

[Come scrivere un articolo scientifico]

.....e come pubblicarlo

Paola Rucci

*Dipartimento di Scienze Biomediche e Neuromotorie
Alma Mater Studiorum Università di Bologna*

1

[Perche' scrivere e pubblicare?]

- Uno studio non pubblicato e' come uno studio non fatto
- Rendere uno studio accessibile a tutta la comunita' scientifica
- Accrescerne l'impatto (health policy)
- Abituarsi alla sintesi delle informazioni rilevanti

2

[La ricerca scientifica]



3

Rem tene, verba sequuntur....

Attribuita a Catone (o Cicerone)

Forse tratta dall'Art rethorica di Giulio Vittore



4



5

[Le caratteristiche di un buon articolo]

- Aspetti di contenuto e stilistici
 - Revisione della letteratura aggiornata
 - Completezza dell'informazione
 - Omogeneità della scrittura delle varie parti

6

[Revisione della letteratura]

- PubMed
 - <https://www.ncbi.nlm.nih.gov/pubmed>
- PsycINFO
 - <https://www.apa.org/pubs/index.aspx>

7

[Completezza dell'informazione]

- Citare sempre le fonti
 - Rintracciare sempre se possibile l'articolo originario
 - Se si utilizzano nello studio scale o strumenti di valutazione, citare sempre l'articolo di validazione dello strumento
 - Indicare il software utilizzato per le analisi statistiche

8

[Omogeneità della scrittura]

- L'articolo deve sembrare scritto da una sola mano e non un patchwork di pezzi scritti da varie persone
- Far tradurre in inglese un articolo pensato in italiano e' di solito un'idea poco felice (Italish....)

9

[Caratteristiche di un brutto articolo]

- L'autoreferenzialità e le citazioni unilaterali
- La mancanza di coerenza tra le parti
- La mancanza di un filo conduttore
- L'assenza di un chiaro 'messaggio' principale

10

[Caratteristiche di un brutto articolo]

- E' controproducente riportare molti risultati e molte analisi
 - Non è un risultato 'scientifico' avere condotto uno studio molto impegnativo
 - Più analisi si fanno, più aumenta il rischio di trovare risultati significativi per effetto del caso (errore di tipo I)

11

[Come scrivere un articolo originale]

Studi condotti in setting di cui si sa poco
Uso di metodi statistici innovativi

12

[Come scrivere un articolo originale]

-di solito, qualunque idea 'originale' e' già stata perseguita (con successo) da altri

13

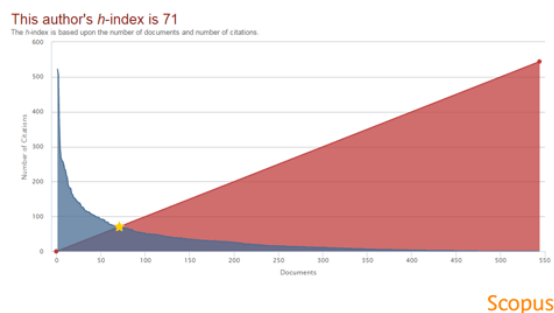
[L'impact factor (di una rivista)]

- A= Citazioni nel 2018 di articoli pubblicati nel 2016-2017 dalla rivista
- B= Numero totale articoli pubblicati dalla rivista X nel 2016-2017
- **IF= A/B**

14

[H-index (di una persona)]

- Un ricercatore ha un indice n se ha pubblicato almeno n lavori, ciascuno dei quali è stato citato almeno n volte.



15

[Publish or Perish]

<https://harzing.com/resources/publish-or-perish>

Eseguite una ricerca in Google scholar inserendo

‘cognome iniziali’ e intervallo degli anni per vedere l’ h -index personale e il numero di citazioni

16

[Leading journals]

	IF	% accettazione
N Eng J Med	79,258	8,75%
Lancet	53,254	5%
JAMA	47,661	11%

17

[Leading journals]

- Scegliere la rivista in base al ranking del settore
- Scimago Journal and Country ranks
 - Il primo quartile comprende le riviste più prestigiose
 - Pubblicare su riviste nel primo quartile ha un impatto importante sui finanziamenti e sulla carriera accademica
- Esempio: pediatria

<https://www.scimagojr.com/journalrank.php?category=2735>

18

[Tipi di articoli]

- Full-Length Research Papers (up to 5000 words, excluding references and up to 6 tables/figures)
- Review Articles and Meta-analyses (up to 8000 words, excluding references and up to 10 tables/figures)
- Short Communications (up to 2000 words, 20 references, 2 tables/figures)
- Correspondence (up to 1000 words, 10 references, 1 table/figure).

19

[La struttura dell'articolo]

- Abstract
- Introduzione
- Materiali e metodi
- Risultati
- Discussione

20

[L'ordine di stesura dell'articolo]

- Scopi
- Titolo
- Materiali e metodi
- Risultati
- Discussione
- Introduzione mirata
- Abstract

21

[Scopi]

- Devono essere formulati in modo chiaro e non generico
- Devono avere una rilevanza clinica o un impatto sulle politiche sanitarie

22

[Scopi]

- Tenere presente che il senso dello studio sta nella generalizzazione e nella replicabilità

23

[Scopi]

- We aimed to establish whether reinstitutionalisation is taking place and, if so, to what extent and with what variation between European countries

Reinstitutionalisation in mental health care: comparison of data on service provision from six European countries
Priebe et al., BMJ, 2005

24

[Scopi]

- We also wished to investigate whether reinstitutionalisation compensates for the loss of conventional psychiatric hospital beds and how it compares against changes in the general prison population.

Reinstitutionalisation in mental health care: comparison of data on service provision from six European countries
Priebe et al., BMJ, 2005

25

[Scopi]

- The aim of this study was to estimate the prevalence of multimorbidity in a Northern Italian region, to investigate its distribution by age, gender and citizenship and to analyse the correlations of diseases.

Lenzi et al., BMJ Open 2016;6: e012812.

26

[Scopi]

.....we investigated the association between 5HTTLPR genotype and development of insomnia and agitation, adverse effects that could be confused with, or contribute to, antidepressant-induced mood elevation.

Perlis et al, 2003

27

[La scelta del titolo]

- Titoli che forniscono la variabile indipendente, la dipendente e la popolazione
- Titoli formulati come domanda
- Titoli che danno una risposta

28

[Titoli con variabile indipendente,
dipendente e popolazione]

- | | x | y |
|---|-------------------------|-------------------------------|
| ■ | Effect of asthma | on linear growth in children |
| ■ | Asthma | and linear growth in children |
| ■ | Final height attainment | of asthmatic children |

$$y=f(x)$$

29

[Titoli formulati come domanda]

- Does asthma reduce linear growth?
- Are asthmatic children shorter than non-asthmatic children?

