Appendix A. Exact Search Strings

PsycInfo Searches
Searched: 1/7/05

Off-label & drug names – 6 citations
Off-label & conditions –- 41 citations
clinical trials & drug names & conditions –- 28 citations
clinical trials & drug names & conditions & off-label – 0 citations
drug names & conditions – 657 citations
off-label & drug names & conditions – 1 citation

Total Unique Results in PsycInfo: 702

Search Strategies:

Conditions
(((su= "personality disorders" OR su= "obsessive compulsive disorder" OR su= "obsessive compulsive personality disorder" OR su= "posttraumatic stress disorder")) or ((su: dementia OR su: depression)) or (kw: severe w geriatric w agitation OR kw: geriatric w agitation) and yr: 1990-2005) or (((kw: personality w disorders OR kw: obsessive w compulsive w disorder OR kw: obsessive w compulsive w personality w disorder OR kw: posttraumatic w stress w disorder OR kw: ptsd OR kw: ocd OR kw: post w traumatic w stress OR kw: obsessive w compulsive)) or ((kw: dementia OR kw: depression)) or (kw: severe w geriatric w agitation OR kw: geriatric w agitation) and yr: 1990-2005)
Total Results: 96355

Off-Label
kw: off w label or kw: off-label OR kw: offlabel OR kw: atypical w use OR kw: non w intended w use OR kw: non w intentional w use OR kw: "not" w intended w use and yr: 1990-2005
Total Results: 346

Clinical Trials
(de= "clinical trials") or ((kw: controlled w clinical w trial OR kw: controlled w clinical w trials OR kw: randomized w trial OR kw: randomized w trials OR kw: randomized w controlled w trial OR kw: randomized w controlled w trials OR kw: clinical w trial OR kw: clincal w trials)) and yr: 1990-2005
Total Results: 4709

Drug Names
(kw: Risperidone OR kw: olanzapine OR kw: quetiapine OR kw: aripiprazole OR kw: ziprasidone) or ((de: Risperidone OR de: olanzapine OR de: quetiapine OR de: aripiprazole OR de: ziprasidone)) and yr: 1990-2005
Total Results: 3698

The Cochrane Central Register of Controlled Trials (CENTRAL) Searches
(Note: Clinical trial terms were not included in search strategy as this database is limited to controlled trials already)
Searched: 1/7/05

Off-label & drug names -- 0
Off-label & conditions -- 0
Drug names & conditions & off-label -- 0
Drug names & conditions -- 299

Total Unique Results in Cochrane CENTRAL: 299

Search Strategies:

Off-label
("atypical use" OR "off label" OR "non intended use" OR "non intentional use" OR "not intended use" OR "use not intended") in All Fields,
Limited to: 1990 to 2005
Total Results: 1

Drug names
(Risperidone OR olanzapine OR quetiapine OR aripiprazole OR ziprasidone) in Abstract or
(Risperidone OR olanzapine OR quetiapine OR aripiprazole OR ziprasidone) in Keywords or
(Risperidone OR olanzapine OR quetiapine OR aripiprazole OR ziprasidone) in Record Title or
(MeSH descriptor Risperidone explode all trees in MeSH products)
Limited to: 1990 to 2005
Total Results: 1901

Conditions
("Personality Disorder*" OR "Dementia" OR "Depression" OR "Depressive Disorder" OR depress* OR "Obsessive Compulsive Disorder" OR ocd OR "Post-Traumatic Stress disorder*" OR ptsd OR severe geriatric agitation OR geriatric agitation) in Abstract or ("Personality Disorder*" OR "Dementia" OR "Depression" OR "Depressive Disorder" OR depress* OR "Obsessive Compulsive Disorder" OR ocd OR "Post-Traumatic Stress disorder*" OR ptsd OR severe geriatric agitation OR geriatric agitation) in Record Title or ("Personality Disorder*" OR "Dementia" OR "Depression" OR "Depressive Disorder" OR depress* OR "Obsessive Compulsive Disorder" OR ocd OR "Post-Traumatic Stress disorder*" OR ptsd OR severe geriatric agitation OR geriatric agitation) in Keywords
OR
(MeSH descriptor Personality Disorders explode all trees in MeSH products OR
MeSH descriptor Dementia explode all trees in MeSH products OR MeSH descriptor Depression explode all trees in MeSH products OR MeSH descriptor Depressive Disorder explode all trees in MeSH products OR MeSH descriptor Obsessive-Compulsive Disorder explode all trees in MeSH products ORMeSH descriptor Stress Disorders, Post-Traumatic explode all trees in MeSH products)
Limited to: 1990 to 2005
Total Results: 16389

Cochrane Database - Search Strategy
(Antipsychotic Agents[MeSh descriptor] OR risperidone OR olanzapine OR quetiapine OR aripiprazole OR ziprasidone) AND (depression OR dementia OR obsessive compulsive disorder OR post traumatic stress disorder OR ptsd OR off label OR off-label)
Date Searched: 12/15/2004
Limited search to: The Cochrane Database of Systematic Reviews
Total Results: 78

PubMed Search Strategy
("Antipsychotic Agents"[MeSH] OR "Antipsychotic Agents"[Pharmacological Action] OR aripiprazole OR olanzapine OR quetiapine OR risperidone OR ziprasidone) AND (depression OR dementia OR obsessive compulsive disorder OR post traumatic stress disorder OR ptsd OR off label OR off-label)
Date Searched: 12/15/2004
Limited to: Systematic Reviews
Total Results: 95

PubMed Search Strategy

Limited: 1990-2005
Database searched: January 4, 2005
Total Results: 996

[(Risperidone OR olanzapine OR quetiapine OR aripiprazole OR ziprasidone) OR ("Risperidone"[MeSH] OR "olanzapine"[Substance Name] OR "quetiapine"[Substance Name] OR "aripiprazole"[Substance Name] OR "ziprasidone"[Substance Name])
AND
“atypical use” OR “off label” OR “non intended” OR “non intentional”
AND
("Personality Disorders"[MeSH] OR "Dementia"[MeSH] OR "Depression"[MeSH] OR "Depressive Disorder"[MeSH] OR "Obsessive-Compulsive Disorder"[MeSH] OR "Stress Disorders, Post-Traumatic"[MeSH]) OR ("Personality Disorder*" OR "Dementia" OR "Depression" OR "Depressive Disorder" OR depress* OR "Obsessive Compulsive Disorder" OR ocd OR "Post-Traumatic Stress disorder*” OR ptsd OR severe geriatric agitation OR geriatric agitation)]

OR

[(Risperidone OR olanzapine OR quetiapine OR aripiprazole OR ziprasidone) OR ("Risperidone"[MeSH] OR "olanzapine"[Substance Name] OR "quetiapine"[Substance Name] OR "aripiprazole"[Substance Name] OR "ziprasidone"[Substance Name])
AND
“atypical use” OR “off label” OR “non intended” OR “non intentional”]

OR

[“atypical use” OR “off label” OR “non intended” OR “non intentional”
AND
("Personality Disorders"[MeSH] OR "Dementia"[MeSH] OR "Depression"[MeSH] OR "Depressive Disorder"[MeSH] OR "Obsessive-Compulsive Disorder"[MeSH] OR "Stress Disorders, Post-Traumatic"[MeSH]) OR ("Personality Disorder*" OR "Dementia" OR "Depression" OR "Depressive Disorder" OR depress* OR "Obsessive Compulsive Disorder" OR ocd OR "Post-Traumatic Stress disorder*” OR ptsd OR severe geriatric agitation OR geriatric agitation)]

OR

[(Risperidone OR olanzapine OR quetiapine OR aripiprazole OR ziprasidone) OR ("Risperidone"[MeSH] OR "olanzapine"[Substance Name] OR "quetiapine"[Substance Name] OR "aripiprazole"[Substance Name] OR "ziprasidone"[Substance Name])
AND
("Personality Disorders"[MeSH] OR "Dementia"[MeSH] OR "Depression"[MeSH] OR "Depressive Disorder"[MeSH] OR "Obsessive-Compulsive Disorder"[MeSH] OR "Stress Disorders, Post-Traumatic"[MeSH]) OR ("Personality Disorder*" OR "Dementia" OR "Depression" OR "Depressive Disorder" OR depress* OR "Obsessive Compulsive Disorder" OR ocd OR "Post-Traumatic Stress disorder*” OR ptsd OR severe geriatric agitation OR geriatric agitation)]

SCEPC Anti-psychotic Drug Review
Article Screener- Final

Reviewers: **Assigned on:**

Article ID

#Error

Citation: #Error

#Error

1. Research topic(s): **Check all that apply**

Aripiprazole..... ☐
Olanzapine ..... ☐
Quetiapine ..... ☐

Risperidone ..... ☐
Ziprasidone..... ☐
None of the above…… ☐ **(STOP)**

2. Condition(s) studied: **Check all that apply**

Dementia ..... ☐
Depression ..... ☐
Obsessive-compulsive disorder..... ☐

Personality disorders (DSM IV) ..... ☐
PTSD..... ☐
Severe geriatric agitation..... ☐

Insomnia..... ☐
Autism (including children 17 & under)..... ☐
Tourette's (including children 17 & under).... ☐

None of the above…… ☐(**STOP)**

3. Study population: **Circle one**

Human included..... 1
Only animal or cell lines ……..2**(STOP)**

4. Study design: **Circle one**

Descriptive (historical, editorial etc.) ..1**(STOP)**
Non-systematic review…… 2**(STOP)**
Systematic review / Meta-analysis…..3**(STOP)**

RCT *only* 4
CCT *only* 5
Trial + Open label extension..... 6
Case series / Case report..... 7
Cohort..... 8
Case control 9
Other 10

5. Was a placebo used in this study? **Circle one**

Yes 1
No..... 2

6. Total sample size entering study. If entering sample not reported then total completing sample size:

Enter # or 999 if no sample reported)

___ ___ ___ ___ ___

7. Does article report on the following: **Circle one**

Efficacy 1
Safety / Adverse events..... 2
Both 3
Neither ..... 4 **(STOP)**

8. Total duration of study:
(For Duration enter # or 999 if not reported.
For Units enter code from below.)

___ ___ ___ ___ ___

Duration **Units**

Units

01. Hour	03. Week	05. Year
02. Day	04. Month	99. NR

9. Language of article: **Circle one**

English..... 1
Other..... 2

10. Do you think that this article might be a duplicate or include the same data as another study? **Circle one**

Yes..... 1
No 2
If YES, which one(s) :

_____
(Enter study ID #, author or 9999 if don't know.)

11. Is there a reference that needs to be checked? **Circle one**

Yes..... 1
No 2
If YES, which one(s) :

