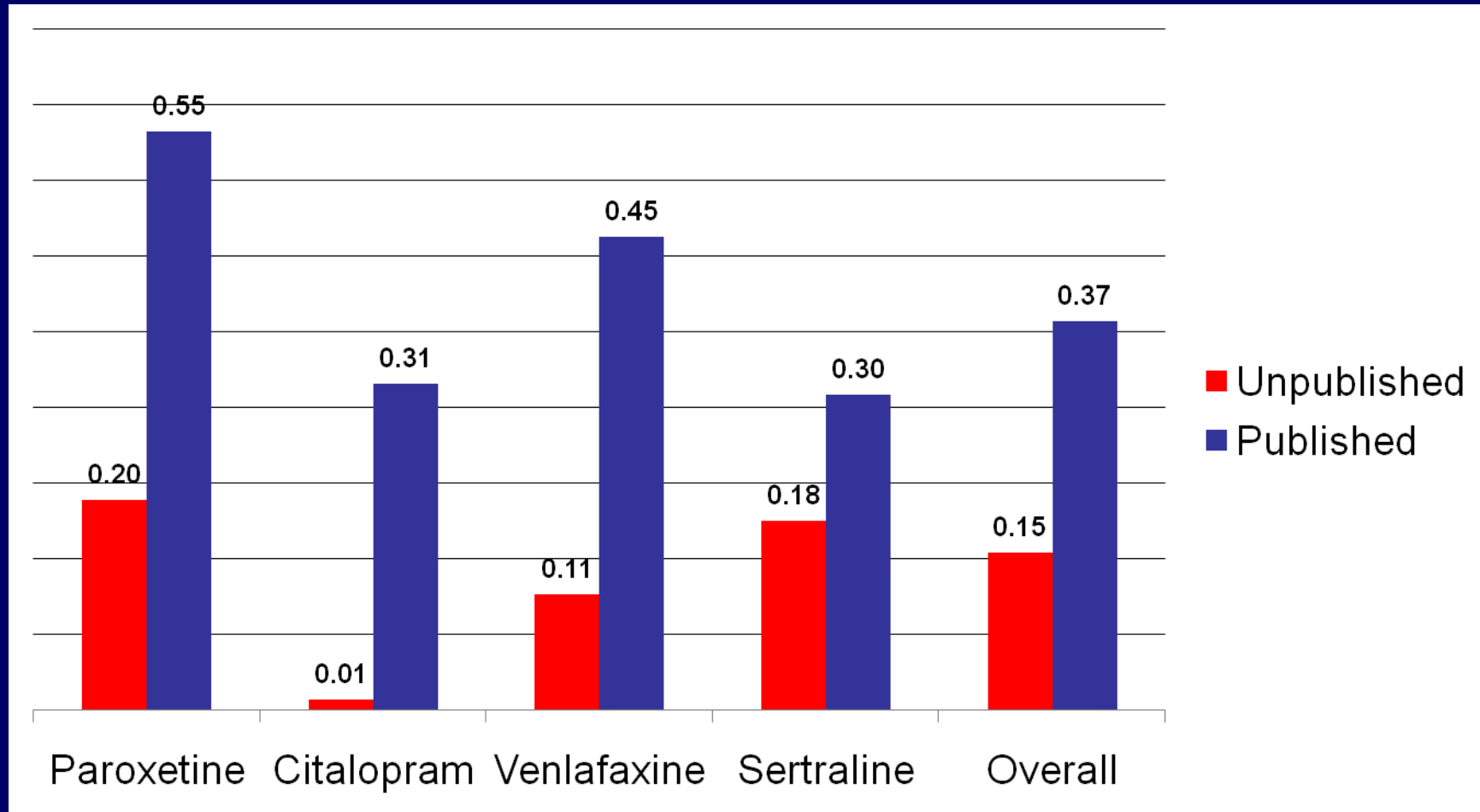
Levels of disability

DAS Overall Behavior and Social Role Performance scores (n = 137)

	DAS-Overall Behavior				DAS-Social Role Performance			
	Baseline		Follow-up		Baseline		Follow-up	
	N	%	N	%	N	%	N	%
Mild	48	35	68	50	22	16	38	28
Moderate	61	45	44	32	52	38	46	34
Severe	28	20	25	18	63	46	53	39
Mean (SD)	1.30 (0.83)		1.18(1.02)		1.80(0.94)		1.59(1.05)	
	ES 0.13 (IC 0.37; -0.11)				ES 0.21 (IC 0.45; -0.03)			

