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SEMINARIO REGIONALE

Programma regionale "Giuseppe Leggieri"

Integrazione tra NPIA e pediatria: attualità e prospettive

DEPICS Study

DEpression in Primary care: Interpersonal Counselling vs. SSRI

30 marzo 2011
9.15-13.30

Aula Magna
Viale Aldo Moro n. 30
Bologna

Studio multicentrico randomizzato e controllato

Coinvolgimento di 9 centri universitari (Bologna centro coordinatore)

Progetti di collaborazione con Psi-MG a livello locale

La presente ricerca è stata finanziata dal Ministero dell'Università e della Ricerca come Programma di Ricerca di Rilevante Interesse Nazionale 2005

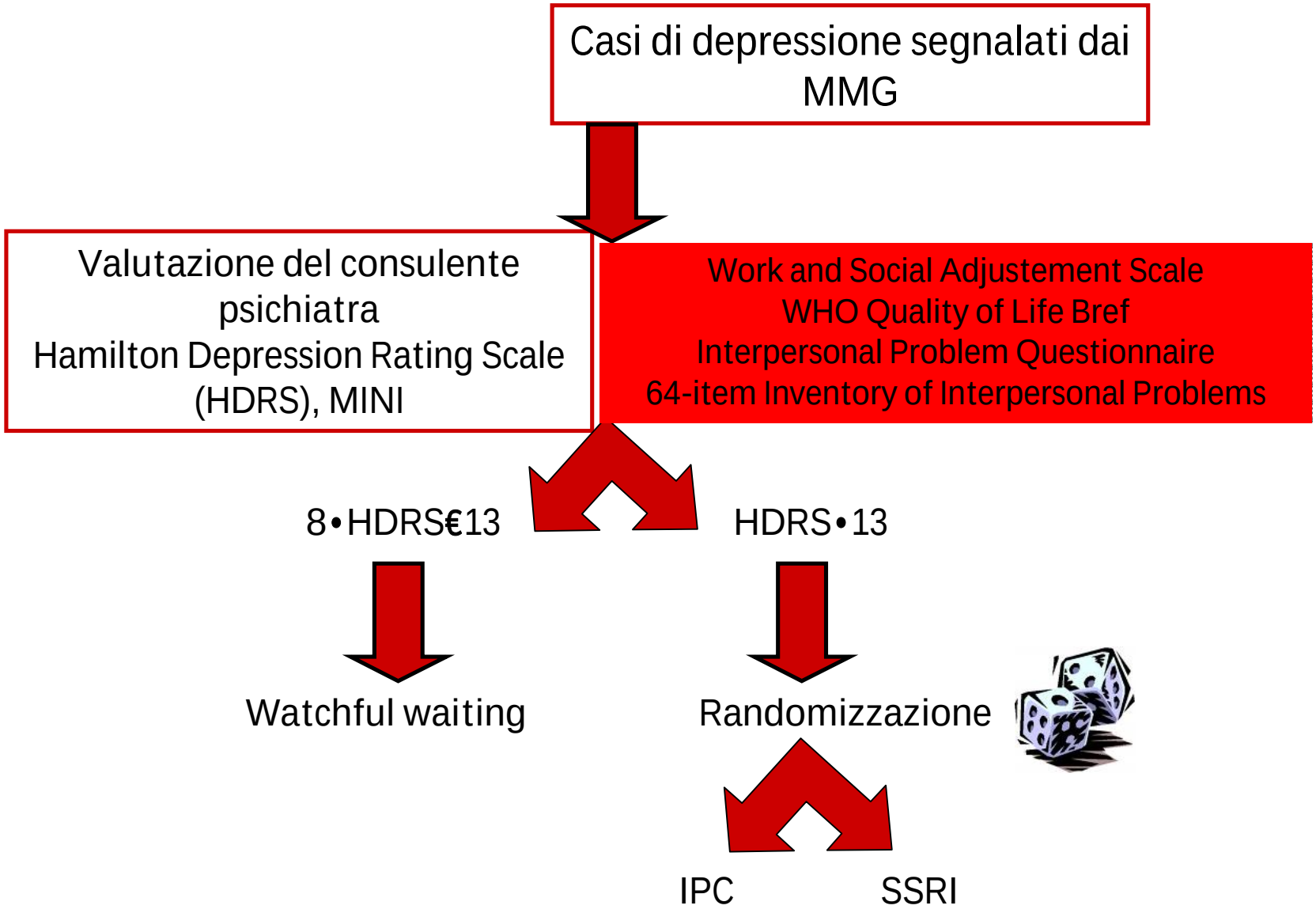
PRIN

Obiettivi dello studio

- Comparare il Counseling Interpersonale (IPC) con i farmaci SSRI nel trattamento della depressione in medicina generale
  - ü Outcome primario: remissione della sintomatologia depressiva a 2 mesi (HDRS score < o =7)
  - ü Outcomes secondari: miglioramento del funzionamento a 6 mesi (WSAS), recidiva ad 1 anno (MINI + scheda anamnestica)