_____
(Enter reference # &/or author or 9999 if don't know.)

NOTES:

RAND SCEPC Anti-Psychotic Drugs Project
Detailed Abstraction Form

FINAL 06-20-05

Article ID:_____ Reviewer:_____

First Author: _____
(Last Name Only)

Study Number: ___of____Description:_____
(Enter '1of 1' if only one) (if more than one study)

Design: (CIRCLE ONE)
RCT 1
CCT 2
Trial + open label extension 3
Other design 4 (STOP)

Is the study described as randomized? (CIRCLE ONE)
Yes 1
No 2

If the study was randomized, was method of randomization appropriate? (CIRCLE ONE)
Yes 1
No 2
Method not described 8
Not applicable (not randomized) 9

Is the study described as: (CIRCLE ONE)
Double blind 1
Single blind, patient 2
Single blind, outcome assessment 3
Single blind, not described 4
Open 5
Blinding not described 8
Not applicable 9

If reported, was the method of double blinding appropriate? (CIRCLE ONE)
Yes 1
No 2
Double blinding method not described 8
Not applicable 9

If study was randomized, did the method of randomization provide for concealment of allocation? (CIRCLE ONE)
Yes 1
No 2
Concealment not described 8
Not applicable (not randomized) 9

Are withdrawals (W) and dropouts (D) described? (CIRCLE ONE)
Yes, reason described for **all** W and D 1
Yes, reason described for **some** W and D 2
Not described 8
Not applicable 9

What was the study's funding source? (CHECK ALL THAT APPLY)
Government ❑
Hospital ❑
Industry ❑
Private (non-industry) ❑
Other (code(s): _____) ❑
Unclear ❑
Not reported ❑

Last saved: 1/16/2007

RAND SCEPC Anti-Psychotic Drugs Project
Detailed Abstraction Form

In what country was the study conducted? (CHECK ALL THAT APPLY)

US ❑
Canada ❑
UK ❑

Western Europe ❑
Australia/New Zealand ❑
Other (enter code _____ , _____ , _____)❑
Not reported.....❑

What was the percent of male participants?
(ENTER NUMBER OR 999)

___ ___ ___ %

What was the racial/ethnic population studied?
(Check all that apply)

Caucasian..... ❑
African Ancestry..... ❑
Hispanic..... ❑

Asian/Pacific Islander ..... ❑
Native American ..... ❑
Eskimo/Inuit ..... ❑

Other-Not otherwise specified ..... ❑
Other (enter code): ..... ❑

_____ , _____ , _____ , _____
Not reported..... ❑

What was reported for the following questions regarding subjects ages? (Enter number 999 for not reported)

Mean Age..... _____
Median Age ..... _____
Age Range .... _____ to _____

What were the study's inclusion criteria?
(Enter code or 999 if NR)

Enter code: _____ , _____ , _____ , _____ ,
_____ , _____ , _____ , _____

What were the study's exclusion criteria?
(Enter code or 999 if NR)

Enter code: _____ , _____ , _____ , _____ ,
_____ , _____ , _____ , _____

What were the comorbidities reported in the study?
(Enter code or 999 if NR)

Enter code: _____ , _____ , _____ , _____ ,
_____ , _____ , _____ , _____

RAND SCEPC Anti-Psychotic Drugs Project
Detailed Abstraction Form

CHARACTERISTICS OF THE CONDITIONS:

Which of the following patient characteristics are described for the following conditions? Please check the appropriate boxes. For each condition please note the criteria that was used to establish the primary diagnosis and the method by which the primary diagnosis was establish. Use codes in box below for criteria & method.

Criteria	Method
1. DSM-IV	1. Clinician established
2. DSM-III-R	2. Structured interview
3. Not reported	3. Not reported
4. Not applicable	4. Not applicable

Depression: Criteria: _____ Method: _____

- Mood disorder (depression or bipolar) without psychotic features ❑
- Mood disorder (depression or bipolar) with psychotic features ❑
- Psychosis with depression ❑
- Psychosis without depression ❑
- Other depression (specify: _____) ❑

Personality Disorder: Criteria: _____ Method: _____

- Paranoid ❑
- Schizoid ❑
- Schizotypal ❑
- Antisocial ❑
- Borderline ❑
- Histrionic ❑
- Narcissistic ❑
- Avoidant ❑
- Dependent ❑
- Obsessive-compulsive ❑
- Personality disorder not otherwise specified ❑
- Other personality disorder (specify _____) ❑

Dementia: Criteria: _____ Method: _____

- Alzheimer's type ❑
- Vascular Dementia ❑
- With behavioral disturbance ❑
- Without behavioral disturbance ❑
- Dementia not otherwise specified ❑
- Other Dementia (specify _____) ❑

OCD: Criteria: _____ Method: _____

- Obsessive compulsive disorder ❑

PTSD: Criteria: _____ Method: _____

- Civilian ❑
- Military ❑
- Other PTSD (specify _____) ❑

Severe Geriatric Agitation: Criteria: _____ Method: _____

- Delirium ❑
- Dementia with agitation ❑
- Other severe geriatric agitation (specify _____) ❑

Insomnia: Criteria: _____ Method: _____

- Insomnia ❑

Autism: Criteria: _____ Method: _____

- Autism ❑

Tourette's: Criteria: _____ Method: _____

- Tourette's syndrome ❑

Primary condition(s) not listed above with outcomes of interest ❑

Enter code: _____ , _____ , _____ , _____ , _____

RAND SCEPC Anti-Psychotic Drugs Project
Detailed Abstraction Form

INTERVENTIONS

Enter sample size and intervention data for each arm beginning with placebo or control, then in order of first mention.

Arm/ Group	Sample size	Intervention	Dose	Units	Frequency	Dose Description	Duration of treatment	Units	Co-intervention(s)
1	_____ N ENTERING _____ N COMPLETING	_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
2	_____ N ENTERING _____ N COMPLETING	_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
3	_____ N ENTERING _____ N COMPLETING	_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
4	_____ N ENTERING _____ N COMPLETING	_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
	Enter a number for N entering and N completing or enter 9999 if not reported.	Enter code(s): 1.Placebo 2.Control ETC…	Enter # or range 998. Not applicable 999. Not reported	Enter a number 1. g 2. mg 3. 4. 9.NR	Enter a number 1. Hour 2. Day 3. Week 4. Month 5. Year 9. NR	Enter a number 1.Fixed single dose 2.Fixed titration schedule 3.Flexible dose 4.Average final dose 9.NR	Enter a number 997. Variable 998. NA 999. NR	Enter a number 1.Hour 2.Day 3.Week 4.Month 5.Year 8.NA 9. NR	Enter code(s) or 998. Not applicable 999. Not reported

RAND SCEPC Anti-Psychotic Drugs Project
Detailed Abstraction Form

Interventions (continued)

Enter sample size and intervention/exposure data for each arm beginning with placebo or control, then in order of first mention.

Arm/ Group	Sample size	Intervention	Dose	Units	Frequency	Dose Description	Duration of treatment	Units	Co-intervention(s)
5	_____ N ENTERING _____ N COMPLETING	_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
6	_____ N ENTERING _____ N COMPLETING	_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
7	_____ N ENTERING _____ N COMPLETING	_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
8	_____ N ENTERING _____ N COMPLETING	_____	_____	_____	_____	_____	_____	_____	_____ _____ _____ _____ _____ _____
	Enter a number for N entering and N completing or enter 9999 if not reported.	Enter code(s): 1.Placebo 2.Control ETC…	Enter # or range 998. Not applicable 999. Not reported	Enter a number 1. g 2. mg 3. 4. 9.NR	Enter a number 1. Hour 2. Day 3. Week 4. Month 5. Year 9. NR	Enter a number 1.Fixed single dose 2.Fixed titration schedule 3.Flexible dose 4.Average final dose 9.NR	Enter a number 997. Variable 998. NA 999. NR	Enter a number 1.Hour 2.Day 3.Week 4.Month 5.Year 8.NA 9. NR	Enter code(s) or 998. Not applicable 999. Not reported

18. OUTCOMES: Please enter the outcomes measured and the final followup time for each outcome measured.

Outcome code	Final Followup	
Outcome code	Number	Unit

Units:

1. Hour
2. Day
3. Week
4. Month
5. Year
9. NR

RAND SCEPC Anti-Psychotic Drugs Project
Observational Data Abstraction Form

Article ID:_____ Reviewer: Walter Mojica

Study Number: ___of____

Evidence Table

1. What is the study trial name?

   Enter code or 999 for no name:_____

2. Is the study design trial with crossover? (CIRCLE ONE)

   Yes 1
   No 2

3. What was the study's setting? (CHECK ALL THAT APPLY)

   Multi-center ..... ❑
   Single setting ..... ❑
   Community practice ..... ❑
   Other (enter code: _____, _____, _____, _____)... ❑

   [ ] Setting not reported..... ❑

4. Run-in period table: (Enter 999 in first column if no run-in.)

Length	Units	Placebo/Medication	How used for randomization?

5. Wash-out period table: (Enter 999 in first column if no wash-out.)

Length	Units	Placebo/Medication	How used for randomization?

6. Time of assessment: When were outcomes measured? (CIRCLE ONE)

(Enter the number/code in the appropriate box, or circle YES/NO.)