30

Titoli che danno una risposta

- Asthma is negatively associated with growth in height during adolescence
- Linear growth deficit in children

31

Il disegno dello studio

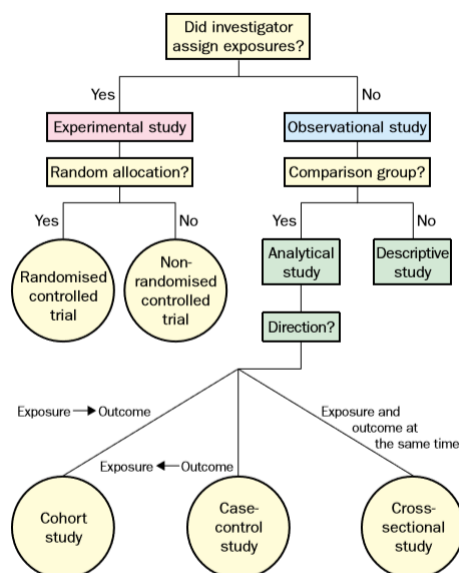


Figure 1: Algorithm for classification of types of clinical research

32

Most Read Articles

Uterine distention as a factor in birth timing: retrospective nationwide cohort study in Sweden 31 October, 2018 

Randomised trial of coconut oil, olive oil or butter on blood lipids and other cardiovascular risk factors in healthy men and women 6 March, 2018 

Corporal punishment bans and physical fighting in adolescents: an ecological study of 88 countries 16 October, 2018 

Impact of the communication and patient hand-off tool SBAR on patient safety: a systematic review 23 August, 2018 

Temporal and geographic patterns of stab injuries in young people: a retrospective cohort study from a UK major trauma centre 6 November, 2018

Latest Articles

Health facility structure and maternal characteristics related to essential newborn care in Brazil: a cross-sectional study 31 December, 2018

Preventing PTSD, depression and associated health problems in student paramedics: protocol for PREVENT-PTSD, a randomised controlled trial of supported online cognitive training for resilience versus alternative online training and standard practice 31 December, 2018 

Implementing online evidence-based care pathways: A mixed-methods study across primary and secondary care 31 December, 2018

"Tell them you smoke, you'll get more breaks": a qualitative study of occupational and social contexts of young adult smoking in Scotland 31 December, 2018

Evaluation of types of poisoning exposure calls managed by the Malaysia National Poison Centre (2006–2015): A retrospective review 31 December, 2018 

[L'abstract - struttura]

- Obiettivi
- Disegno
- Setting
- Partecipanti
- Misure d'esito principali
- Risultati
- Conclusioni

35

[L'abstract - struttura]

- La lunghezza non deve eccedere 250 parole (vincoli imposti da Medline)
- Science e Nature richiedono 100 parole

36

[L'abstract corto non strutturato]

- Br J Psychiatry. 2007 Jul;191:84-5.
 - **Depressive symptoms during pregnancy and low birth weight at term: Longitudinal study.**
 - Evans J, Heron J, Patel RR, Wiles N.
 - There is conflicting evidence regarding the effect of depression during pregnancy on birth weight. We used data from the Avon Longitudinal Study of Parents and Children to investigate whether depressive symptoms during pregnancy in 10 967 women led to low birth weight at term in their offspring. Those with a high depressive symptom score during pregnancy were more likely to have babies of low birth weight (95% CI 1.16-2.40, $P < 0.01$), but this attenuated after adjustment for confounders (OR=1.29, 95% CI 0.87-1.91, $P = 0.210$). Hence there is little evidence of an independent association between depressive symptoms during pregnancy and birth weight.

37

[L'abstract corto strutturato]

- Br J Psychiatry. 2007 Jul;191:50-4.
 - **The Depression Scale as a screening instrument for a subsequent depressive episode in primary healthcare patients.**
 - Poutanen O, Koivisto AM, Joukamaa M, Mattila A, Salokangas RK.
 - **BACKGROUND:** There are numerous instruments for screening for depression. A feasible screen is good at both recognising and predicting depression.
 - **AIMS:** To study the ability of the Depression Scale and its items to recognise and predict a depressive episode.
 - **METHOD:** A sample of patients attending primary care was examined in 1991-1992 and again 7 years later. The accuracy of the Depression Scale at baseline and at follow-up was tested against the Short Form of the Composite International Diagnostic Interview (CIDI-SF) diagnosis of depression at follow-up. The sensitivity and specificity of the Depression Scale and its items were assessed.
 - **RESULTS:** Both baseline and follow-up Depression Scale scores were consistent with the CIDI-SF diagnoses. It was possible to find single items efficient at both recognising and predicting depression.
 - **CONCLUSIONS:** The Depression Scale is a useful screening instrument for depression, with both diagnostic and predictive validity.

38

L'abstract di lunghezza standard strutturato

- ***Reinstitutionalisation in mental health care: comparison of data on service provision from six European countries***

Stefan Priebe, Alli Badesconyi, Angelo Fioritti, Lars Hansson, Reinhold Kilian, Francisco Torres-Gonzales, Trevor Turner, Durk Wiersma

- **BMJ VOLUME 330 15 JANUARY 2005**
bmj.com

39

L'abstract di lunghezza standard strutturato

- **Objective** To establish whether reinstitutionalisation is occurring in mental health care and, if so, with what variations between western European countries.
- **Design** Comparison of data on changes in service provision.
- **Setting** Six European countries with different traditions of mental health care that have all experienced deinstitutionalisation since the 1970s—England, Germany, Italy, the Netherlands, Spain, and Sweden.
- **Outcome measures** Changes in the number of forensic hospital beds, involuntary hospital admissions, places in supported housing, general psychiatric hospital beds, and general prison population between 1990-1 and 2002-3.

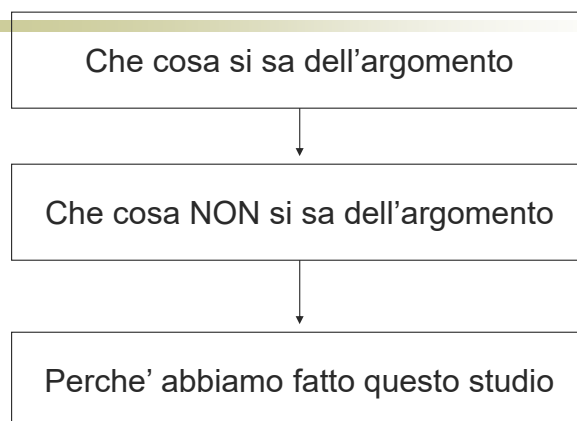
40

L'abstract di lunghezza standard strutturato

- **Results** Forensic beds and places in supported housing have increased in all countries, whereas changes in involuntary hospital admissions have been inconsistent. The number of psychiatric hospital beds has been reduced in five countries, but only in two countries does this reduction outweigh the number of additional places in forensic institutions and supported housing. The general prison population has substantially increased in all countries.
- **Conclusions** Reinstitutionalisation is taking place in European countries with different traditions of health care, although with significant variation between the six countries studied. The precise reasons for the phenomenon remain unclear. General attitudes to risk containment in a society, as indicated by the size of the prison population, may be more important than changing morbidity and new methods of mental healthcare delivery.