- Inoltre lo studio intende valutare l'efficacia di una strategia di combinazione (IPC+SSRI) nei pazienti che non rispondono alla monoterapia

Disegno dello studio



Menchetti et al. BMC Psychiatry 2010, 10:97
http://www.biomedcentral.com/1471-244X/10/97

BMC Psychiatry

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

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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 ≥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 ≤ 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 ACTRN12608000479303

Interpersonal Counselling (IPC)

- IPC è un intervento psicologico breve manualizzato (Weissman & Klerman, 1983) che deriva dalla Interpersonal Psychotherapy (IPT)

INTERPERSONAL COUNSELING (IPC) FOR STRESS AND DISTRESS IN PRIMARY CARE SETTINGS

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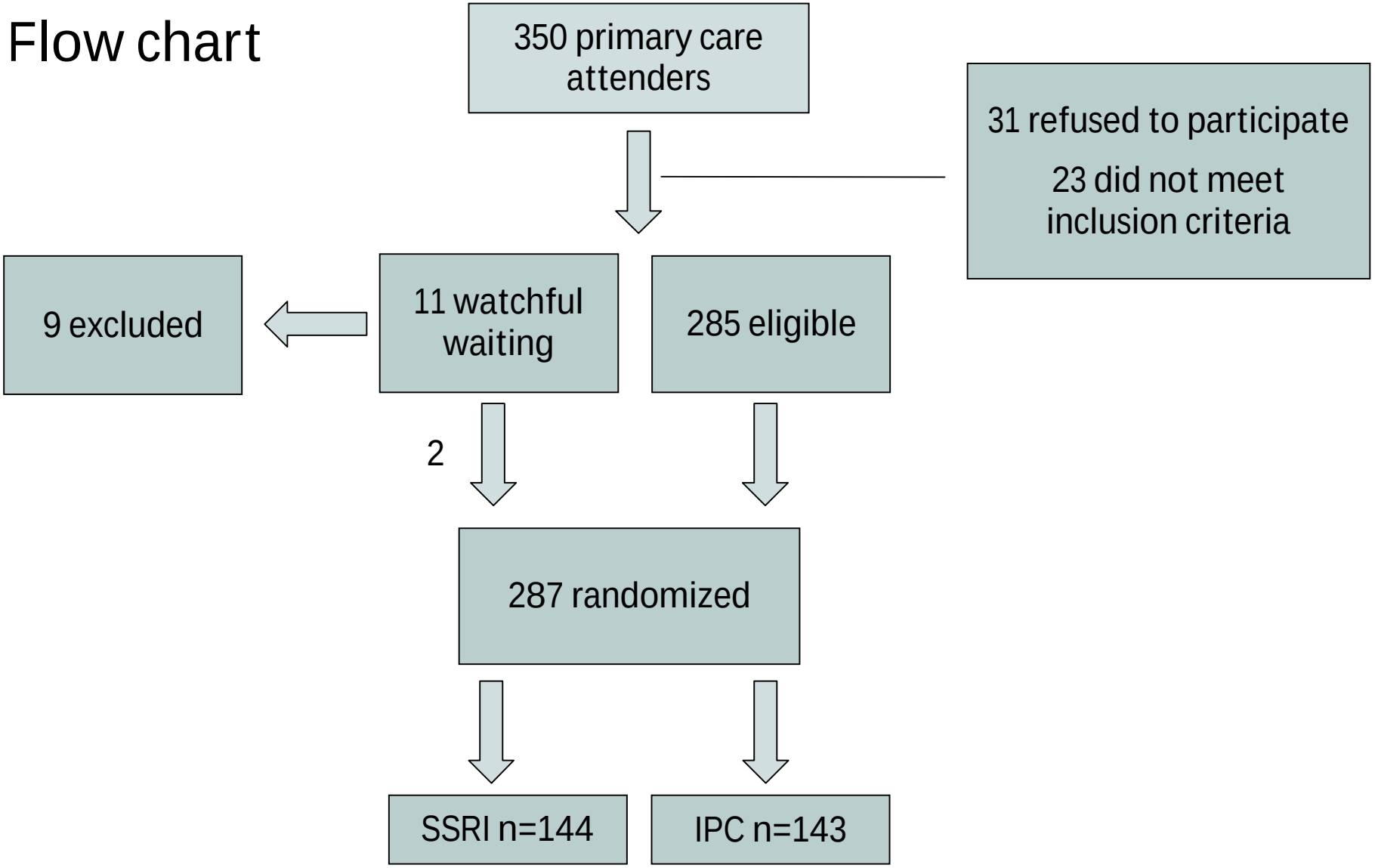
- Revisione della letteratura: IPC è stato utilizzato in 7 RCTs (pubblicati 1996-2010), adattato e testato per diverse situazioni cliniche (distress dopo traumi fisici maggiori, aborto spontaneo, tumore al seno) o disturbi mentali (depressione sottosoglia nell'anziano, depressione maggiore in associazione con AD).
- Finalità: aiutare i pazienti a identificare strategie efficaci per affrontare problemi interpersonali
- Prima sessione iniziale di 1 ora + 5-6 sessioni di 30-40 min
- Formazione per 18 terapeuti (psichiatri e psicologi in formazione, counsellors): seminario di 2 giorni + gruppo di supervisione mensile con discussione di casi clinici video registrati