Baseline?	YES / NO	
Follow-up	Number	Unit
1st		
2nd		
3rd		
4th		
5th		
6th		
7th		
8th		
Additional		

Units for Q4, Q5, Q6

1. Hour	5. Year
2. Day	8. ND
3. Week	9. NA
4. Month	997. Variable
	999. NR

7. Sample size: (Enter N or 999 for not reported)

   Screened: _____ Eligible: _____

   Withdrawn: _____ Loss to follow-up: _____

8. What was the method of adverse events assessment?

(CHECK ALL THAT APPLY)

Monitored ..... ❑
Elicited by investigator ..... ❑
Reported spontaneously by patient ..... ❑
Other (enter code: _____, _____, _____, _____)... ❑
Not reported ..... ❑

Quality Assessment

9. Were outcome assessors masked to the treatment allocation?

(CIRCLE ONE)

Yes 1
Yes, but not described 2
No 3
Not reported 9

10. Was the care provider masked to the treatment allocation?

(CIRCLE ONE)

Yes 1
Yes, but not described 2
No 3
Not reported 9

11. Was the patient masked to the treatment allocation?

(CIRCLE ONE)

Yes 1
Yes, but not described 2
No 3
Not reported 9

12. Did the article report the following? (CHECK ALL THAT APPLY)

	Yes	No
Attrition	❑	❑
Crossovers	❑	❑
Adherence	❑	❑
Contamination	❑	❑

13. Did the study include an intention-to-treat analysis, or provide the data needed to calculate it?

(CIRCLE ONE)

Yes 1
No 2

14. Were there post-randomization exclusions, any differences between groups at follow-ups?

(CIRCLE ONE)

Yes (Enter numbers in table below) 1
No 2
Unable to determine 3

Arm	# Exclusions	Arm	# Exclusions
1		5	
2		6	
3		7	
4		8	

15. Were patients class-naive?

(CIRCLE ONE)

Yes 1
No 2
Not reported 9
(If NO, enter code(s): _____, _____, _____, _____,
_____, _____, _____, _____)

16. Any authors from drug companies funding the study? (CIRCLE ONE)

Yes 1
No 2
Unclear 3
Not reported 9

17. Did the article include a statement on the role of the funder?

(CIRCLE ONE)

Yes 1
No 2

RAND SCEPC Anti-Psychotic Drugs Project
Observational Data Abstraction Form

Article ID:_____ Reviewer:_____

First Author: _____Year: _____
(Last Name Only)

Study Number: ___of____Description:_____
(Enter '1of 1' if only one) (if more than one study)

1. In what country was the study conducted? **(CHECK ALL THAT APPLY)**
   - US ..... ❑
   - Canada ..... ❑
   - UK ..... ❑
   - Western Europe ..... ❑
   - Australia/New Zealand ..... ❑
   - Other (enter text: _____) .... ❑
   - Not reported ..... ❑

2. What was the percent of male participants?
   (ENTER NUMBER OR NR)
   ___ ___ ___ %

3. What was reported for the following questions regarding subjects ages? (Enter NR for not reported)
   - Mean Age ..... _____
   - Median Age ..... _____
   - Age Range ..... _____ to _____

4. Sample size: (Enter NR for not reported)
   - Screened: _____ Eligible: _____
   - Withdrawn: _____ Loss to follow-up: _____

5. What was the racial/ethnic population studied?
   (Check all that apply)
   - Caucasian ..... ❑
   - African Ancestry ..... ❑
   - Hispanic ..... ❑
   - Asian/Pacific Islander ..... ❑
   - Native American ..... ❑
   - Eskimo/Inuit ..... ❑
   - Other-Not otherwise specified ..... ❑
   - Other (enter text): ..... ❑
     _____
   - Not reported ..... ❑

6. What were the study's inclusion criteria?
   Enter text or NR for not reported:
   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____

7. What were the study's exclusion criteria?
   Enter text or NR for not reported:
   _____
   _____
   _____
   _____
   _____
   _____

RAND SCEPC Anti-Psychotic Drugs Project
Observational Data Abstraction Form

_____
_____

INTERVENTIONS

8. Enter sample size and intervention data for each arm beginning with placebo or control, then in order of first mention.

Arm/ Group	Sample size	Intervention	Dose	Units	Frequency	Dose Description	Co-intervention(s)
1	P PY _____ CNTRL N ENTERING CASES _____ N COMPLETING	_____	_____	____	____	_____	_____ _____ _____ _____ _____ _____
2	P PY _____ CNTRL N ENTERING CASES _____ N COMPLETING	_____	_____	____	____	_____	_____ _____ _____ _____ _____ _____
3	P PY _____ CNTRL N ENTERING CASES _____ N COMPLETING	_____	_____	____	____	_____	_____ _____ _____ _____ _____ _____
4	P PY _____ CNTRL N ENTERING CASES _____ N COMPLETING	_____	_____	____	____	_____	_____ _____ _____ _____ _____ _____

RAND SCEPC Anti-Psychotic Drugs Project
Observational Data Abstraction Form

9. When, relative to the start of the intervention or exposure, Were outcomes reported?

(Enter the number/text in the appropriate box)

	Number	Unit
1st follow-up		
2nd follow-up		
3rd follow-up		
4th follow-up		
5th follow-up		
6th follow-up		
7th follow-up		
8th follow-up		
9th follow-up		
10th follow-up		
11th follow-up		
12th follow-up		
13th follow-up		
14th follow-up		
15th follow-up		
16th follow-up		
17th follow-up		
18th follow-up		
19th follow-up		
20th follow-up		
21st follow-up		
22nd follow-up		
23rd follow-up		
24th follow-up		

C1: Evidence Tables – Head to Head Trials

Condition, Drug Author, Year Country, Trial named	**Study design Setting Quality (Jadad Score)**	**Eligibility criteria**	**Interventions (drug, dose, duration)**	**Run-in period/ Randomization Method Wash-out period/ Randomization Method**
Dementia and Agitation Olanzapine & Risperidone (Fontaine CS et al., 2003) US	Design: RCT Setting: Long-term care Jadad: 3	Inclusion criteria: Medically stable, Able to comply with oral, non-liquid medication, CGI >= 4, ADCS >= 25 Exclusion criteria: Neuroleptic malignant syndrome, Atypical antipsychotics sensitivity, Major depressive disorder, Schizophrenia, Bipolar disorder, Some antihypertensive drugs, Some antibiotics, Antiparkinsonian drug treatment	Olanzapine-6.65 mg/day average final dose Risperidone-1.47 mg/day average final dose Duration: 0.5 month	None 3 dy of Psychotropics for randomization not described
Dementia and Agitation Olanzapine & Risperidone (Herz LR et al., 2002) US	Design: RCT Setting: Veterans Jadad: 3	Inclusion criteria: Age > 65 Exclusion criteria: NR	Placebo-dosage not reported Risperidone-0.5-4 mg/day flexible dose Olanzapine-2.5-20 mg/day flexible dose Duration: 1.5 months	None None
Dementia and Depression Quetiapine & Risperidone (Mullen J et al., 2001) US	Design: RCT Setting: Multi-center Jadad: 1	Inclusion criteria: Age >= 18 Exclusion criteria: Lactating, Medically significant disorders, Clozapine treatment, Clozapine unresponsiveness, Previous drug-induced agranulocytosis, Pregnant, Participation in previous quetiapine trial, Participation in previous clinical trial within 4 months, Risperidone treatment within 4 months	Quetiapine mean dose 253.9 mg/day Risperidone mean dose 4.4 mg/day Duration: 4.0 months	None None

Condition, Drug Author, Year Country, Trial named	**Study design Setting Quality (Jadad Score)**	**Eligibility criteria**	**Interventions (drug, dose, duration)**	**Run-in period/ Randomization Method Wash-out period/ Randomization Method**
Dementia, Depression and Agitation Olanzapine & Risperidone (Deberdt WG et al., 2005) US	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: Age >= 40, NPI or NPI/NH >= 6 sum of hallucinations and delusional items, Assisted Living Facility resident or Nursing home resident Exclusion criteria: Frontotemporal dementia, Lewy body dementia, MMSE > 24, Parkinsons disease, Picks disease	Placebo Olanzapine-5.2 mg mean daily dose Risperidone-1.0 mg mean daily dose Duration: 2.5 months	None 3-14 dy of Placebo for patients who completed the wash-out period
Depression Olanzapine & Risperidone (Levitt A et al., 2004) Canada	Design: RCT Setting: Outpatient Jadad: 3	Inclusion criteria: Treatment-resistant depression, Failed SSRI, 18-65 years, ≥16 on HAM-D, SNRI for at least 4 weeks Exclusion criteria: Suicidal, current Axis 1 DSM IV diagnosis other than anxiety disorder, substance abuse in past 3 months, pregnant, lactating or certain other medications	SRIs or Velanfaxine + Risperidone-mean dose 1.6±0.9 mg/day SRIs or Velanfaxine + Olanzapine-mean dose 9.0±4.6 mg/day Duration: 1.5 months	None None
Dementia Olanzapine & Risperidone (Mulsant BH et al., 2004) US	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: Age > 65, 1 year duration primary condition, MMSE score of 7-26 and NPI frequency times severity score of ≥4 on delusions, hallucinations or both Exclusion criteria: Psychosis before dementia onset, Delirium, Inability to swallow oral medication or unable to cooperate with study	Risperidone-0.76 mg/day average final dose Olanzapine-5.22 mg/day average final dose Duration: 1.5 months	7 dy of Placebo for randomization not described 3 dy of ND for randomization not described

Condition, Drug Author, Year Country, Trial named	**Study design Setting Quality (Jadad Score)**	**Eligibility criteria**	**Interventions (drug, dose, duration)**	**Run-in period/ Randomization Method Wash-out period/ Randomization Method**
Depression Olanzapine & Risperidone (Tollefson GD et al., 1999) Belgium France Switzerland Netherlands South Africa Germany Spain UK US	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: Schizophrenia, schizophreniform disorder or schizoaffective disorder, ≥18 years old Exclusion criteria: Comorbid or major axis1 disorder, pregnant or lactating, Failure to show at least minimal clinical response with at least 3 antipsychotics in 3 classes	Olanzapine-17.2 mg/day mean modal dose Risperidone-7.2 mg/day mean modal dose Duration: 7.0 months	None 2-9 days for oral antipsychotic and at least one injection cycle for depot antipsychotics
Depression Olanzapine & Ziprasidone (Kinon BJ et al., 2005) US	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: MADRS >= 16, MADRS >= 4 on Item 2 Exclusion criteria: Previous sensitivity or unresponsiveness to stuffy drug	Olanzapine-10 mg/day fixed single dose Olanzapine-15 mg/day fixed single dose Olanzapine-20 mg/day fixed single dose Ziprasidone-80 mg/day fixed single dose Ziprasidone-120 mg/day fixed single dose Ziprasidone-160 mg/day fixed single dose Duration: 24.0 months	None None

Condition, Drug Author, Year Country, Trial named	**Study design Setting Quality (Jadad Score)**	**Eligibility criteria**	**Interventions (drug, dose, duration)**	**Run-in period/ Randomization Method Wash-out period/ Randomization Method**
Depression Olanzapine & Ziprasidone (Simpson GM et al., 2004) US	Design: RCT Setting: Multi-center Jadad: 4	Inclusion criteria: CGI >= 4, PANSS with score >= 4 on at least 1 items on positive symptoms subscale Exclusion criteria: Pregnant, Hospitalized >= 2 wks, Abnormal laboratory results, DSM-IV Axis I disorder, not including primary condition studied, Depot neuroleptic within 1 treatment cycle, Resistant to antipsychotic treatment, Suicidal or violent, Olanzapine > 14 days life time exposure or olanzapine daily dose >10 m	Ziprasidone-139.0 mg/day average final dose Olanzapine-13.0 mg/day average final dose Duration: 1.5 months	None 1-3 wk of Antipsychotics for randomization not described