41

Schema introduzione



42

[Introduzione]

- Lunghezza: una pagina
- Sviluppo: dal generale al particolare (lo studio oggetto dell'articolo)

43

[Citazioni tratte da]

Serotonin transporter polymorphisms and adverse effects with fluoxetine treatment.

Perlis RH, Mischoulon D, Smoller JW, Wan YJ, Lamon-Fava S, Lin KM, Rosenbaum JF, Fava M. Biol Psychiatry. 2003 Nov 1;54(9):879-83.

IF=11,982



44

[Introduzione: esempio]

Selective serotonin reuptake inhibitors (SSRIs) are associated with treatment-emergent adverse effects that may lead to rates of early discontinuation as high as 30% (Kaplan 1997). For example, treatment-emergent insomnia is seen in up to 30% of SSRI-treated patients (Fava et al 2002). Agitation and akathisia have also been reported to be more common with SSRIs than with tricyclic antidepressants (Geretsegger et al 1995) and have been linked to treatment discontinuation and switch to other agents (Chelben et al 2001).

**LA
RILEVANZA
DEL
PROBLEMA**

COSA SI SA

Perlis et al. Serotonin Transporter Polymorphisms and Adverse Effects with Fluoxetine Treatment Biol. Psychiatry 2003; 54: 879-883.

45

[Introduzione: esempio]

To date, the 5HTTLPR polymorphism has not been investigated in antidepressant treatment-emergent adverse effects, with one notable exception. The 5HTTLPR "S" allele has been associated with antidepressant-induced mood elevation among bipolar subjects (Mundo et al 2001). That preliminary report did not examine other adverse effects, however, which could contribute to or even mediate mood switch. We hypothesized that the 5HTTLPR polymorphism might similarly moderate some SSRI-induced adverse effects, particularly those related to sleep or agitation

COSA NON SI SA....

46

[Introduzione: un esempio]

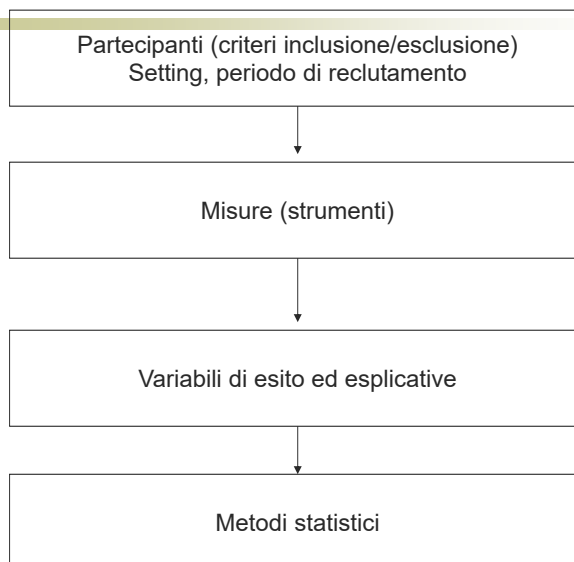
SCOPO DELLO STUDIO.....

In a subset of outpatients participating in an open-label clinical trial of fluoxetine for up to 12 weeks, we investigated the association between 5HTTLPR genotype and development of insomnia and agitation, adverse effects that could be confused with, or contribute to, antidepressant-induced mood elevation

Perlis et al. Serotonin Transporter Polymorphisms and Adverse Effects with Fluoxetine Treatment Biol. Psychiatry 2003; 54: 879-883.

47

[Schema metodi]



48

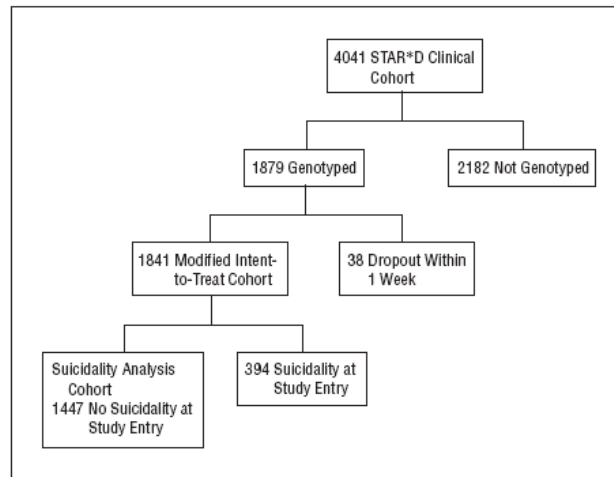


Figure 1. CONSORT diagram of Sequenced Treatment Alternatives to Relieve Depression (STAR*D) genetics and suicidality cohort. Of 1879 individuals in the STAR*D cohort from whom DNA was available, 1447 remained in the study for at least 1 week and did not express suicidal ideation at study entry. These 1447 represent the risk cohort examined in subsequent genetic analyses.

49

Chi partecipa?

Eligible subjects were outpatients between the ages of 18–65 meeting criteria for MDD, diagnosed with the use of the Structured Clinical Interview for DSM-IV Axis I Disorders— Patient Edition (SCID-I/P; First et al 1996). Exclusion criteria included pregnancy or childbearing potential without medically accepted contraception, breast-feeding, serious suicidal risk, history of seizure disorder, unstable physical disorder, clinical or laboratory evidence of untreated hypothyroidism, or meeting criteria for the following DSM-IV diagnoses: organic mental disorders; substance use disorders, including alcohol, active within the last 6 months; schizophrenia; delusional disorder; psychotic disorders; bipolar disorder; or presence of psychotic features. Subjects were also excluded for history of allergy to fluoxetine or a history of nonresponse to an adequate trial of fluoxetine in a past or current depressive episode, defined as a 4-week trial of a minimum of 40 mg/day of fluoxetine

Perlis et al. Serotonin Transporter Polymorphisms and Adverse Effects with Fluoxetine Treatment Biol. Psychiatry 2003; 54: 879-883.

50

[La rappresentativita' del campione]

- Dei soggetti (o unita' statistiche) potenzialmente elegibili per studio, quanti hanno effettivamente partecipato?

51

[La rappresentativita' del campione]

- Negli studi cross-sectional
 - rifiuti
- Negli studi longitudinali
 - Rifiuti
 - Drop-out

52

[La rappresentatività del campione]

- Negli studi cross-sectional e longitudinali confrontare con test statistici le caratteristiche di chi partecipa e di chi rifiuta
- Negli studi longitudinali, valutare anche se la perdita al follow-up è regolata da meccanismi specifici (MCAR, MAR)

53

[Periodo di riferimento]

- Indicare data di inizio e fine del reclutamento
- Periodo di riferimento della raccolta dei dati

54

[Setting]

- Dove e' stato condotto lo studio?
- Chi ha effettuato le valutazioni previste?
- Che tipo di formazione hanno ricevuto i valutatori?

55

[Misure]

At each study visit, subjects were rated with the 17-item Hamilton Rating Scale for Depression (HAM-D-17; Hamilton 1960). Spontaneously reported treatment-emergent adverse effects were systematically documented as part of the interview. For the purposes of this analysis, any adverse effect reported on at least one visit during the trial was included.