DEPICS Study

Flow chart

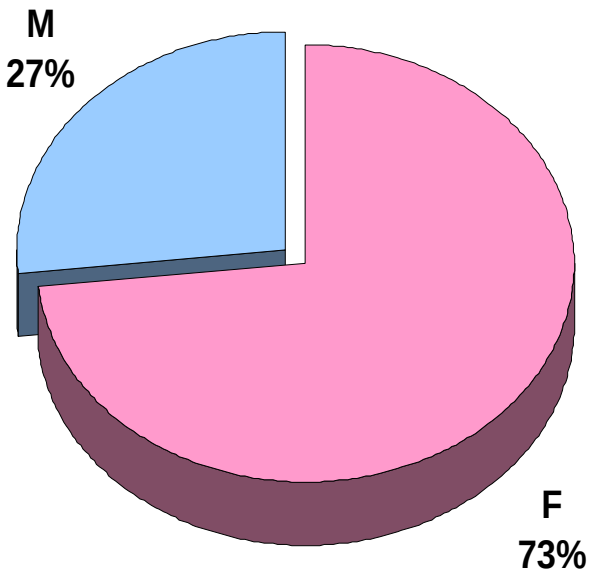


Caratteristiche demografiche e cliniche del campione

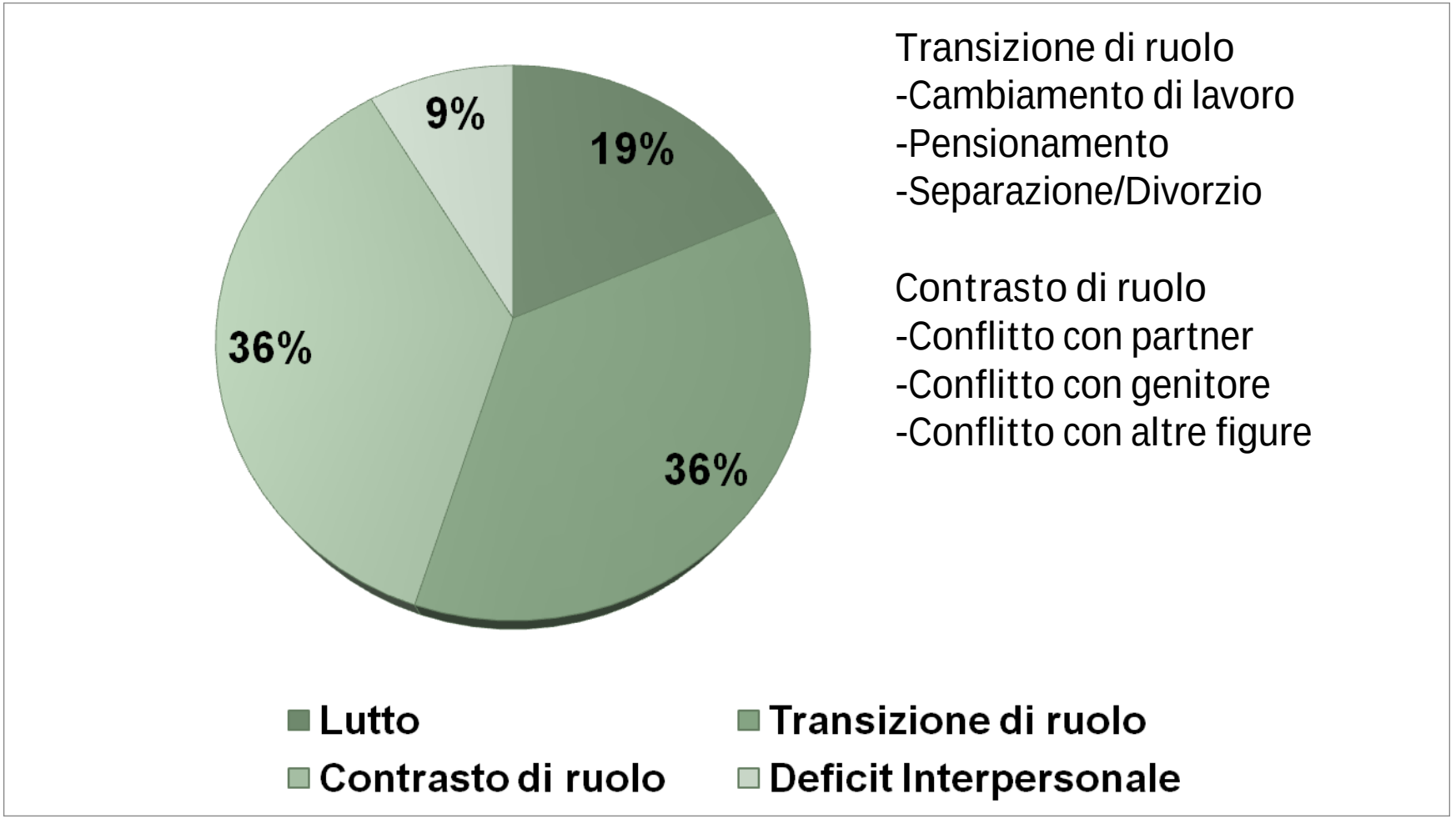
- Età media = 44.9 ± 14.1 (range 20-87)
- Livello di scolarizzazione: diploma 40.4%, laurea 13.9%
- Stato civile: coniugato 58.0%, single 28.2%, separato 15.3%
- Lavoro: occupato 57.8%, casalinga 13.8%, pensionato 13.8%
- Senza occupazione 7.3%

- Comorbidità con malattie fisiche 61.6%

- Punteggio medio HDRS = 17.4 ± 3.4 (range 13-29)
- Primo episodio di depressione = 38.3%
- Disturbi d'ansia in comorbidità = 19.9%