Condition, Drug Author, Year Country, Trial named	**Allowed other medications**	**Method of outcome assessment Timing of assessment**	**Age mean/Age range Gender Ethnicity**	**Screened/ Eligible/ Enrolled**	**Withdrawn/ Lost to FU/ Analyzed**
Dementia and Agitation Olanzapine & Risperidone (Fontaine CS et al., 2003) US	Lorazepam	Assessed at baseline and 15 day: CGI, NPI, E-BEHAVE-AD, PGDRS, MOSES, QUALID, MMSE .	83/NR 33% male Caucasian, NOS	NR/47/39	4/0/35
Dementia and Agitation Olanzapine & Risperidone (Herz LR et al., 2002) US	NR	Assessed at baseline and 6 weeks: BPRS, CMPNB	NR/NR 100% male NR	NR/29/29	1/0/28
Dementia and Depression Quetiapine & Risperidone (Mullen J et al., 2001) US	Anticholinergic medications, Antidepressants , Antipsychotics (except olanzapine, sertindole, clozapine), Mood stabilizers, Rescue Medications (haloperidol, benzodiazepines, anti-EPS)	Assessed at baseline and 16 weeks: HAM_D_HDRS, CGI, PANSS	45/18-87 51% male Caucasian, African-American, Hispanic, Asian, Other	NR/728/ 728	235/NR/NR
Dementia, Depression and Agitation Olanzapine & Risperidone (Deberdt WG et al., 2005) US	Anticholinergics , Benzodiazepines permitted	Assessed at baseline and 10 weeks: NPI, CGI, NPI-NH, CMAI, BPRS, CSDD, PDS, MMSE	79/NR 34% male Caucasian, African-American, NOS	NR/494/ 494	NR/NR/493

Condition, Drug Author, Year Country, Trial named	**Allowed other medications**	**Method of outcome assessment Timing of assessment**	**Age mean/Age range Gender Ethnicity**	**Screened/ Eligible/ Enrolled**	**Withdrawn/ Lost to FU/ Analyzed**
Depression Olanzapine & Risperidone (Levitt A et al., 2004) Canada	NR	Assessed at baseline and 6 weeks: HAM_D_HDRS, MADRS, HAM-A, CGI-I	47.4±11.7 RIS; 43.2±9.2 OLA 46% male RIS; 36% male OLA NR	NR/43/43	NR/NR/43
Dementia Olanzapine & Risperidone (Mulsant BH et al., 2004) US	Lorazepam, Benzodiazapine, Cholinesterase inhibitors	Assessed at baseline and 6 weeks: NPI, CGI	84/68-95 23% male Caucasian, African-American, Hispanic	NR/86/86	NR/NR/85
Depression Olanzapine & Risperidone (Tollefson GD et al., 1999) Belgium France Switzerland Netherlands South Africa Germany Spain UK US	Anticholinergic medications	Assessed at baseline and 28 weeks: PANSS, PDC, CGI	36/18-65 65% male Caucasian, NOS	NR/339/339	NR/NR/254
Depression Olanzapine & Ziprasidone (Kinon BJ et al., 2005) US	NR	Assessed at baseline and 24 weeks: MADRS, GAF, CDSS	42/NR 63% male Caucasian, NOS	NR/394/NR	NR/NR/NR
Depression Olanzapine & Ziprasidone (Simpson GM et al., 2004) US	Anti-EPS medications, Lorazepam	Assessed at baseline and 6 weeks: BPRS, PANSS, CGI, CDSS	38/8-59 65% male Caucasian, African-American, Hispanic, Asian, NOS	367/269/ 269	NR/NR/269

Condition, Drug Author, Year Country, Trial named	Results	Method of adverse events assessment	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Dementia and Agitation Olanzapine & Risperidone (Fontaine CS et al., 2003) US	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of followups.	Monitored	Olanzapine vs Risperidone: Asystole: 5.0%(1/20) vs 0.0%(0/19) Brain stem stroke: 5.0%(1/20) vs 0.0%(0/19) Diaphoresis, fainting, & asystole: 5.0%(1/20) vs 0.0%(0/19) Drowsiness: 0.0%(0/20) vs 21.1%(4/19) Dystonia: 0.0%(0/20) vs 5.3%(1/19) Falls: 30.0%(6/20) vs 21.1%(4/19) Mild EPS: 0.0%(0/20) vs 10.5%(2/19) Rash w/elevated BP, pulse, white blood cell count, & temperature: 5.0%(1/20) vs 0.0%(0/19) Unsteady gait, falls: 10.0%(2/20) vs 0.0%(0/19)	Olanzapine vs Risperidone: Withdrawals: 20.0%(4/20) vs 10.5%(2/19) Withdrawals due to adverse events: 20.0%(4/20) vs 0.0%(0/19)
Dementia and Agitation Olanzapine & Risperidone (Herz LR et al., 2002) US	Insufficient statistics for effect-size calculation.	NR	No adverse events reported.	Placebo vs Risperidone vs Olanzapine: Withdrawals: Not reported Withdrawals due to adverse events: Not reported

Condition, Drug Author, Year Country, Trial named	Results	Method of adverse events assessment	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Dementia and Depression Quetiapine & Risperidone (Mullen J et al., 2001) US	Depression_mood-Change in HAM-D at 16 weeks: Quetiapine vs Risperidone-SMD = 0.174(-0.009,0.357)	Monitored	Quetiapine vs Risperidone: At least one adverse event: 72.3%(400/553) vs 61.1%(107/175) Agitation: 6.1%(34/553) vs 1.7%(3/175) Death: 0.7%(4/553) vs 0.0%(0/175) Dizziness: 12.7%(70/553) vs 6.9%(12/175) Dry mouth: 14.5%(80/553) vs 6.9%(12/175) EPS: 29.8%(161/541) vs 40.9%(70/171) Headache: 9.4%(52/553) vs 6.3%(11/175) Insomnia: 11.8%(65/553) vs 9.7%(17/175) Somnolence: 31.3%(173/553) vs 15.4%(27/175) Weight gain: 2.5%(14/553) vs 3.4%(6/175) Weight loss: 0.7%(4/553) vs 0.0%(0/175)	Quetiapine vs Risperidone: Withdrawals: 31.8%(175.854/553) vs 33.7%(58.975/175) Withdrawals due to adverse events: 8.7%(48.111/553) vs 5.1%(8.925/175)

Condition, Drug Author, Year Country, Trial named	Results	Method of adverse events assessment	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Dementia, Depression and Agitation Olanzapine & Risperidone (Deberdt WG et al., 2005) US	Dementia_agitation-Change in CMAI-aggression at 10 weeks: Placebo vs Olanzapine-SMD = 0.106(-0.145,0.356) Dementia_agitation-Change in CMAI-aggression at 10 weeks: Placebo vs Risperidone-SMD = -0.021(-0.272,0.23) Dementia_agitation-Change in CMAI-aggression at 10 weeks: Olanzapine vs Risperidone-SMD = -0.127(-0.328,0.074) Dementia_global-Change in NPI-NH total at 10 weeks: Placebo vs Olanzapine-SMD = 0.095(-0.155,0.344) Dementia_global-Change in NPI-NH total at 10 weeks: Placebo vs Risperidone-SMD = 0.016(-0.234,0.266) Dementia_global-Change in NPI-NH total at 10 weeks: Olanzapine vs Risperidone-SMD = -0.079(-0.279,0.122) Dementia_psychosis-Change in NPI-NH Psychosis at 10 weeks: Placebo vs Olanzapine-SMD = 0.201(-0.049,0.45) Dementia_psychosis-Change in NPI-NH Psychosis at 10 weeks: Placebo vs Risperidone-SMD = 0.12(-0.13,0.37) Dementia_psychosis-Change in NPI-NH Psychosis at 10 weeks: Olanzapine vs Risperidone-SMD = -0.08(-0.281,0.12) Dementia_severity-Change in CGI-S at 10 weeks: Placebo vs Olanzapine-WMD = 0(-0.186,0.186) Dementia_severity-Change in CGI-S at 10 weeks: Placebo vs Risperidone-WMD = 0(-0.186,0.186) Dementia_severity-Change in CGI-S at 10 weeks: Olanzapine vs Risperidone-WMD = 0(-0.148,0.148)	Monitored, reported by patient	placebo vs olanzapine vs risperidone: Abnormal gait: 3.2%(3/94) vs 9.9%(20/203) vs 10.7%(21/196) Accidental injury: 10.6%(10/94) vs 13.3%(27/203) vs 8.2%(16/196) Agitation: 13.8%(13/94) vs 18.2%(37/203) vs 15.3%(30/196) Anorexia: 8.5%(8/94) vs 6.4%(13/203) vs 5.6%(11/196) Asthenia: 2.1%(2/94) vs 7.4%(15/203) vs 8.7%(17/196) Confusion: 6.4%(6/94) vs 14.3%(29/203) vs 10.2%(20/196) Delusions: 5.3%(5/94) vs 9.4%(19/203) vs 7.7%(15/196) Dizziness: 4.3%(4/94) vs 6.4%(13/204) vs 5.6%(11/196) Dyspnea: 3.2%(3/94) vs 0.0%(0/203) vs 3.1%(6/196) Flu symptom: 3.2%(3/94) vs 1.0%(2/203) vs 0.0%(0/196) Hallucinations: 5.3%(5/94) vs 12.8%(26/203) vs 8.7%(17/196) Hostility: 1.1%(1/94) vs 6.9%(14/203) vs 6.6%(13/196) Insomnia: 5.3%(5/94) vs 6.9%(14/203) vs 5.6%(11/196) Nervousness: 9.6%(9/94) vs 7.9%(16/203) vs 10.2%(20/196) Peripheral edema: 1.1%(1/94) vs 5.4%(11/203) vs 6.1%(12/196) Somnolence: 8.5%(8/94) vs 23.2%(47/203) vs 18.9%(37/196) Urinary incontinence: 1.1%(1/94) vs 9.4%(19/203) vs 12.8%(25/196) Weight gain: 1.1%(1/94) vs 5.4%(11/203) vs 3.1%(6/196) Weight change in kg: Placebo-90 people (-0.1 kg mean, SD) vs Olanzapine-194 people (1.0 kg mean, SD) vs Risperidone-190 people (0.1 kg mean, SD)	placebo vs olanzapine vs risperidone: Withdrawals: 20.2%(18.988/94) vs 37.7%(76.908/204) vs 31.1%(60.956/196) Withdrawals due to adverse events: 3.2%(3.008/94) vs 16.2%(33.048/204) vs 8.7%(17.052/196)