Perlis et al. Serotonin Transporter Polymorphisms and Adverse Effects with Fluoxetine Treatment Biol. Psychiatry 2003; 54: 879-883.

56

[Analisi statistiche]

JAMA. 2012 Aug 22;308(8):773-4.

The value of statistical analysis plans in observational research: defining high-quality research from the start.

Thomas L, Peterson ED.

57

[Analisi statistiche]

Because this analysis was intended to consider SSRI-associated adverse effects, a modified intent-to-treat approach was used: all subjects who attended at least one postscreening visit were included. Fisher's exact tests were used to compare genotypes between subjects with and without the adverse effect of interest. The primary analyses compared subjects with SS ("short" homozygous) genotype to those with either SL (heterozygous) or LL ("long" homozygous) genotype, for consistency with some previous reports (Rausch et al 2002; Smeraldi et al 1998).

Perlis et al. Serotonin Transporter Polymorphisms and Adverse Effects with Fluoxetine Treatment Biol. Psychiatry 2003; 54: 879-883.

58

[Analisi statistiche]

The primary analyses compared subjects with SS ("short" homozygous) genotype to those with either SL (heterozygous) or LL ("long" homozygous) genotype, for consistency with some previous reports (Rausch et al 2002; Smeraldi et al 1998).

*Multiple **logistic regressions** considered adverse effect as outcome, baseline depression severity (HAM-D-17), and Hamilton anxiety-somatization factor items (Hamilton items 10,11,12,13,15, and 17; Fava et al 2000) as covariates, and two dummy-coded terms for genotype as predictors, which does not assume a particular model of gene effect.*

Perlis et al. Serotonin Transporter Polymorphisms and Adverse Effects with Fluoxetine Treatment Biol. Psychiatry 2003; 54: 879-883.

59

[Analisi statistiche]

Total number of reported adverse effects, excluding agitation and insomnia, were compared by genotype using the Mann–Whitney U score. This test was also used to compare fluoxetine dosage at time of adverse effect emergence, and fluoxetine dosage at end point. The Kaplan–Meier log rank test was used to compare time to adverse effect emergence or to study discontinuation. The Wilcoxon signed-ranks test was used to evaluate change in HAM-D among subjects with insomnia or agitation. Analysis of covariance (ANCOVA) was used to compare end point HAM-D-17 scores, covarying for baseline HAM-D-17 scores.

Perlis et al. Serotonin Transporter Polymorphisms and Adverse Effects with Fluoxetine Treatment Biol. Psychiatry 2003; 54: 879-883.

60

Schema risultati



61

La descrizione del campione

62

Table 6. Item 15: Example of Reporting of Baseline Demographic and Clinical Characteristics of Trial Groupst

Characteristic	Vitamin Group (n = 141)	Placebo Group (n = 142)
Mean age $\pm$ SD, y	28.9 $\pm$ 6.4	29.8 $\pm$ 5.6
Smokers, n (%)	22 (15.6)	14 (9.9)
Mean body mass index $\pm$ SD, kg/m ²	25.3 $\pm$ 6.0	25.6 $\pm$ 5.6
Mean blood pressure $\pm$ SD, mm Hg		
Systolic	112 $\pm$ 15	110 $\pm$ 12
Diastolic	67 $\pm$ 11	68 $\pm$ 10
Parity, n (%)		
0	91 (65)	87 (61)
1	39 (28)	42 (30)
2	9 (6)	8 (6)
>2	2 (1)	5 (4)
Coexisting disease, n (%)		
Essential hypertension	10 (7)	7 (5)
Lupus or antiphospholipid syndrome	4 (3)	1 (1)
Diabetes	2 (1)	3 (2)

† Adapted from part of Table 1 of reference 111.

63

Brutto!!!

Table 2: Characteristics of the patients

Gender	Male	2073	44,0%
Age group	15/24 years	222	4,7%
	25/34 years	992	21,1%
	35/44 years	1127	23,9%
	45/54 years	994	21,1%
	55/64 years	805	17,1%
	more than 65 years	562	11,9%
	missing	10	0,2%
Marital status	single	2352	49,9%
	married	1646	34,9%
	separated – divorced	413	8,9%
	widow	246	5,2%
	missing	55	1,2%
Education level	primary school	1533	32,5%
	secondary school	1918	40,7%
	high school – university	1082	23,0%
	missing	179	3,8%
Living situation	alone	703	15,3%
	with parents	1858	38,6%
	with partner	1775	38,7%
	with other relatives	170	3,6%
	other living situation	125	2,0%
	missing	81	1,8%

64

Risultati 'descrittivi'

Number of forensic beds, involuntary hospital admissions, places in residential care or supported housing, psychiatric hospital beds, and prison population in six countries in 1990-1 and 2002-3. Values are numbers per 100 000 population unless stated otherwise

Service provision	England	Germany	Italy	Netherlands	Spain	Sweden
Forensic beds:						
1990	1.3 (1991)	4.6	2.0	4.7 (1991)	1.2 (1992)	9.8 (1993)
2002	1.8* (2001)	7.8	2.2 (2001)	11.4 (2001)	1.5	14.3 (2001)
Change (%)	+38	+70	+10	+143	+25	+46
Involuntary admissions:						
1990	40.5 (1991)	114.4 (1992)	20.51	16.4	33.8	39.0 (1992)
2001	50.3	190.5	18.14†	19.1‡ (1999)	31.8§ (2000)	32.4¶
Change (%)	+24	+67	-12	+16	-6	-17
Places in supported housing:						
1990	15.9 (1997)	8.9	8.8 (1992)	24.8 (1992)	5.1 (1994)	76.0 (1997)
2002	22.3	17.9 (1996)	31.6† (2000)	43.8 (2001)	12.7§	88.1
Change (%)	+40	+101	+259	+77	+149	+15
Psychiatric hospital beds:						
1990	131.8	141.7	4.5 (1992)	159.2	59.5 (1991)	168.6
2001	62.8	128.2 (2000)	5.3† (2000)	135.5	43.0 (1999)	58.3
Change (%)	-52	-10	+18	-15	-28	-65
Prison population:						
1992	90	71	81	49	90	63
2002	141 (2003)	98 (2003)	100	100	136 (2003)	73
Change (%)	+57	+38	+23	+104	+51	+16

65

Ancora risultati



66

Risultati di analisi di regressione multipla

Table 3. Observed and Risk Score-Standardized 30-Day Mortality Rates

Year	No. of Events	No. of Patients	30-Day Mortality, % (95% CI)		Multivariable Logistic Regression Analyses, OR (95% CI) ^a	P Value
			Observed	Standardized		
1995	210	1536	13.7 (12.0-15.4)	11.3 (9.5-13.2)	1 [Reference]	
2000	160	1844	8.7 (7.4-10.0)	7.6 (5.7-9.5)	0.64 (0.51-0.81)	.001
2005	111	1611	6.9 (5.7-8.2)	6.4 (5.1-7.7)	0.52 (0.40-0.68)	.001
2010	75	1716	4.4 (3.5-5.4)	4.4 (3.5-5.4)	0.39 (0.29-0.53)	.001

^aAdjusted for patient risk profile, infarct location, region, type of institution and reperfusion therapy.