Antidepressant drugs-placebo difference

Effect sizes according to trials publication status



Discontinuation of antidepressant drug therapy in real world practice

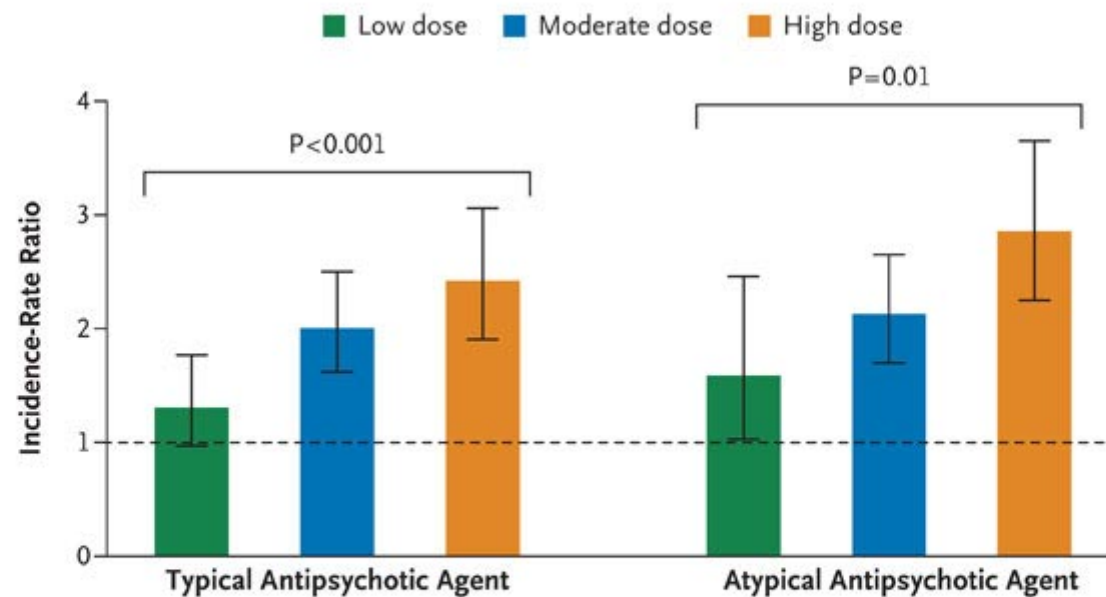
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Recovery and remission in schizophrenia by drug treatment strategies

7-year follow-up (n=103)

	No. (%)	
	Dose reduction/discontinuation (n=52)	Maintenance treatment (n=51)
Recovery*	21 (40.4)	9 (17.6)
Remission		
Symptomatic	36 (69.2)	34 (66.7)
Functional**	24 (46.2)	10 (19.6)
Neither	13 (25)	16 (31.4)
*p 0.004 **p 0.01		

Incidence of sudden cardiac death in relation to antipsychotic drug treatment Tennessee (USA) 1990-2005



No. of Deaths	46	104	105	22	108	93
No. of Person-Years	21,438	33,671	31,626	10,435	41,513	27,641
Incidence-Rate Ratio	1.31	2.01	2.42	1.59	2.13	2.86
95% CI	0.97-1.77	1.62-2.50	1.91-3.06	1.03-2.46	1.70-2.65	2.25-3.65

Outcome of anorexia nervosa by age at onset

119 patient series (n=3,009)

	% Subjects by age at onset	
	Adolescents	Adults
Death	1.8	5.9
Recovery	57.1	44.2
Improvement	25.9	30.7
Chronicity	16.9	23.5

What does evidence of efficacy mean ?

Examples from drug treatment - 1

Therapy of acute mania
Short term symptom remission rates
13 controlled trials

Antipsychotics and/or mood stabilizers		Placebo	
N	%	N	%
868/1713	51% (45-56%)	506/1716	29% (21-36%)
Relative Benefit Increase 75% Absolute Benefit Increase 22% NNT 5			

What does evidence of efficacy mean ?

Examples from drug treatment - 2

Therapy of schizophrenia
Clinically significant improvement rates
12 controlled trials

Any antipsychotic drug		Placebo	
N	%	N	%
266/880	30% (18-80%)	75/644	12% (0-33%)
Relative Benefit Increase 150% Absolute Benefit Increase 18% NNT 6			

Controlled trials of family intervention in schizophrenia (n=53)

Relapse risk 1 year after remission from an acute episode

Family Intervention+Standard Care		Standard Care	
N	%	N	%
290/1488	19% (3-57%)	513/1493	34% (9-67%)
Relative Benefit Increase 55% Absolute Benefit Increase 15% NNT 7			

Controlled trials of vocational rehabilitation (Individual Placement and Support) (n=11)

Employment rate during 1-2 year follow-up

Individual Placement and Support		Standard care	
N	%	N	%
475/812	61% (27-78%)	186/811	23% (7-40%)
Relative Benefit Increase 165% Absolute Benefit Increase 38% NNT 3			

Outcome studies of anti-stigma programs (n=79, 38364 cases)