Condition, Drug Author, Year Country, Trial named	Results	Method of adverse events assessment	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Depression Olanzapine & Risperidone (Levitt A et al., 2004) Canada	Insufficient statistics for effect-size calculation.	Monitored	No adverse events reported. Weight change in kg: Risperidone-21 people (0.4 kg mean, SD NR) vs Olanzapine-22 people (3.6 kg mean, SD NR)	Risperidone + (SRI or venlafaxine) vs Olanzapine + (SRI or venlafaxine): Withdrawals: Not reported Withdrawals due to adverse events: Not reported
Depression Olanzapine & Risperidone (Mulsant BH et al., 2004) US	Insufficient statistics for effect-size calculation.	Monitored	Risperidone vs Olanzapine: Somnolence: 2.8%(2/71) vs 7.1%(6/84) UKU-based anticholinergic events: 16.9%(12/71) vs 14.3%(12/84)	Risperidone vs Olanzapine: Withdrawals: 17 (19.8%) Withdrawals due to adverse events: 5.6%(4/71) vs 2.4%(2/84)

Condition, Drug Author, Year Country, Trial named	Results	Method of adverse events assessment	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Depression Olanzapine & Risperidone (Tollefson GD et al., 1999) US	Depression_mood-Change in PDC at 8 weeks: Olanzapine vs Risperidone-SMD = 0.254(0.007,0.501)	Monitored	Olanzapine vs Risperidone: Backache: 6.6%(11/167) vs 13.3%(22/165) Blurred vision: 9.6%(16/167) vs 20.6%(34/165) Breathing difficulties: 7.2%(12/167) vs 14.5%(24/165) Delayed ejaculation: 1.8%(3/167) vs 7.3%(12/165) Early waking: 12.0%(20/167) vs 24.2%(40/165) Increased dreams/nightmares: 11.4%(19/167) vs 19.4%(32/165) Dystonic events: 1.7%(3/167) vs 6.0%(10/165) Parkinsonian events: 9.9%(17/167) vs 18.6%(31/165) Pseudoparkinsonism as per Simpson-Angus rating scale: 12.5%(21/167) vs 22.3%(37/165) EPS: 18.6%(31/167) vs 31.1%(51/165) Akathisia (spontaneously reported): 9.9%(17/167) vs 10.8%(18/165) Akathisia as per Barnes Akathisia Scale: 15.9%(27/167) vs 27.3%(37/165) Dyskinetic events (spontaneously reported): 2.3%(4/167) vs 3.0%(5/165) Dyskinetic symptoms at last visit as per categorical analysis of AIMS & diagnositc criteria of Schooler & Kane: 4.6%(7/167) vs 10.7%(45/165) Residual events: 1.7%(3/167) vs 0.6%(1/165) High prolactin concentration at any time: 51.2%(86/167) vs 94.4%(156/165) Low neutrophil concentrations at any time: 4.3%(7/167) vs 0.6%(1/165) Hypersalivation: 6.4%(7/167) vs 16.3%(17/165) Palpitations: 5.5%(6/167) vs 14.4%(15/165) Weight change in kg: Olanzapine – 167 people (mean 4.1, SD 5.9) vs Risperidone – 165 people (mean 2.3, SD 4.8)	Olanzapine vs Risperidone: Withdrawals: 42.4%(73/172) vs 52.7%(88/167) Withdrawals due to adverse events: Not reported

Condition, Drug Author, Year Country, Trial named	Results	Method of adverse events assessment	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Depression Olanzapine & Ziprasidone (Kinon BJ et al., 2005) US	Depression_mood-Change in MADRS at 24 weeks: Olanzapine vs Ziprasidone-SMD = 1.032(0.822,1.243)	Monitored	Olanzapine vs Ziprasidone: Appetite decrease: 1.0%(2.02/202) vs 5.3%(10.176/192) Appetite increase: 10.4%(21.008/202) vs 4.2%(8.064/192) Bruxism: 0.0%(0/202) vs 2.1%(4.032/192) Dry mouth: 15.8%(31.916/202) vs 10.6%(20.352/192) Headache: 15.8%(31.916/202) vs 10.6%(20.352/192) Influenza: 0.0%(0/202) vs 2.6%(4.992/192) Insomnia: 12.4%(25.048/202) vs 18.0%(34.56/192) Irritability: 1.0%(2.02/202) vs 3.7%(7.104/192) Migraine NOS: 0.0%(0/202) vs 2.6%(4.992/192) Muscle twitching: 2.5%(5.05/202) vs 0.0%(0/192) Nausea: 7.9%(15.958/202) vs 11.1%(21.312/192) Peripheral edema: 3.0%(6.06/202) vs 0.0%(0/192) Psychosis NOS: 2.5%(5.05/202) vs 7.9%(15.168/192) Weight increased: 20.3%(41.006/202) vs 5.8%(11.136/192) Weight change in kg: Olanzapine-202 people (2.53 mean,4.91 SD) vs Ziprasidone-192 people (-1.65 mean,4.16 SD)	Olanzapine vs Ziprasidone: Withdrawals: 55.4% (111.908/202) vs 70.3% (134.976/192) Withdrawals due to adverse events: 16.0%(32.32/202) vs 26.0%(49.92/192)

Condition, Drug Author, Year Country, Trial named	Results	Method of adverse events assessment	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Depression Olanzapine & Ziprasidone (Simpson GM et al., 2004) US	Depression_severity-Change in CGI-S at 6 weeks: Olanzapine vs Ziprasidone-WMD = -0.05(-0.256,0.156)	Monitored, reported by patient, clinical observation	Ziprasidone vs Olanzapine: At least one adverse event: 84.6%(115/136) vs 71.4%(95/133) Body as a whole: 38.2%(52/136) vs 29.3%(39/133) Cardiovascular: 5.1%(7/136) vs 7.5%(10/133) Digestive: 40.4%(55/136) vs 30.8%(41/133) Endocrine: 0.7%(1/136) vs 0.0%(0/133) Hematic & lymphatic: 2.2%(3/136) vs 3.8%(5/133) Metabolic & nutritional: 3.7%(5/136) vs 10.5%(14/133) Musculoskeletal: 5.9%(8/136) vs 6.0%(8/133) Nervous: 60.3%(82/136) vs 48.1%(64/133) Respiratory: 17.6%(24/136) vs 12.0%(16/133) Skin & appendages: 10.3%(14/136) vs 7.5%(10/133) Special senses: 5.9%(8/136) vs 4.5%(6/133) Urogenital: 6.6%(9/136) vs 3.8%(5/133) Weight change in kg: Ziprasidone-136 people (0.9 mean, SD NR) vs Olanzapine-133 people (3.57 mean, SD NR)	Ziprasidone vs Olanzapine: Withdrawals: 48.5%(66/136) vs 36.8%(49/133) Withdrawals due to adverse events: 7.3%(10/136) vs 3.0%(4/133)

Acronyms in Evidence Table:

CCT	Clinical control trial
kg	kilograms
lbs	pounds
ND	Not described
NOS	Not otherwise specified
NR	Not reported
RCT	Randomized control trial
RR	Risk ratio
SMD	Standard mean difference
WMD	Weighted mean difference

Outcomes:

ABC	Aberrant Behavior Checklist
ACES	Agitation-Calmness Evaluation Scale
ADAS-cog	Alzheimer's Disease Assessment Scale
ADHDRS	DuPaul Attention Deficit Hyperactivity Scale
ADL	Activities of Daily Life
AIAQ	Anger, Irritability, and Assault Questionnaire
ASI	Addiction Severity Index
BABS	Brown Assessment of Beliefs Scale
BAI	Beck Anxiety Index
BDHI	Buss-Durkee Hostility Index
BDI	Beck Depression Index
BDS	Blessed Dementia Scale
BEHAVE-AD	Behavioral Pathology in Alzheimer's Disease Rating Scale
BPRS	Brief Psychiatric Rating Scale
BRMES	Bech-Rafaelsen Melancholia Scale
CAPS	Clinician Administered PTSD Scale
CDSS	Calgary Depression Scale for Schizophrenia
CES-D	Center for Epidemiologic Studies Depression Scale
CGI	Clinical Global Impression Scale
CMAI	Cohen-Mansfield Agitation Inventory
CM-PNB	Cohen-Mansfield Physically Non-Aggressive Behavior
CPRS	Children's Psychiatric Rating Scale
CSDD	Cornell Scale for Depression in Dementia
CY-BOCS	Children's Yale-Brown Obsessive-Compulsive Scale
DCM	Dementia Care Mapping
DES	Dissociative Experiences Scale
DTS	Davidson Trauma Scale
E-BEHAVE-AD	Empirical Behavioral Pathology in Alzheimer's Disease Rating Scale
FAST	Functional Assessment Staging Rating Scale
GAF	Global Assessment of Functioning Scale
HAM-A	Hamilton Rating Scale for Anxiety
HAM-D/HDRS	Hamilton Rating Scale for Depression
IGT	Iowa Gambling Task
MADRS	Montgomery-Asberg Depression Rating Scale
MDRS	Mattis Dementia Rating Scale
MMSE	Mini-Mental State Examination
M-NCAS	Modified Strain in Nursing Care Assessment

MOSES	Multidimentional Observational Scale for Elderly Subjects
MOVES	Motor Tic, Obsessions, and Compulsions, Vocal Tic Evaluation Survey
N-CBRF	Nisonger Child Behavior Rating Scale
NIMH-OC	National Institute of Mental Health Obsessive-Compulsive Scale
NPI	Neuropsychiatric Inventory
NPI/NH	Neuropsychiatric Inventory/Nursing Home
NPI-Q	Neuropsychiatric Inventory Questionnaire
OAS-M	Overt Aggression Scale-Modified
PANSS	Positive and Negative Symptom Scale
PCL-M	Patient Checklist for PTSD--Military Version
PDC	Depression cluster
PDS	Progressive Deterioration Scale
PGDRS	Psychogeriatric Dependency Rating Scale
PGI	Patient Global Impressions
QLDS	Quality of Life in Depression Scale
Q-LES-Q	Quality of Life Enjoyment and Satisfaction Questionnaire
QLS	Quality of Life Scales
QUALID	Quality of Life in Late-Stage Dementia Scale
ROAS	Retrospective Overt Aggression Scale
SANS	Scale for the Assessment of Negative Symptoms
SCL-90	Symptom Checklist-90
SDS	Sheehan Disability Scale
SF-36	Medical Outcomes Study 36-Item Short-Form Health Survey
SIB	Severe Impairment Battery
SIB-Q	Self-injurious Behavior Questionnaire
SIP	Structured Interview for PTSD
SPQ	Schizotypal Personality Questionnaire
SPRINT	Short PTSD Rating Interview
STAS-AX	State-Trait Anger Expression Inventory
STAT-S	Spielberger State-Trait Anger Scale, state version
STAT-T	Spielberger State-Trait Anger Scale, trait version
TOP-8	Treatment Outcome PTSD Scale
TSSS	Tourette's Syndrome Severity Scale
VAS	Visual Analog Scale
Y-BOCS	Yale-Brown Obsessive-Compulsive Scale
YGTSS	Yale Global Tic Severity Scale
YMRS	Young Mania Rating Scale