67

Schema discussione

Cosa mostra questo studio?
Riprendere gli scopi dichiarati nell'introduzione



Punti di forza e punti deboli dello studio



Discutere se i risultati dello studio supportano
la letteratura o sono in contrasto



Prospettive future 'so what??? where next ???'
Impatto sulle conoscenze attuali o sulla pratica

68

[Discussione – esempio]

This report is to our knowledge one of the first to investigate the effects of genetic variation in pharmacodynamic (as opposed to pharmacokinetic) candidate loci on antidepressant-induced adverse effects. We found an association between homozygosity for the “short” form of 5HTTLPR and antidepressant-induced insomnia and agitation.

This association does not appear to be the result of greater levels of anxiety or insomnia at baseline, worsening of depression during treatment, nor a greater overall rate of adverse effect reporting. We also replicated multiple previous findings of an association between the “S” allele and poorer SSRI response (Rausch et al 2002; Smeraldi et al 1998; Yu et al 2002; Zanardi et al 2000, 2001).

Perlis et al. Serotonin Transporter Polymorphisms and Adverse Effects with Fluoxetine Treatment Biol. Psychiatry 2003; 54: 879-883.

69

[I punti deboli]

- La dimensione campionaria e' piccola
- La dimensione campionaria non era stata definita per gli scopi dello studio
- I risultati non sono generalizzabili
 - Criteri di inclusione/esclusione
- I metodi utilizzati non sono 'robusti'
 - Diagnosi clinica invece che con intervista
 - Inter-rater reliability non valutata

70

I punti deboli

- Gli strumenti non sono stati validati
- Lo studio non e' in cieco:
 - Il clinico puo' avere delle forti aspettative rispetto ad uno specifico trattamento
 - Il paziente puo' avere la tendenza a esagerare o minimizzare i sintomi

71

Discussione – punti deboli: esempio

- *No subjects in this study actually developed hypomania as assessed by study clinicians; however, because no structured assessment of manic or hypomanic symptoms was included in our study, we cannot rule out the possibility that some subjects developed hypomanic or mixed states.*

Perlis et al. Serotonin Transporter Polymorphisms and Adverse Effects with Fluoxetine Treatment Biol. Psychiatry 2003; 54: 879-883.

72

[Punti deboli: un esempio]

- *We note three limitations of our findings.*
 - *First, this report includes a limited number of subjects, so the risk for type II errors is relatively high, and these results require confirmation in larger studies.*
 - *Second, no structured assessment of adverse effects was included, so the results are influenced by patient willingness to report adverse effects. For some SSRI-associated side effects (e.g., sexual dysfunction), reported prevalence is substantially greater when structured assessments are used.*
 - *Finally, in the absence of a structured measure of akathisia, such as the Barnes Akathisia Scale (Barnes 1989), we were not able to reliably distinguish between agitation and akathisia.*

Perlis et al. Serotonin Transporter Polymorphisms and Adverse Effects with Fluoxetine Treatment Biol. Psychiatry 2003; 54: 879-883.

73

[Prospettive future – un esempio]

- *Consideration of alternative models of allele expression will be important in subsequent studies.*
- *In summary, these preliminary findings indicate variations in the serotonin transporter gene may be associated with treatment-emergent insomnia and agitation with fluoxetine, in addition to their apparent association with response in depressive symptoms. If these results can be confirmed in a larger sample, they may provide a basis for identifying patients at greater risk for certain adverse effects with fluoxetine treatment.*



Perlis et al. Serotonin Transporter Polymorphisms and Adverse Effects with Fluoxetine Treatment Biol. Psychiatry 2003; 54: 879-883.

74

Linee guida per la costruzione dell'articolo

- Titolo
 - Breve, accurato e non ambiguo
 - Deve dare all'articolo una sua personalita'
 - Iniziare con l'argomento trattato
- Introduzione
 - Cosa si sa
 - Cosa non si sa
 - Perche' e' stato fatto lo studio

75

Linee guida per la costruzione dell'articolo

- Metodi
 - Partecipanti
 - Misure utilizzate
 - Esiti e variabili esplicative
 - Metodi statistici
- Risultati
 - Caratteristiche del campione
 - Analisi univariate
 - Analisi bivariate
 - Analisi multivariate

76

Linee guida per la costruzione dell'articolo

- Tabelle e figure
 - Non piu' di 6 in tutto
 - Usare la tabella 1 per le caratteristiche del campione
 - Mettere i risultati piu' importanti **in una figura**
- Discussione
 - Dire cosa si e' trovato
 - Indicare punti di forza e di debolezza
 - Discutere la rilevanza rispetto alla letteratura
 - Indicare le implicazioni dei risultati

77

Linee guida per la costruzione dell'articolo

- Reference
 - Tutte le citazioni devono essere accurate
 - Includere solo le piu' rigorose, le piu' importanti, le piu' recenti
 - Citare solo articoli pubblicati
 - Evitare citazioni di seconda mano
 - Citare circa 25-30 reference
- Formattazione
 - Aderire alle linee guida della rivista

78

[Websites]

ICMJE	International committee of medical journal editors	www.icmje.org
WAME	World association of medical editors	www.wame.org
CSE	Council of science editors	www.councilscienceditors.org
Cochrane collaboration	Evidence-based medicine	www.cochrane.org
Instruction to authors in the health sciences	Link alle norme editoriali di tutte le riviste	http://mulford.utoledo.edu/instr/
Users' guides to the medical literature	Standard di preparazione di tutti i tipi di articoli	www.jama.com

79

[Reporting guidelines]

<u>Randomised trials</u>	<u>CONSORT</u>
<u>Observational studies</u>	<u>STROBE</u>
<u>Systematic reviews</u>	<u>PRISMA</u>
<u>Study protocols</u>	<u>SPIRIT</u>
<u>Diagnostic/prognostic studies</u>	<u>STARD</u>
<u>Case reports</u>	<u>CARE</u>
<u>Clinical practice guidelines</u>	<u>AGREE</u>
<u>Qualitative research</u>	<u>SRQR</u>
<u>Animal pre-clinical studies</u>	<u>ARRIVE</u>
<u>Quality improvement studies</u>	<u>SQUIRE</u>
<u>Economic evaluations</u>	<u>CHEERS</u>

80

[Websites]

- Epidemiologia <http://www.epidem.com>
- British Medical Journal <http://www.bmj.com/>
 - Guida alla stesura dei lavori, copyright, aspetti etici, ecc.