Reduction of stigmatizing attitudes/behaviors

	Attitudes		Behaviors	
	All studies	Controlled studies (n=13)	All studies	Controlled studies (n=13)
	Dimensione dell'effetto			
Education	0.31	0.21	0.25	0.19
Contact	0.21	0.63*	0.10	0.27

Outcome studies of supported housing (n=18, 7954 cases)

Effect on various outcome indicators

	Dimensione dell'effetto
Residential stability	0.63
Hospital admission	0.72
Psychopathological symptoms	0.08
Consumer satisfaction	0.73

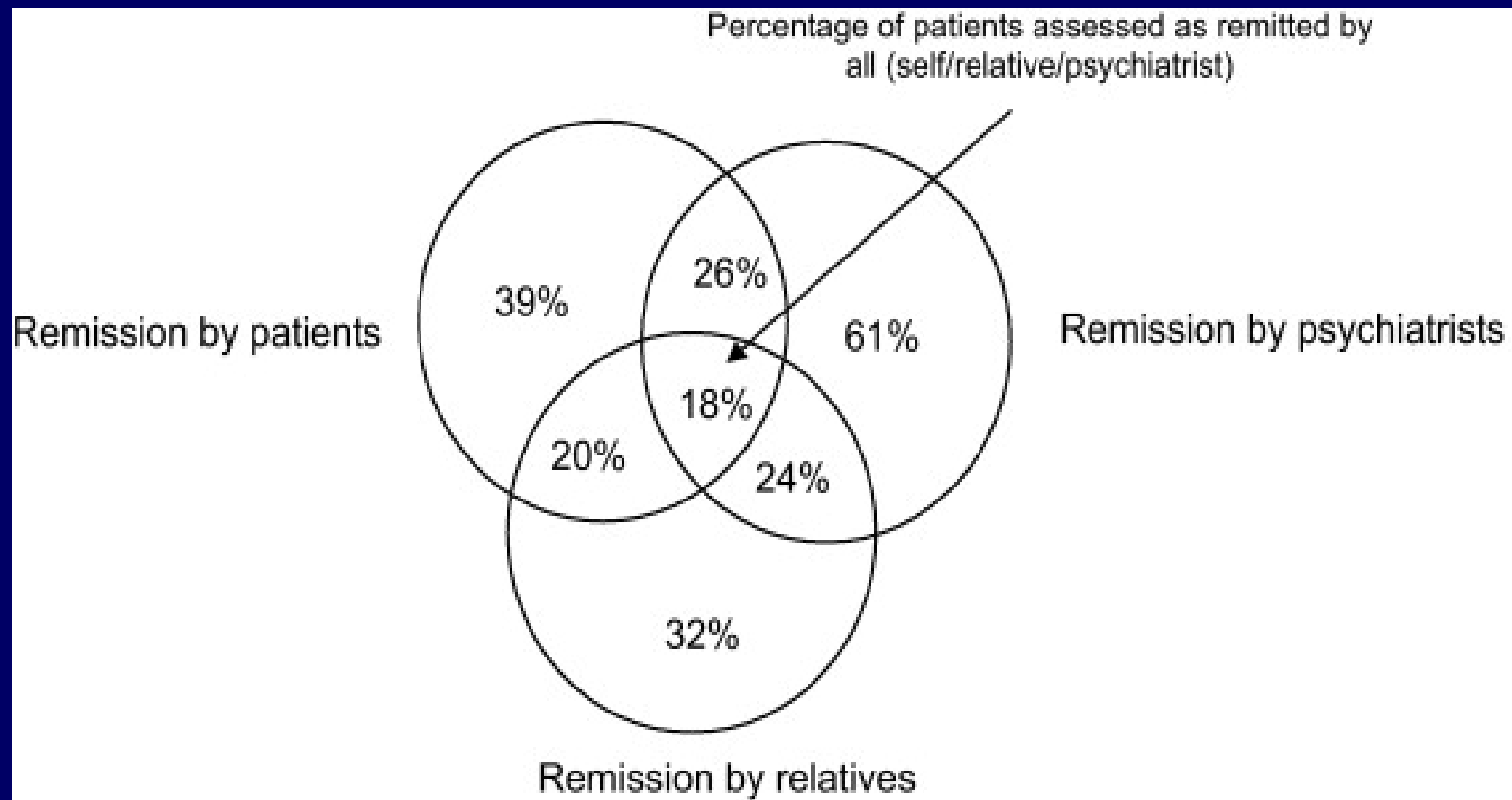
Consumer outcome research

Studies in real-world settings of endpoints of health practices, processes and interventions in unselected groups of people, by shifting the focus from biomedical or clinical measures to outcomes that matter most to consumers. End results include effects that people experience and care about, such as change in the ability to function, quality of life and general wellbeing.