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C2: Evidence Tables – Active Control Trials

≥Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)
Autism Olanzapine (Malone RP et al., 2001) US	Design: RCT Setting: NR Jadad: 3	Inclusion criteria: Age 5-17, CPRS = moderate impairment ≥ any 2 items Exclusion criteria: Medically significant disorders, Seizure disorder or epilepsy or risk, Neurological disorder, Psychotropic medications, Previous exposure to study drug	Haloperidol-1.4 mg/day average final dose Olanzapine-7.9 mg/day average final dose Duration: 1.5 months
Dementia and Agitation Olanzapine (Meehan KM et al., 2002) US, Russia	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: Hospitalized/institutionalized, Nursing home resident, Age ≥ 55, PANSS ≥ 14 on the Excited Component and at least one individual PANSS ≥ 4 item score on scale 1-7, Clinically significant agitation, Exclusion criteria: Anticholinergic medications, Antipsychotic medications, Benzodiazepines, Neurological conditions, excluding Alzheimers or vascular dementia, contributing to psychosis or dementia, Abnormal laboratory results, Suicidal or violent,	Placebo-dosage not reported Lorazepam 1.0 mg/day Olanzapine-2.5-6.25 mg/day flexible dose Olanzapine-5.0-12.5 mg/day flexible dose Duration: 24 hours
Dementia and Agitation Quetiapine (Ballard C et al., 2005) UK	Design: RCT Setting: Multi-center Jadad: 4	Inclusion criteria: CMAI ≥ 39, Age ≥ 60, NPI = 4 Exclusion criteria: Antipsychotics treatment ≥ 4 wks, Cholinesterase treatment ≥ 4 wks, Previous sensitivity or unresponsiveness to stuffy drug, Severe internal or neurological disease, Medically significant disorders,	Placebo-dosage not reported Rivastigmine- min 9 mg/day Quetiapine-100 mg/day average final dose Duration: 6.5 months
Dementia and Agitation Risperidone (Chan WC et al., 2001) China	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: Age ≥ 55, CMAI of at least 4 in one item and at least 3 in another, BEHAVE-AD ≥ 8 Exclusion criteria: Lewy body dementia, Neurological or medical conditions diminishing cognitive function, Psychosis/psychotic features, Medically significant disorders, Abnormal laboratory results, Allergic or toxic reactions to psychotropic medications, Neuroleptic malignant syndrome	Haloperidol-.90 mg/day average final dose Risperidone-.85 mg/day average final dose Duration: 3.0 months

≥Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)
Dementia and Agitation Risperidone (De Deyn PP et al., 1999) Canada, UK, Europe	Design: RCT Setting: Multi-center Jadad: 4	Inclusion criteria: Age ≥ 55, Hospitalized/institutionalized, FAST ≥ 4, MMSE ≤ 23, BEHAVE-AD behavior pathology > 1, BEHAVE-AD ≥ 8 Exclusion criteria: Neurological or medical conditions diminishing cognitive function, Other psychiatric disorders, Severe internal or neurological disease, Abnormal laboratory results, Depot neuroleptic within 1 treatment cycle, Allergic or toxic reactions to psychotropic medication, Participation in a clinical trial with investigational drugs during the 4 weeks preceding trial	Placebo-dosage not reported Haloperidol-1.2 mg/day average final dose Risperidone-1.1 mg/day average final dose Duration: 3.0 months
Dementia and Agitation Risperidone (Suh GH et al., 2004) Korea	Design: RCT, Crossover Setting: Single center Jadad: 4	Inclusion criteria: Age ≥ 65, FAST ≥ 4, BEHAVE-D ≥ 8, CMAI ≥ 3 on any 2 items Exclusion criteria: Neurological or medical conditions diminishing cognitive function, Psychotic disorder, Severe internal or neurological disease, Medically significant disorders, Abnormal laboratory results, Allergic or toxic reactions to antipsychotic medications, Neuroleptic malignant syndrome,	Haloperidol-0.83 mg/day average final dose Risperidone-0.80 mg/day average final dose Duration: 2.0 months
Depression Olanzapine (David S JBAKWP, 2002) NR	Design: RCT Setting: NR Jadad: 2	Inclusion criteria: NR Exclusion criteria: NR	Placebo-dosage not reported Lorazepam-1.0-3.0 mg/day flexible dose Lorazepam l-2.0-6.0 mg/day flexible dose IM Haloperidal 7.5 mg/d IM Olanzapine 2.5-10.0 mg/d Duration: 24 hours
Depression Olanzapine (McEvoy J et al.,) US, Canada, UK, Europe HGDH Study	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: Age 16-40, Psychotic symptoms before age 35, Psychotic symptoms for at least 1 mth, but not > 60 mth, PANSS with score ≥ 4 on at least 2 items on positive symptoms subscale, PANSS ≥ 5 in 1 psychotic item, CGI ≥ 4, Psychosis/psychotic features, Exclusion criteria: Pregnant, Clozapine treatment, Antipsychotic treatment > 16 wks in a lifetime, Lactating, Medically significant disorders, Previous sensitivity or unresponsiveness to stuffy drug, Alcohol or substance abuse or dependency, Suicidal or violent	Haloperidol-4.8 mg/day average final dose Olanzapine-10.2 mg/day average final dose Duration: 26.0 months

≥Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)
Depression Olanzapine (Shelton RC et al., 2001)[1] (Tohen M et al., 1999) US	Design: Trial + open label Setting: NR Jadad: 2	Inclusion criteria: Resistant to antidepressant therapy, HAM-D ≥ 20 Exclusion criteria: Psychosis/psychotic features, Dysthymic disorder, Bipolar disorder	Fluoxetine- 52 mg/day average final dose Olanzapine-12.5 mg/day average final dose Olanzapine-13.5 mg/day average final dose, Fluoxetine-52 mg/day average final dose Duration: 4.0 months
Depression Olanzapine (Street JS et al., 2000)[1] (Street JS et al., 2000)[1] (Satterlee WG et al., 1995) NR	Design: RCT Setting: NR Jadad: 1	Inclusion criteria: Alzheimers, Psychosis/psychotic features Exclusion criteria: NR	Placebo Olanzapine Duration: 2.0 months
Depression Olanzapine (Svestka J SO, 2000) Czech Republic	Design: RCT Setting: Single center Jadad: 3	Inclusion criteria: HAM-D ≥ 21 Exclusion criteria: NR	Control-dosage not reported Olanzapine-18.25 mg/day average final dose Duration: 1.0 month
Depression Olanzapine (Tohen M et al., 2002) US	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: YMRS ≥ 20, Age 18-75 Exclusion criteria: Medically significant disorders, Alcohol or substance abuse or dependency, Atypical antipsychotics sensitivity, Sensitivity to mood stabilizer, Treatment with lithium, anticonvulsant, or antipsychotic within 24 hrs,	Divalproex- 1,402 mg/day average final dose Olanzapine-17.4 mg/day average final dose Duration: 0.8 month
Depression Olanzapine (Tohen M et al., 2005) Canada, Europe, Australia/NZ, South Africa HGHT Study	Design: RCT Setting: Multi-center Jadad: 4	Inclusion criteria: YMRS ≥ 20, 2 manic or mixed episodes in the preceding 6 years Exclusion criteria: Medically significant disorders, Alcohol or substance abuse or dependency, Depot neuroleptic within 6 weeks, Suicidal or violent, Previous sensitivity or unresponsiveness to stuffy drug	Lithium-1102.7 mg/day average final dose Olanzapine-11.9 mg/day average final dose Duration: 13.0 months
Depression Olanzapine (Tollefson GD et al., 1997) US & Europe	Design: RCT Setting: Multi-center Jadad: 5	Inclusion criteria: Age ≥ 18, BPRS ≥ 18 Exclusion criteria: NR	Haloperidol-11.8 mg/day average final dose Olanzapine-13.2 mg/day average final dose Duration: 1.5 months

≥Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)
Dementia Olanzapine & Risperidone (Gareri P et al., 2004) Western Europe	Design: RCT Setting: NR Jadad: 3	Inclusion criteria: Age ≥ 65 Exclusion criteria: NR	Promazine-50-100 mg/day flexible dose Risperidone-1-2 mg/day flexible dose Olanzapine-5-10 mg/day flexible dose Duration: 2.0 months
Depression Quetiapine (Altamura AC et al., 2003) Western Europe	Design: RCT Setting: Single center Jadad: 2	Inclusion criteria: Previous depressed, manic, or mixed episode, CGI ≥ moderate severity, MMSE ≤ 23, PANSS ≥ 50, Stable on risperidone, PANSS with score ≥ 4 on at least 2 items on positive symptoms subscale, Exclusion criteria: Abnormal laboratory results, HIV dementia	Control-dosage not reported Quetiapine-157.7 mg/day average final dose Duration: 12.0 months
Depression Risperidone (Muller-Siecheneder F et al., 1998) Western Europe	Design: RCT Setting: Multi-center Jadad: 4	Inclusion criteria: Age 18-65, PANSS ≥ 60, PANSS with score ≥ 4 on at least 2 items on positive symptoms subscale, BRMS ≥ 15 with ≥3 on its depression item, Coexisting major depressive, paranoid and/or hallucinatory symptoms Exclusion criteria: Suicidal or violent, Severe internal or neurological disease, Abnormal laboratory results, Allergic or toxic reactions to psychotropic medications, Participation in previous clinical trial within 4 weeks, Pregnant, Lactating,	Haloperidol-9.0 mg/day average final dose, Amitriptyline- 180 mg Risperidone-6.9 mg/day average final dose Duration: 1.5 months
Depression Risperidone (Shelton RC et al., 2004) US	Design: RCT Setting: NR Jadad: 4	Inclusion criteria: Treatment = lithium, carbamazepine, or valproate at therapeutic level, HAM-D ≥ 18, YMRS ≤ 8, Medically stable Exclusion criteria: Current psychosis, Alcohol or substance abuse or dependency, Other psychotropic herbs, History of non-affective disorder	Paroxetine- 20-40 mg/day Risperidone-2.15 mg/day average final dose Risperidone-1.16 mg/day average final dose, Paroxetine-20-40 mg/day Duration: 3.0 months