81

[Testo consigliato]

- Maina – Jannone
Pubblicazioni mediche – Guida alla
scrittura
Ed SEEd Torino, 2007

82



[Gli aspetti etici della ricerca]

83



[Gli aspetti etici della ricerca]

- Comitato Etico:
 - Tutela della privacy
 - Valutazione dei rischi/benefici per i partecipanti
 - Monitoraggio degli eventi avversi

ATTENZIONE! Tutti i protocolli (anche quelli relativi a studi osservazionali e a tesi) vanno sottoposti al comitato etico

84

[Gli aspetti etici della ricerca]

- Conflitto di interessi

*‘insieme di condizioni in cui il giudizio professionale relativo ad un interesse primario (**benessere del paziente, validita' della ricerca**) puo' essere influenzato in modo improprio da interessi secondari (**vantaggi economici**)’*

85

[Gli aspetti etici della ricerca]

Frode

- Plagio
- Publication bias
- Pubblicazione ripetuta

86

[Plagio]

- E' considerato plagio appropriarsi di idee, procedure e risultati tratti da un altro articolo senza darne adeguato credito
- Lo e' anche copiare pezzi di testo tratti da un altro articolo (senza citarlo) compreso un proprio articolo

87

[Publication bias]

- Pubblicazione selettiva di ricerche che mostrano dei risultati 'positivi'

88

[Pubblicazione ripetuta]

- Pubblicazione su piu' riviste dei risultati della stessa ricerca
- Pubblicazione su riviste di lingua diversa dei risultati della stessa ricerca

89

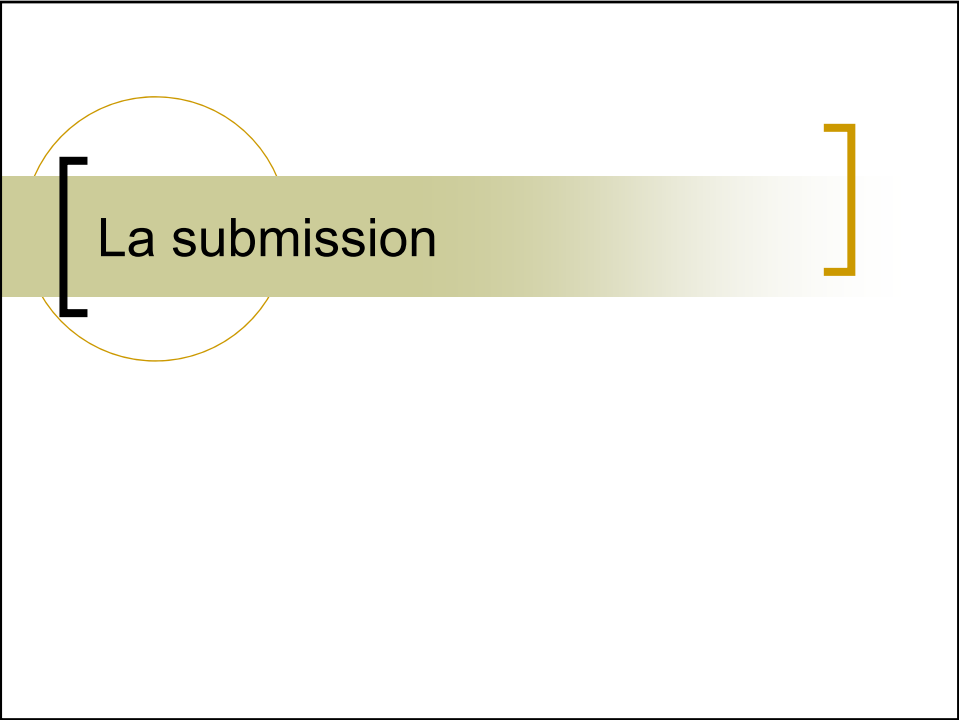
[Gli aspetti etici della ricerca]

Authorship: 4 condizioni da soddisfare

International Committee of Medical Journal Editors (ICMJE)

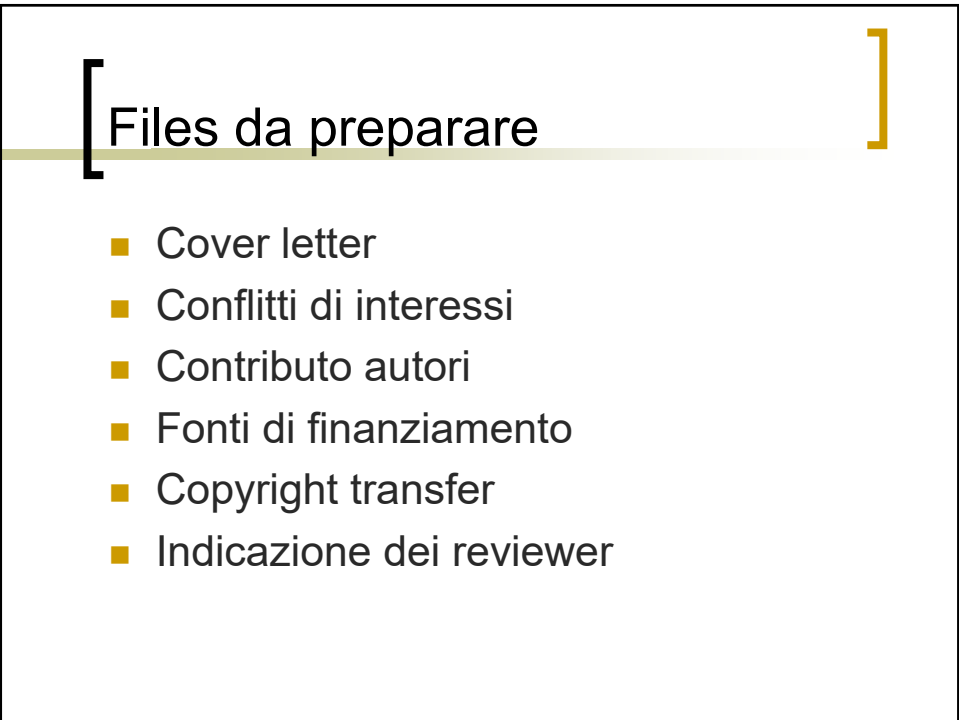
- *Contributo sostanziale al disegno, all'analisi e all'interpretazione dei dati*
- *Scrivere o rivedere criticamente un articolo apportando un contributo significativo*
- *Approvarne la stesura definitiva*
- *Disponibilità ad assumersi la responsabilità di tutti gli aspetti del lavoro e a garantire che eventuali problemi relativi all'accuratezza o l'integrità di qualsiasi parte del lavoro siano adeguatamente studiati e risolti*

90



La submission

91



Files da preparare

- Cover letter
- Conflitti di interessi
- Contributo autori
- Fonti di finanziamento
- Copyright transfer
- Indicazione dei reviewer

92

[La cover letter]

- Destinatario: editor-in-chief
- Titolo
- Autori e loro affiliazioni
- Corresponding author
- Tipo di articolo
- Altre dichiarazioni

93

[Conflitti di interesse]

- I finanziamenti dell'industria (non necessariamente legati all'articolo) vanno dichiarati e non precludono la possibilità di pubblicare

94

[Contributo autori]

All authors participated in the design of the study. EM, AL and PL wrote the manuscript. AE and GV reviewed the manuscript. PL and GV performed the statistical analysis. All authors read and approved the final manuscript.