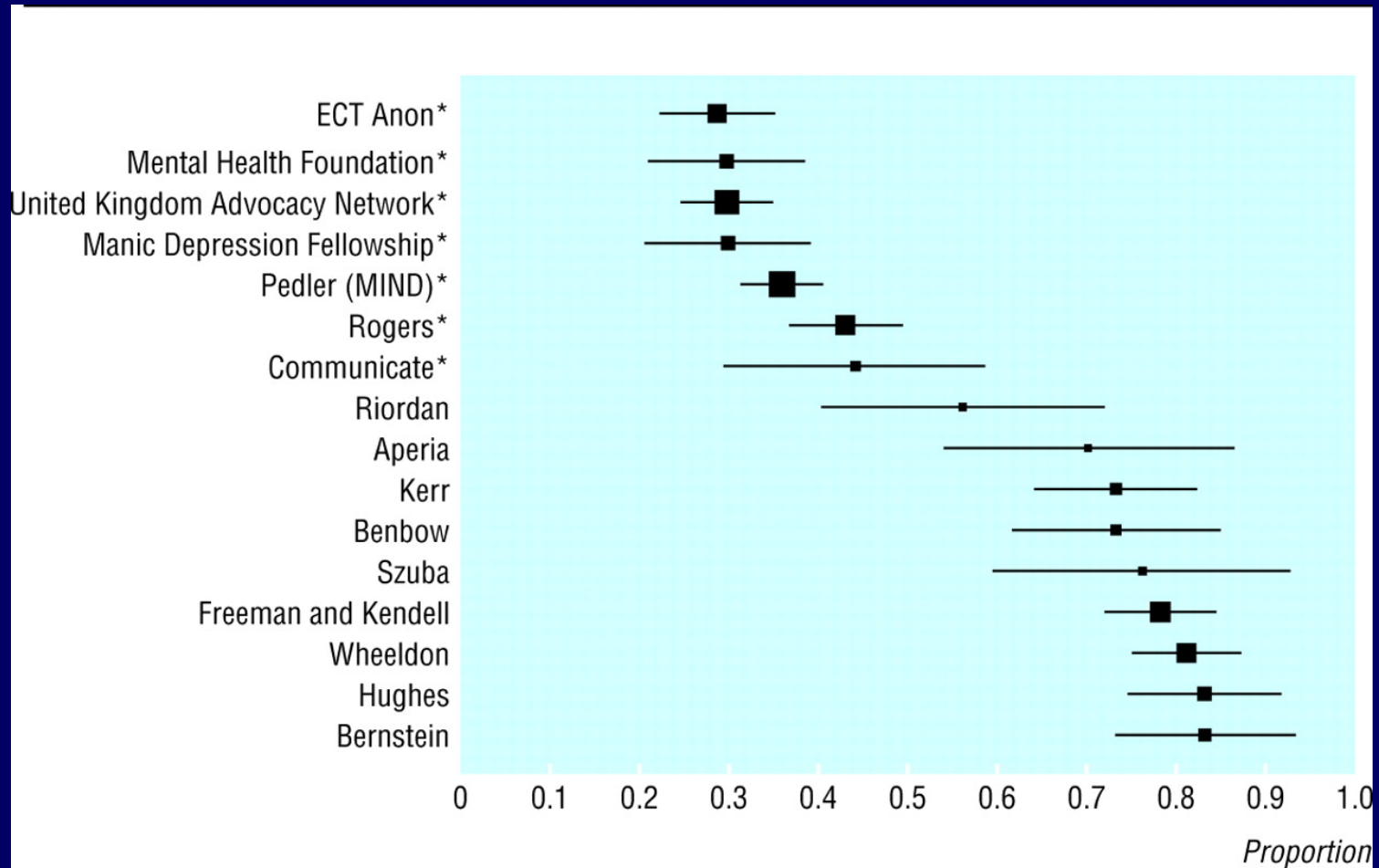
In mental health standardized instruments traditionally define illness severity and change through symptom-based measures, i.e. by counting the number and severity of symptoms and signs. By contrast, consumer-based measures assess the impact of a disorder on the individual.

Remission in schizophrenia assessed by self-rating, relatives and psychiatrists

(n=131)



Proportion of consumers who found ECT helpful by study



Quality assessment of mental health care by people with severe mental disorders (n=204, 34 areas assessed)

Area	% negative evaluation
Choice of professional	57%
Waiting times	35%
Information on illness	29%
Medication side effects	27%
Information on drugs	25%

Consumer preference

**Antidepressant drugs and counselling for treatment of major depression
in primary care: randomised trial with patient preference arms
(Chilvers et al, 2001)**

- q For randomized patients no difference between treatments**
- q Better results for patients choosing preferred treatment
irrespective of the chosen treatment**

Take home messages

Start with questions, not with answers

Make it easy

Look at resources available

Select cohorts

Set up an ongoing monitoring

Adequate time frame for assessment

Consider regression towards the mean

Look at differences

Ask consumers