≥Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)
Dementia Risperidone (Weiser M et al., 2002) NR The Rivastigmine-Risperidone Study	Design: RCT Setting: Multi-center Jadad: 1	Inclusion criteria: MMSE = 5-26, NPI/NH ≥ 3 Exclusion criteria: NR	Control-dosage not reported, Rivastigmine- 3 -12 mg/day Risperidone-0.8 mg/day average final dose Risperidone-0.8 mg/day average final dose, Rivastigmine, 3-12 mg/day Risperidone-0.8 mg/day average final dose, Rivastigmine- 3-12 mg/day Duration: 5.0 months
Personality Disorder Olanzapine (Zanarini MC et al., 2004) US	Design: RCT Setting: NR Jadad: 2	Inclusion criteria: Age 18-40 Exclusion criteria: Fluoxetine successful treatment, Olanzapine successful treatment, Medically significant disorders, Seizure disorder or epilepsy or risk, Psychotropic medications, Alcohol or substance abuse or dependency, Suicidal or violent, Major depressive disorder	Fluoxetine- 15.0 mg/day average final dose Olanzapine-3.3 mg/day average final dose Olanzapine-3.2 mg/day average final dose, Fluoxetine- 12.7 mg/day average final dose Duration: 2.0 months
Tourettes Risperidone (Bruggeman R et al., 2001) Western Europe, South Africa	Design: RCT Setting: Multi-center Jadad: 5	Inclusion criteria: Age 10-65, TSSS ≥ moderate severity, CGI ≥ moderate severity Exclusion criteria: NR	Pimozide-2.9 mg/day average final dose Risperidone-3.8 mg/day average final dose Duration: 3.0 months
Tourettes Risperidone (Gaffney GR et al., 2002) US	Design: RCT Setting: Single center Jadad: 3	Inclusion criteria: Children and adolescents aged 7-17 years, Healthy, able to oral medication, able to adhere to required evaluation schedule Exclusion criteria: Epilepsy, Neurological disorder, Pregnant, Abnormal laboratory results	Risperidone-1.5 mg/day average final dose Clonidine-0.175 mg/day average final dose Duration: 2.0 months
Dementia, Depression and Agitation Olanzapine (Kinon BJ et al., 2005) US	Design: RCT Setting: NR Jadad: 2	Inclusion criteria: NR Exclusion criteria: Tardive dyskinesia	Typical antipsychotics - dosed per package insert Olanzapine - 5.9 mg/day average final dose Duration: 12.0 months

≥Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)
Depression Aripiprazole (Kasper S et al., 2003) US, Europe, other countries NOS	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: Age 18-65, Male or female, Experiencing an acute relapse, PANSS ≥ 60, PANSS with score ≥ 4 on at least 1 items on positive symptoms subscale, Previous response to antipsychotics, Continuous outpatient treatment ≥ 3 month period during previous year Exclusion criteria: Pregnant, Lactating, Resistant to antipsychotic treatment, Suicidal or violent, Alcohol or substance abuse or dependency, Neurological disorder, Investigational drug use ≥ 4 wks, Psychiatric disorder, not including primary conditioned studied	Haloperidol - 8.90 mg/day average final dose Aripiprazole - 29.01 mg/day average final dose Duration: 13.0 months
Depression Olanzapine (Corya SA et al., 2005) NR	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: MMSE = 14-26, Age ≥ 18, CGI ≥ 4, MADRS ≥ 30% reduction at week 7, At least 1 SSRI treatment failure ≥ 6 weeks at therapeutic dose Exclusion criteria: Bipolar disorder, Psychotic disorder, Schizophrenia, Schizoaffective disorder, PTSD, Major depressive disorder with seasonal pattern, Dissociative disorder	Fluoxetine-37.5 mg/day average final dose Velanfaxine - 275.4 mg/day average final dose Olanzapine - 7.9 mg/day average final dose Olanzapine - 1 mg/day average final dose, Fluoxetine - 5 mg/day average final dose Olanzapine - 7.9 mg/day average final dose, Fluoxetine - 37.5 mg/day average final dose Duration: 3.0 months
Depression Olanzapine (Dunner DL et al., 2005) NR	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: MADRS ≥ 20, CGI ≥ 4, At least 1 manic or mixed episode requiring treatment with mood stabilizer or antipsychotic Exclusion criteria: Suicidal or violent, Alcohol or substance abuse or dependency, Previous exposure to study drug, Previous failure or responded poorly to olanzapine, antidepressants or lamotrigine, Olanzapine + antidepressants treatment, Lamotrigine treatment, YMRS ≥ 15	Lamotrigine - 150-200 mg/day flexible dos Olanzapine - 6-12 mg/day flexible dose, Fluoxetine - 25-50 mg/day flexible dose Duration: 6.3 months

≥Condition, Drug Author, Year Country, Trial named	**Study design Setting Quality (Jadad Score)**	**Eligibility criteria**	**Interventions (drug, dose, duration)**
Depression Olanzapine (Shelton RC et al., 2005) US & Canada	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: At least 1 SSRI treatment failure > 4 weeks at therapeutic dose, Nortriptyline treatment failure after week 7, MADRS ≥ 20 Exclusion criteria: BPRS positive item score ≥ 3, Pregnant, Lactating, ECT treatment history or requiring during study	Fluoxetine - 35.8 mg/day average final dose Nortriptyline - 103.5 mg/day average final dose Olanzapine - 8.3 mg/day average final dose Olanzapine - 8.5 mg/day average final dose, Fluoxetine - 36.5 mg/day average final dose Duration: 2.0 months
Tourettes Risperidone (Gilbert DL et al., 2004) US	Design: CCT, Crossover Setting: Multi-center Jadad: 5	Inclusion criteria: Age 7-17, CGI ≥ 4 of tic severity score Exclusion criteria: Psychotic disorder, Alcohol or substance abuse or dependency, Pervasive developmental disorder, Eating disorders, Transient tic disorder, Medically significant disorders, Abnormal laboratory results, Sexually active females of child bearing age not using an effective contraceptive method	Pimozide - 4 mg/day average final dose Risperidone - 2 mg/day average final dose Duration: 3.0 months

Condition, Drug **Author, Year** **Country, Trial named**	**Run-in period/** **Randomization Method** **Wash-out period/** **Randomization Method**	**Allowed other medications**	**Method of outcome assessment** **Timing of assessment**	**Age mean/Age range** **Gender** **Ethnicity**
Autism Olanzapine (Malone RP et al., 2001) US	None None	NR	Assessed at baseline and 6 weeks: CGI, CPRS	8/5-12 67% male Caucasian, African-American, Hispanic
Dementia and Agitation Olanzapine (Meehan KM et al., 2002) US, Russia	None None	NR	Assessed at baseline and 24 hours: PANSS, CMAI, ACES, BPRS, MMSE, CGI	78/54-97 39% male Caucasian, NOS
Dementia and Agitation Quetiapine (Ballard C et al., 2005) UK	None None	NR	Assessed at baseline and 26 weeks: CMAI, SIB	84/NR 20% male NR
Dementia and Agitation Risperidone (Chan WC et al., 2001) China	None 7-14 dy of Psychotropics, Antiparkinsonians for randomization not described	Acetylcholinesterase inhibitors, Benzhexol, Benzodiazepines, Chloral hydrate	Assessed at baseline and 12 weeks: CMAI, BEHAVE-AD, FAST, MMSE	81/NR 28% male Chinese
Dementia and Agitation Risperidone (De Deyn PP et al., 1999) Canada, UK, Europe	None 1 wk of Psychotropics, for patients who completed the wash-out period	NR	Assessed at baseline and 12 weeks: BEHAVE-AD, CMAI, CGI	Median age 81/56-97 44% male Caucasian, African-American, Asian
Dementia and Agitation Risperidone (Suh GH et al., 2004) Korea	None 1 wk of Psychotropics for randomization not described	NR	Assessed at baseline and 15 weeks: BEHAVE-AD, CMAI, CGI	81/65-97 18% male Korean
Depression Olanzapine (David S JBAKWP, 2002) NR	None None	NR	Assessed at baseline and 999 frequency not reported: Adverse events	NR/NR NR NR

Condition, Drug **Author, Year** **Country, Trial named**	**Run-in period/** **Randomization Method** **Wash-out period/** **Randomization Method**	**Allowed other medications**	**Method of outcome assessment** **Timing of assessment**	**Age mean/Age range** **Gender** **Ethnicity**
Depression Olanzapine (McEvoy J et al.,) US, Canada, UK, Europe HGDH Study	None 12-14 dy of Antipsychotics for randomization not described	Anticholinergic medications, Benzodiazepines	Assessed at baseline and 104 weeks: CGI, MADRS, PANSS	24/NR 82% male Caucasian, African-American, Hispanic, Asian, NOS
Depression Olanzapine (Shelton RC et al., 2001)[1] (Tohen M et al., 1999) US	6 wk of Fluoxetine for non-responders None	NR	Assessed at baseline and 8 weeks: MADRS, HAM_D_HDRS, CGI	42/NR 25% male Caucasian, NOS
Depression Olanzapine (Street JS et al., 2000)[1] (Street JS et al., 2000)[1] (Satterlee WG et al., 1995) NR	None None	NR	Assessed at baseline and 8 weeks: BEHAVE-AD, Extrapyramidel side effects	79/64-94 33% male Caucasian
Depression Olanzapine (Svestka J SO, 2000) Czech Republic	4.7 dy of Placebo for randomization not described None	Amitriptyline	Assessed at baseline and 4 weeks: HAM_D_HDRS, CGI, MADRS	50/NR NR NR
Depression Olanzapine (Tohen M et al., 2002) US	None None	Anticholinergic medications, Benzodiazepines	Assessed at baseline and 3 weeks: YMRS, HAM_D_HDRS	41/18-75 43% male Caucasian, NOS
Depression Olanzapine (Tohen M et al., 2005) Canada, Europe, Australia/NZ, South Africa HGHT Study	None 6-12 wk of Antipsychotics, Antidepressants, Anticonvulsants for patients in symptomatic remission	Anticholinergic medications, Benzodiazepines	Assessed at baseline and 52 weeks: HAM_D_HDRS, YMRS	42/NR 47% male Caucasian, NOS
Depression Olanzapine (Tollefson GD et al., 1997) US & Europe	None 2-9 dy of Placebo for symptomatic patients	Anti-EPS medications, Benzodiazepines	Assessed at baseline and 6 weeks: BPRS, PANSS, MADRS, CGI	39/NR 65% male Caucasian, African-American, Hispanic, Asian, NOS