95

[Fonti di finanziamento dello studio]

- Finanziamenti dell'industria
- Fondi pubblici
- Finanziamenti comunita' europea

96

[Copyright transfer]

- Cessione alla rivista dei diritti sull'articolo

97

[Indicazione dei reviewer]

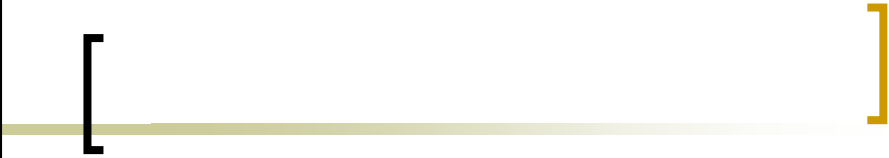
- Specificare chi può essere competente a valutare l'articolo
- Non può essere un ricercatore del proprio istituto
- I revisori devono essere di istituti (città e nazioni) diversi
- Si può anche indicare chi NON si vuole come reviewer

98



Un caso di studio

99



Promoting the well-being of mothers with multidisciplinary psychosocial interventions in the perinatal period

G. Cauli*, E. Iapichino*, P. Rucci[^], M. Quartieri Bollani*, A. M. Marconi[#], M. Bassi[°], C. Gala*

*Division of Psychiatry, 51, ASST Santi Paolo e Carlo, San Paolo Hospital, Milan, Italy.

[^]Department of Biomedical and Neuromotor Sciences, University of Bologna, Bologna, Italy

[#]Obstetric Clinic, ASST Santi Paolo e Carlo, San Paolo Hospital, Milan, Italy

[°]Division of Psychiatry, ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy

100

[Scopo]

The aim of this paper is to report on the acceptability and the effects of the MPI in terms of prevention of PDD in women at no/low risk and treatment of depressive and anxiety symptoms during pregnancy in women at high risk.

101

[Cover letter (submission)]

Home > Journals > Journal of Affective Disorders



ISSN: 0165-0327

Journal of Affective Disorders

Official Journal of the [International Society for Affective Disorders](#)

Editors-in-Chief: [P. Brambilla](#), [J.C. Soares](#)

[View Editorial Board](#)

102

[Cover letter (submission)]

Dear Prof. Brambilla,

Please find enclosed for review and potential publication in the *Journal of Affective Disorders* the paper '**Promoting the well-being of mothers with multidisciplinary psychosocial interventions in the perinatal period**' by **Cauli et al.**

The paper reports the development and the outcomes of a multidisciplinary psychosocial intervention (MPI) program carried out in a large Italian hospital, targeted to pregnant women and aimed at preventing post-partum depression and its negative effects on the mother and the newborn.

Our findings indicate the benefits of these interventions in terms of post-partum recovery among symptomatic women during pregnancy, and in preventing a new onset of depression among non-symptomatic women.

TITOLO

AUTORI

**ARGOMENTO
DEL LAVORO**

**RISULTATI
PRINCIPALI**

103

[Cover letter (submission)]

This study was funded by the Lombardy Region in the framework of the Innovative Regional Programme TF36 'Prevention and Care of Perinatal Disorders in the city of Milan' and contributed to the definition of regional guidelines on the diagnostic-therapeutic pathway for women with risk factors for PDD.

The manuscript includes original material, not submitted elsewhere and all the authors contributed to the writing and/or statistical analysis and interpretation of the results.

The authors have no conflict of interest to declare in relation to the this work.

I look forward to your decision about the paper.
Kind regards,

Paola Rucci (corresponding author)

FINANZIAMENTO

**APPORTO DEGLI
AUTORI**

**(EVENTUALI)
CONFLITTI DI
INTERESSI**

104

[Authorship]

Author contribution

Gilla Cauli and Elena Iapichino wrote the first draft of the paper and carried out the literature review. Paola Rucci conducted the statistical analyses and contributed to the paper writing. Marta Quartieri Bollani, Anna Maria Marconi, Mariano Bassi, Costanzo Gala revised the paper and provided important intellectual contributions. All the authors approved the final version.

105

[Funding source]

Acknowledgement

This study was funded by the Lombardy Region in the framework of the Innovative Regional Programme TR36 'Prevention and Care of Perinatal Disorders in the city of Milan.'

Role of funding source

Lombardy Region has no role in the decision to publish the paper and in the interpretation of data.

106

The multidisciplinary psychosocial intervention

The MPI consisted of screening, diagnostic assessment and interventions (Table 1). The aim of the screening was to stratify women according to the risk of PPD (high risk, low risk and no risk).

The high-risk group (HR) includes women with clinically significant depressive and/or anxiety symptoms, and/or suicide risk. The presence of antenatal depressive or anxiety symptoms (ADAS) was defined as a score of 12 or higher on the EPDS and/or a BDI-II score ≥ 14 , and/or a score ≥ 40 on STAI and/or the presence of suicidality (a score >0 on EPDS item 10 or BDI-II item 7).

The low-risk group (LR) includes women without clinically significant depressive or anxiety symptoms but with a family or personal history of psychological or psychiatric disorders and at least one additional risk factor (major negative life events, low social support, poor partner support).

The no risk group (NR) included women without risk factors or clinically significant depressive or anxiety symptoms.

107

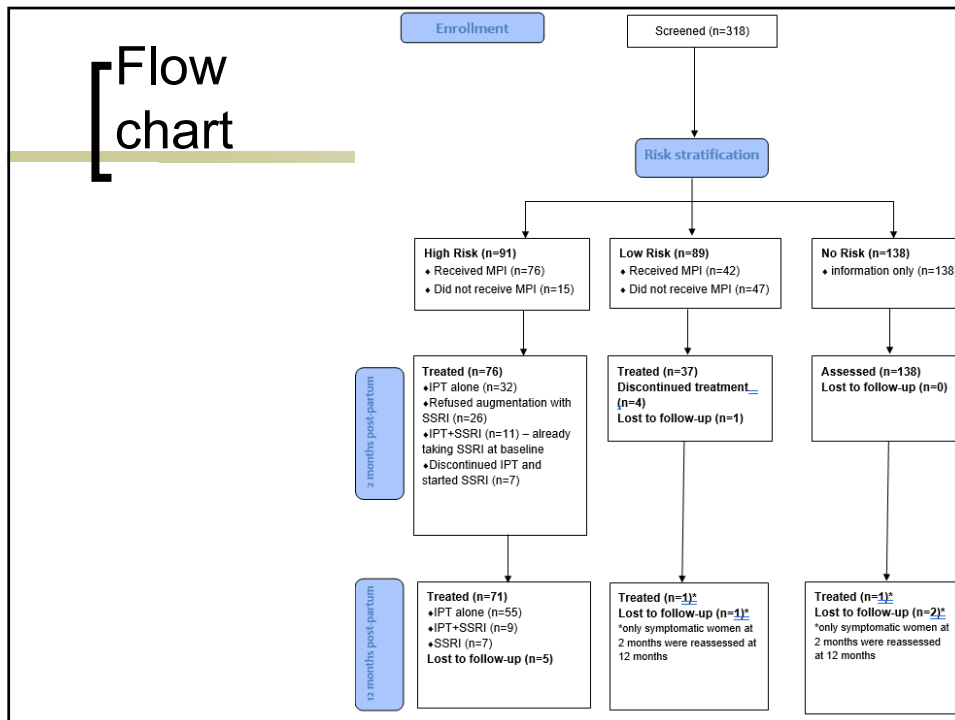
Table. 1

The multidisciplinary psychosocial intervention (MPI).