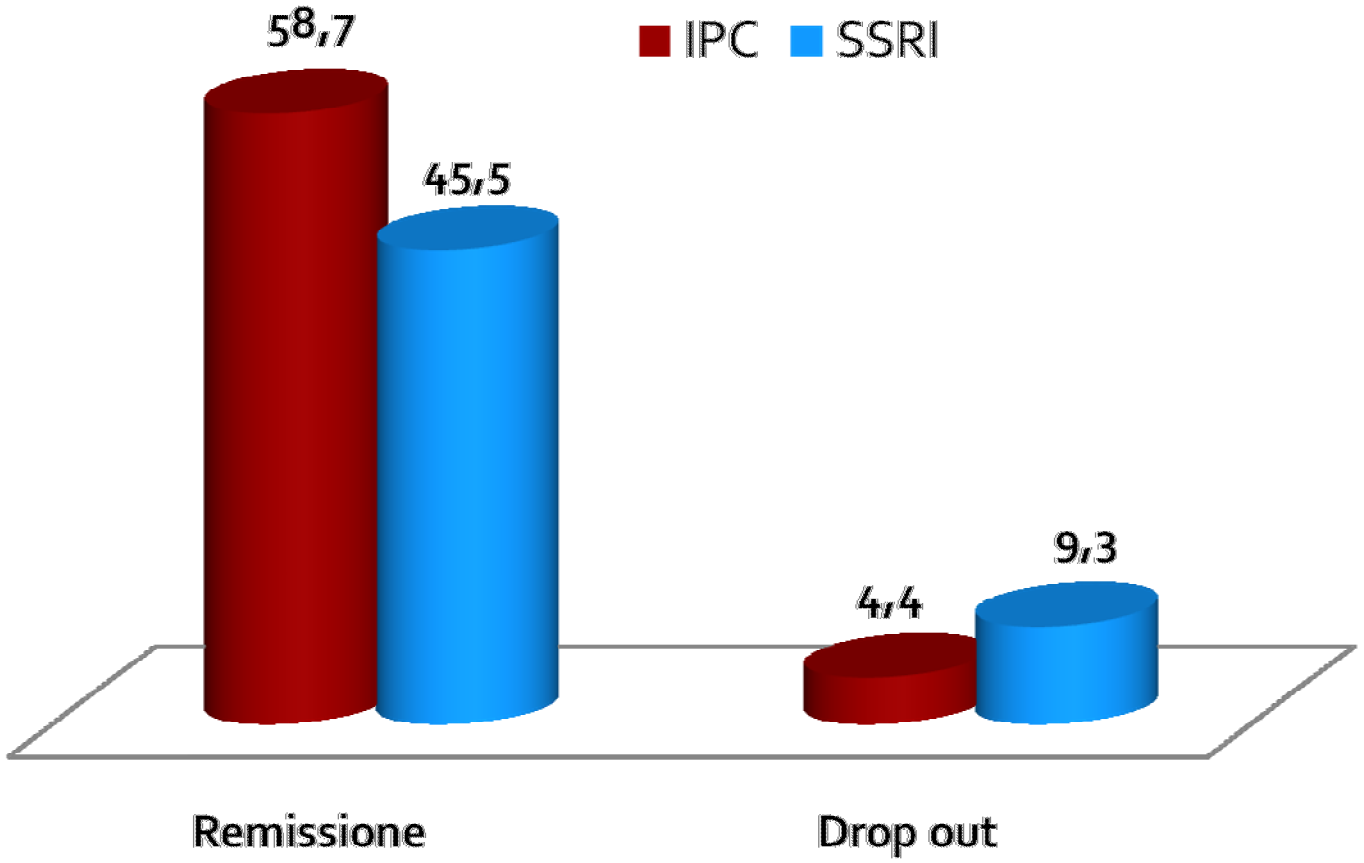
Prevalenza dei Problemi Interpersonali nei pazienti depressi divisi per le 4 aree



Transizione di ruolo
-Cambiamento di lavoro