	High risk	Low risk	No risk
Pregnancy	II or III trimester: screening interview – Socio-demographic information – History of migration – Risk factors – Rating scales (EPDS, BDI-II, STAY Y1 and Y2) High risk Diagnostic interview Interpersonal psychotherapy (12–24 weekly 50 min sessions) during pregnancy Psychiatric clinical monitoring Pharmacological intervention (when needed) <i>Objectives of interpersonal psychotherapy:</i> – to decrease psychological and relational distress; – to provide problem-solving strategies; – to improve internal and social protective factors; – to improve the perception of couple and family support; – to build maternal identity and to provide parental skills; – to improve self-esteem;	Low risk Psychosocial counseling (3/4 sessions – 50 min) and équipe clinical monitoring <i>Objectives of psychosocial counseling:</i> – to help recognizing possible signs and symptoms of depression during the peripartum period; – to improve personal and social protective factors; – to improve the perception of social support and parental skills; – to reduce the impact of risk factors; – to build a support network.	No risk Educational intervention (one-hour session) <i>Objectives of educational intervention:</i> – to return the screening evaluation, personalized on the basis of the woman's history; – to recognize possible signs and symptoms of depression during the peripartum period; – to offer a possible support network if/when needed. - To give informational material of perinatal period and distress.
Post-partum	After delivery: Psychiatric and/ or psychological visit or telephone calling Follow up – 2nd month: – Rating scales (EPDS, BDI-II, STAY Y1 e Y2) Post-partum depression Diagnostic interview Interpersonal Psychotherapy (24 biweekly 50 min sessions) Psychiatric clinical monitoring Pharmacological intervention (when needed) 12-month follow-up – EPDS	Low risk Psychosocial counseling (3/4 sessions – 50 min) and équipe clinical monitoring	No risk

108

Flow chart



109

Il disegno di questo studio?

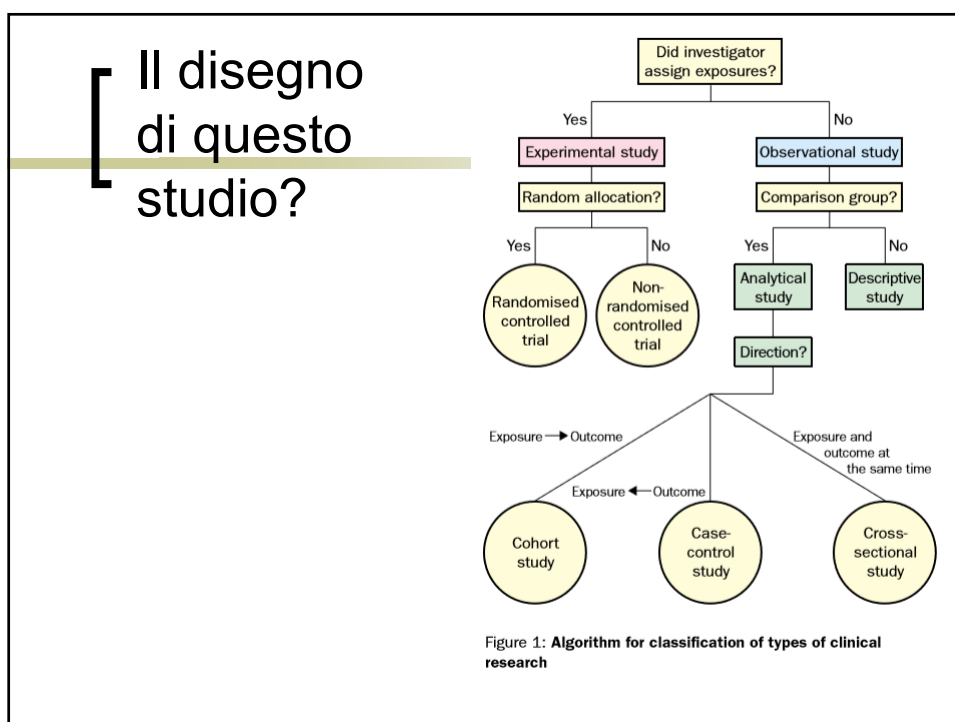


Figure 1: Algorithm for classification of types of clinical research

110

[Revisioni]

1° revisione: 5 revisori

2° revisione: 1 revisore (il 4°)

3° revisione: 4 revisori

4° revisione: 2 revisori

111

[Cover letter (resubmission)]

Dear Prof. Soares,

Thank you for the opportunity to submit a revised version of the manuscript. We were surprised that after the first round of revisions we received the comments only from one reviewer (#4) and after the second round the comments of 4 reviewers. We understand that the clinical trial presented in this paper is complex because of the flexibility of treatments offered as part of a 'real-world' multidisciplinary psychosocial intervention and we hope that in this revised version we have adequately addressed all the points raised.

In particular, we prepared a detailed flow diagram, rearranged the discussion as suggested and examined in deeper detail the effect of drug, controlling for clinical variables and diagnosis. We also understand that the study design does not allow to demonstrate the effectiveness of MPI and used the term 'effect' to avoid misinterpretations.

We are very grateful to the reviewers for their effort. Our changes to the manuscript and the tables are tracked in word.

My coauthors and I look forward to your final decision about the paper.

Kind regards

Paola Rucci

112

 Download PDF
 [Share](#)
[Export](#)



Journal of Affective Disorders
 Volume 246, 1 March 2019, Pages 148-156



Research paper

Promoting the well-being of mothers with multidisciplinary psychosocial interventions in the perinatal period

G. Cauli ^a, E. Iapichino ^a, P. Rucci ^b,  M. Quartieri Bollani ^a, A.M. Marconi ^c, M. Bassi ^d, C. Gala ^a

[Show more](#)

<https://doi.org/10.1016/j.jad.2018.12.028> [Get rights and content](#)

113





Come assicurarsi che l'articolo
sia respinto



114

[Errori da evitare]

- Fornire così poche informazioni sullo studio da renderlo non replicabile
- Giustificare la bassa dimensione campionaria dicendo che anche in altri studi era così
- Fare le analisi con excel
- Non riportare le caratteristiche socio-demografiche e cliniche del campione
- Riportare numeri sbagliati (totali che non tornano, percentuali che non sommano a 100)
- Usare un sottogruppo diverso di pazienti per ogni analisi

115

Stratton & Neil, Diabet. Med 22, 371-273 (2005)

115

[Errori da evitare]

- Usare diagrammi a barre 3D
- Riportare i risultati principali alla fine della discussione
- Enfatizzare al massimo i punti di forza
- Non menzionare mai i limiti dello studio
- Ma soprattutto

**Non parlare mai, per nessun motivo,
con uno statistico!**

116

Stratton & Neil, Diabet. Med 22, 371-273 (2005)

116



117