-Pensionamento
-Separazione/Divorzio

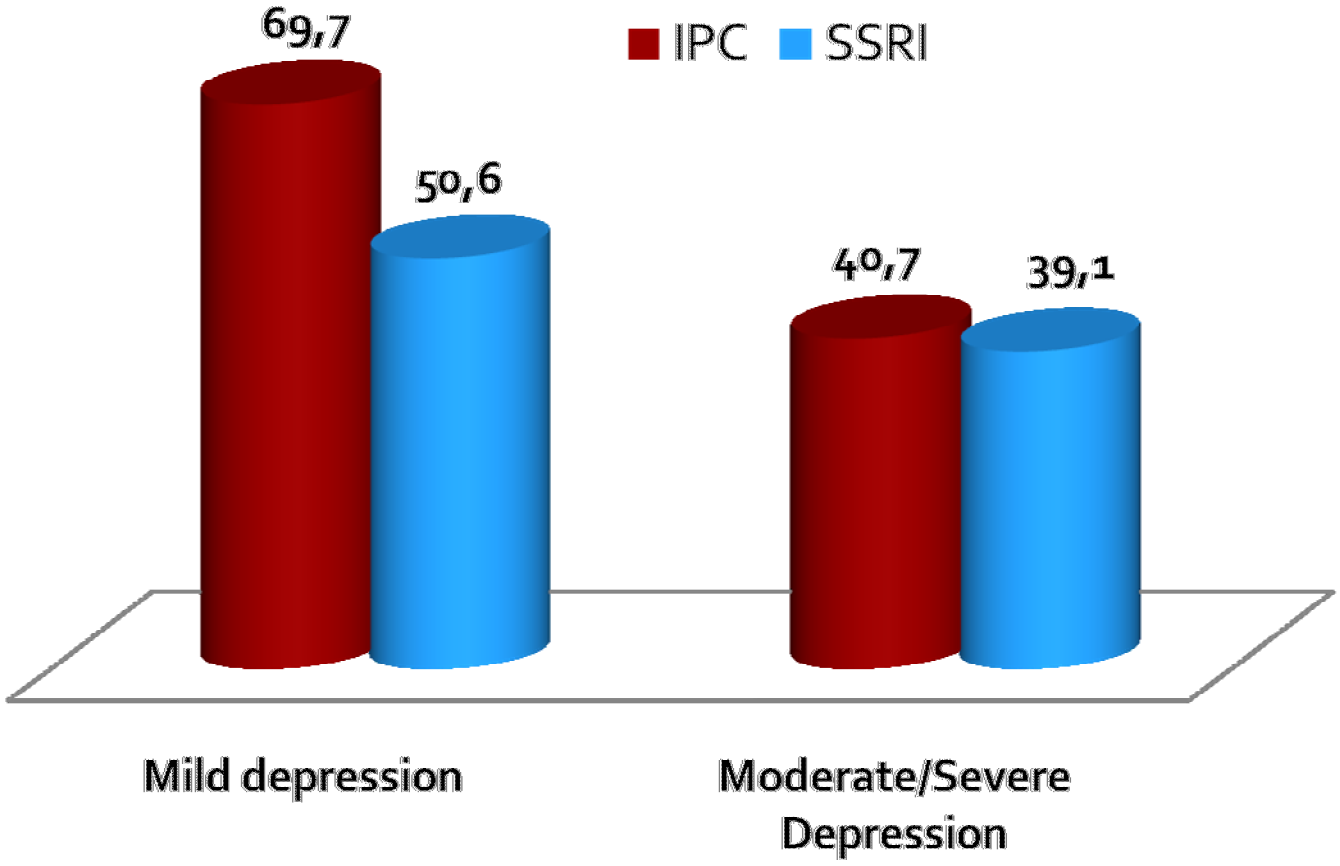
Contrasto di ruolo
-Conflitto con partner
-Conflitto con genitore
-Conflitto con altre figure

Tassi di remissione e drop out a 2 mesi



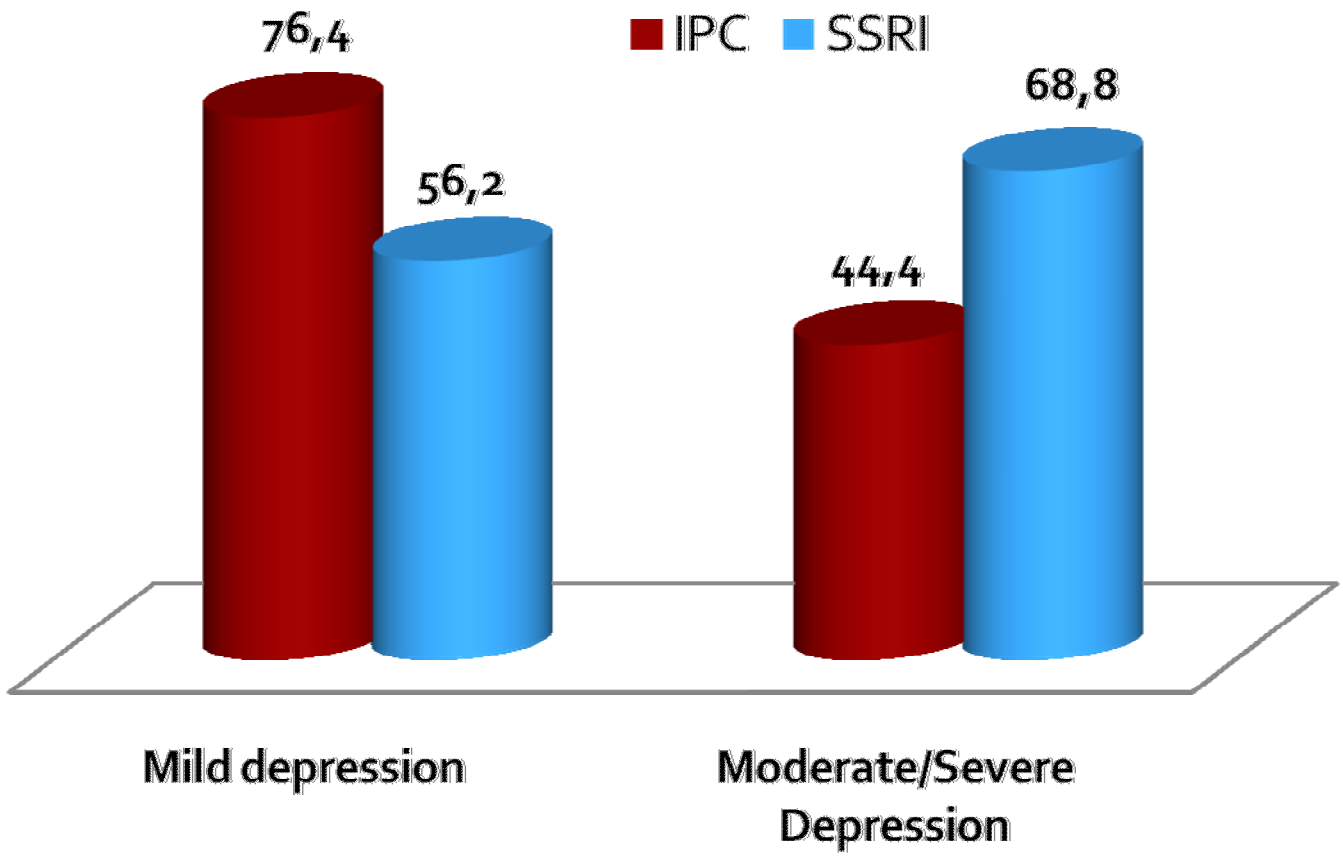
p=0.021

Tasso di remissione a 2 mesi per severità della depressione



p=0.013

Tasso di remissione a 6 mesi per severità della depressione



Dialogues in Clinical Neuroscience

Clinical research

Predictors, moderators, and mediators (correlates) of treatment outcome in major depressive disorder

George I. Papakostas, MD; Maurizio Fava, MD

•A predictor of treatment (efficacy) outcome can involve factors (whether clinical or biologic), the presence or magnitude of which influences the likelihood of a particular outcome occurring during treatment.

•Differential predictors or moderators of efficacy outcome are a special subcategory of outcome predictors. Moderators of outcome involve factors (clinical or biologic), the presence or magnitude of which influences the relative likelihood of a particular outcome occurring following treatment with one versus another agent. Thus, moderators of response can help predict differential efficacy between two or more treatments for MDD (for example, patients who present with a given moderator are more likely to respond to treatment with one antidepressant versus another than patients who do not present with that given moderator).

•Mediators of efficacy outcome are measurable changes (usually biologic) that occur during treatment and correlate with treatment outcome.

• Identification of factors which are simple predictors of treatment outcome would allow for the stratification of patients according to risk for treatment-resistance, which, in turn, could lead to the development of tailored approaches that would improve overall treatment outcome (ie, choosing a more "aggressive" treatment a priori).
• Identification of moderators (ie, differential predictors) of treatment outcome may lead to the development of tailored treatment approaches (algorithms) for a given subgroup of MDD patients that would improve treatment outcome (ie, matching treatment with MDD subtype).
• Predictive or nonpredictive mediators (correlates) of treatment outcome may provide mechanistic insights into the underlying pathophysiology of MDD, thereby helping identify new molecular targets for drug development or for defining clinically relevant subgroups.
• Predictive or nonpredictive mediators (correlates) of treatment outcome may be used in screening for potential new antidepressants (for example, selecting pharmacologic agents that also result in similar changes in clinical or preclinical models).

Table II. Potential clinical, scientific and treatment development applications of predictors, moderators and mediators of treatment outcome in Major Depressive Disorder.

Non-specific predictors and moderators of remission by 2 months of treatment. ITT SAMPLE (N=264 excluding one site).

Odds ratio from logistic regression models. OR>1 in the predictor column indicate a better outcome regardless of treatment assignment. OR>1 in the moderator column indicate a better outcome with IPC.

	Predictor OR (95% CI)	Effect size	Moderator OR (95% CI)	Effect size
Unmarried	1.854 (1.077-3.192)	0,34		
Baseline HDRS score, <17	2.545 (1.421-4.556)	0,52	3.374 (1.052-10.815)	0,67
WSAS score, <20	1.790 (1.012-3.168)	0,32	3.830 (1.223-11.994)	0,74
First episode of depression, yes			6.671 (1.648-27.004)	1,05
No comorbid anxiety disorder			4.349 (1.120-16.888)	0,81
No/mild physical illness	2.199 (1.182-4.090)	0,44		
Smoking			3.408 (1.055-11.013)	0,68

Moderatori di remissione a 2 mesi di trattamento

Primo episodio di depressione

Mild depression (HDRS<17)

Lieve compromissione del funzionamento

Assenza di disturbi d'ansia in comorbidità

Presenza di un pregresso episodio depressivo

Moderate to severe depression (HDRS•17)

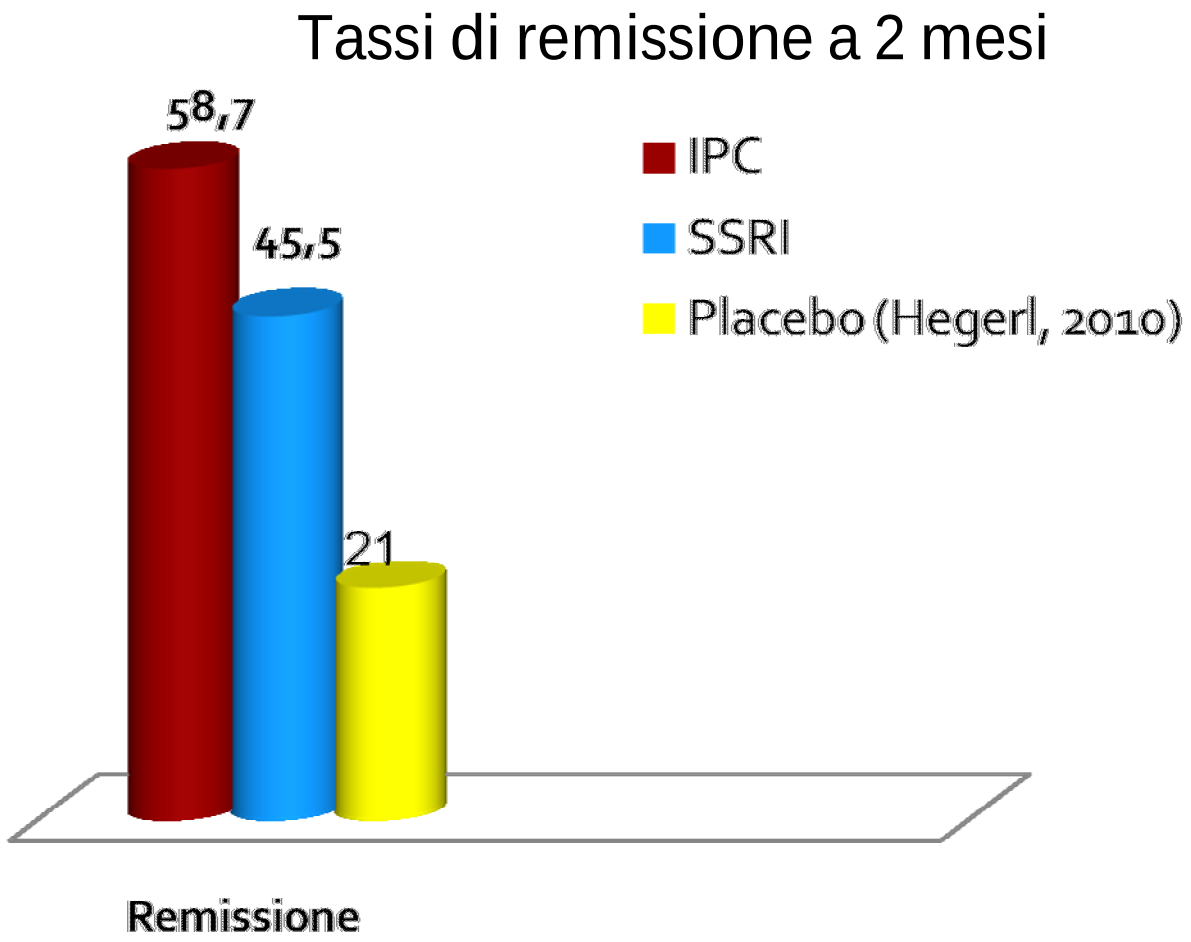
Moderata compromissione del funzionamento

Presenza di disturbi d'ansia in comorbidità

Limiti dello studio

1)Dati non generalizzabili a forme ricorrenti/croniche

2)Mancanza di braccio placebo



Conclusioni

- IPC appare un opzione di trattamento efficace per la depressione in medicina generale, superiore agli antidepressivi SSRI nei pazienti con depressione lieve nel breve e lungo termine
- La valutazione di alcuni parametri relativamente semplici – gravità della sintomatologia depressiva, anamnesi positiva per depressione e comorbidità con disturbi d'ansia – può dare indicazioni sulla scelta del trattamento
- Pazienti con depressione lieve, al primo episodio e non complicati sono candidati ad un primo trattamento con IPC

Prospettive

- Richiesta di fondi al Ministero della Salute (Bando Ricerca Finalizzata) per studio di implementazione IPC (marzo 2009)
- Presentazione dati studio ed ipotesi implementazione alla International Conference on "Interpersonal Psychotherapy" (Amsterdam, June 23-24 2011)
- Corso base IPC nell'ambito della formazione interna DSM Bologna (autunno 2011)

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