Condition, Drug Author, Year Country, Trial named	**Run-in period/ Randomization Method Wash-out period/ Randomization Method**	**Allowed other medications**	**Method of outcome assessment Timing of assessment**	**Age mean/Age range Gender Ethnicity**
Dementia Olanzapine & Risperidone (Gareri P et al., 2004) Western Europe	None 10 dy of Placebo for randomization not described	NR	Assessed at baseline and 8 weeks: NPI	79/NR 45% male NR
Depression Quetiapine (Altamura AC et al., 2003) Western Europe	None None	Valproate, Lithium, Gabapentin	Assessed at baseline and 12 months: BPRS, CGI, YMRS, HAM_D_HDRS	52/NR 43% male NR
Depression Risperidone (Muller-Siecheneder F et al., 1998) Western Europe	None 3 dy of Antipsychotics, Antidepressants for randomization not described	Anti-EPS medications, Benzodiazepines	Assessed at baseline and 6 weeks: PANSS, BPRS, BRMES, CGI	NR/19-63 38% male NR
Depression Risperidone (Shelton RC et al., 2004) US	None None	Anticonvulsants, Carbamazepine, Divalproex, Lithium, Topiramate	Assessed at baseline and 12 weeks: HAM_D_HDRS, MADRS, BDI, CGI, YMRS	36/NR 50% male NR
Dementia Risperidone (Weiser M et al., 2002) NR The Rivastigmine-Risperidone Study	None None	Lorazepam	Assessed at baseline and 20 weeks: NPI, ADAS-cog	75/NR 50% male NR
Personality Disorder Olanzapine (Zanarini MC et al., 2004) US	None None	NR	Assessed at baseline and 8 weeks: OAS-M, MADRS	23/NR 0% male Caucasian, NOS
Tourettes Risperidone (Bruggeman R et al., 2001) Western Europe, South Africa	None 2 wk for oral antipsychotics and antidepressants, A minimum of 1 treatment cycle for depot medication, At least 5 wks for fluoxetine, for randomization not described	Antiparkinson medication and benzodiazepine use was limited during treatment	Assessed at baseline and 12 weeks: TSSS, CGI, PGI, YBOCS, HAM_A, GAF	NR/11-50 88% male NR

Condition, Drug **Author, Year** **Country, Trial named**	**Run-in period/** **Randomization Method** **Wash-out period/** **Randomization Method**	**Allowed other medications**	**Method of outcome assessment** **Timing of assessment**	**Age mean/Age range** **Gender** **Ethnicity**
Tourettes Risperidone (Gaffney GR et al., 2002) US	7-14 dy of Placebo/Randomization not described	None	Assessed at baseline and 8 weeks: Yale Global Tic, YBOCS, ADHDRS, CGI, MOVES, HAM_D_HDRS	11/7-17 90% male NR
Dementia, Depression and Agitation Olanzapine (Kinon BJ et al., 2005) US	6 wk of Olanzapine and typical antipsychotics. Patients who remained without tardive dyskinesia proceed to randomization None	Not reported	Assessed at baseline and 1 years: Adverse events	79 / NR 48% male NR
Depression Aripiprazole (Kasper S et al., 2003) US, Europe, other countries NOS	None ≥ 5 dy of placebo for patients still eligible after washout	Anticholinergic medications, Anti-EPS medications	Assessed at baseline and 52 weeks: PANSS, MADRS, CGI, Extrapyramidel side effects	37 / NR 59% male NR
Depression Olanzapine (Corya SA et al., 2005) NR	7 wk of Venlafaxine for randomization not described None	Benzodiazepines	Assessed at baseline and 12 weeks: MADRS, CGI, HAM_A, BPRS, Extrapyramidel side effects	46 / NR 28% male Caucasian, NOS
Depression Olanzapine (Dunner DL et al., 2005) NR	None None	Not reported	Assessed at baseline and 25 weeks: CGI, MADRS, YMRS, BSI	37 / NR 40% male Caucasian, NOS
Depression Olanzapine (Shelton RC et al., 2005) US & Canada	7 wk of Nortriptyline for patients resistant to nortriptyline treatment 2-7 dy of ND for randomization not described	Lorazepam as long as it was not within 8 hours of psychiatric evaluation	Assessed at baseline and 8 weeks: MADRS, CGI, HAM_A, BPRS, Extrapyramidel side effects	42 / NR 32% male Caucasian, NOS
Tourettes Risperidone (Gilbert DL et al., 2004) US	2 wk of placebo, randomization not described 2 wk of placebo after cross-over	Not reported	Assessed at baseline and 4 weeks: Yale Global Tic, CGI, TSSR, Extrapyramidel side effects	11 / 7-17 79% male Caucasian, African-American

Condition, Drug Author, Year Country, Trial named	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results	Method of adverse events assessment
Autism Olanzapine (Malone RP et al., 2001) US	NR/13/12	1/0/12	Autism-Change in CGI-S at 6 weeks: Haloperidol vs Olanzapine-SMD = -0.233(-1.369,0.904)	Monitored
Dementia and Agitation Olanzapine (Meehan KM et al., 2002) US, Russia	331/272/ 272	NR/NR/NR	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of followups.	Monitored, clinical observation and exam
Dementia and Agitation Quetiapine (Ballard C et al., 2005) UK	282/93/93	20/1/74	Dementia_agitation-Change in CMAI at 6 weeks: Placebo vs Quetiapine-SMD = 0.276(-0.25, 0.803) Dementia_agitation-Change in CMAI at 6 weeks: Rivastigmine vs Quetiapine-SMD = -0.051(-0.601,0.499)	NR
Dementia and Agitation Risperidone (Chan WC et al., 2001) China	NR/58/58	3/NR/55	Dementia_agitation-Change in BEHAVE-AD (aggressiveness) at 12 weeks: Haloperidol vs Risperidone-SMD = 0.057(-0.472,0.585) Dementia_psychosis-Change in BEHAVE-AD (psychosis) at 12 weeks: Haloperidol vs Risperidone-SMD = -0.383(-0.917,0.15)	Monitored, reported by patient

Condition, Drug Author, Year Country, Trial named	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results	Method of adverse events assessment
Dementia and Agitation Risperidone (De Deyn PP et al., 1999) Canada, UK, Europe	371/344/ 344	121/0/NR	Dementia_agitation-Change in BEHAVE-AD (aggressiveness) at 12 weeks: Placebo vs Risperidone-SMD = -0.702(-1.041, -0.362) Dementia_agitation-Change in BEHAVE-AD (aggressiveness) at 12 weeks: Haloperidol vs Risperidone-SMD = -0.401(-0.727,-0.075) Dementia_global-Change in BEHAVE-AD (total) at 12 weeks: Placebo vs Risperidone-SMD = -0.427(-0.76, -0.094) Dementia_global-Change in BEHAVE-AD (total) at 12 weeks: Haloperidol vs Risperidone-SMD = -0.221(-0.545,0.102)	Monitored
Dementia and Agitation Risperidone (Suh GH et al., 2004) Korea	280/120/ 120	6/0/117	Dementia_global-Change in BEHAVE-AD-K (total) at 8 weeks: Haloperidol vs Risperidone-SMD = -0.558(-0.923,-0.193)	Monitored
Depression Olanzapine (David S JBAKWP, 2002) NR	NR/1054/NR	NR/NR/NR	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of followups.	Monitored

Condition, Drug Author, Year Country, Trial named	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results	Method of adverse events assessment
Depression Olanzapine (McEvoy J et al.,) US, Canada, UK, Europe HGDH Study	NR/263/ 263	NR/14/41	Depression_mood-Change in MADRS at 12 weeks: Haloperidol vs Olanzapine-SMD = -0.218(-0.46,0.025) Depression_severity-Change in CGI-S at 12 weeks: Haloperidol vs Olanzapine-WMD = -0.15(-0.352,0.052)	Monitored
Depression Olanzapine (Shelton RC et al., 2001)' (Tohen M et al., 1999) US	34/33/28	NR/1/22	Insufficient statistics for effect-size calculation.	NR
Depression Olanzapine (Street JS et al., 2000)' (Street JS et al., 2000)' (Satterlee WG et al., 1995) NR	NR/NR/ 238	NR/NR/NR	Insufficient statistics for effect-size calculation.	NR
Depression Olanzapine (Svestka J SO, 2000) Czech Republic	NR/40/40	0/0/40	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of followups.	NR
Depression Olanzapine (Tohen M et al., 2002) US	330/251/ 251	84/0/251	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of followups.	Monitored
Depression Olanzapine (Tohen M et al., 2005) Canada, Europe, Australia/NZ, South Africa HGHT Study	543/431/ 431	257/3/431	Depression_mood Follow-up time greater than 48 weeks	Monitored

Condition, Drug Author, Year Country, Trial named	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results	Method of adverse events assessment
Depression Olanzapine (Tollefson GD et al., 1997) US & Europe	2223/1996/1996	773/26/1996	Depression_mood-Change in MADRS at 6 weeks: Haloperidol vs Olanzapine-SMD = -0.389(-0.502,-0.275) Depression_severity-Change in CGI-S at 6 weeks: Haloperidol vs Olanzapine-WMD = -0.3(-0.379,-0.221)	Monitored, elicited by investigator, medical record, clinical exam
Depression Olanzapine & Risperidone (Gareri P et al., 2004) Western Europe	NR/60/60	0/0/60	Insufficient statistics for effect-size calculation.	Monitored
Depression Quetiapine (Altamura AC et al., 2003) Western Europe	NR/28/28	0/0/28	Depression_mood Follow-up time greater than 48 weeks Depression_severity Follow-up time greater than 48 weeks	Monitored
Depression Risperidone (Muller-Siecheneder F et al., 1998) Western Europe	NR/123/ 123	33/0/90	Depression_mood-Change in BRMES at 6 weeks: Haloperidol + amitriptyline vs Risperidone-SMD = -0.427(-0.828,-0.026)	Monitored, elicited by investigator

Condition, Drug Author, Year Country, Trial named	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results	Method of adverse events assessment
Depression Risperidone (Shelton RC et al., 2004) US	NR/30/30	9/2/30	Depression_improvement-Change in CGI-I at 12 weeks: Paroxetine + placebo vs Risperidone + placebo-WMD = 0.7(-0.62,2.02) Depression_improvement-Change in CGI-I at 12 weeks: Paroxetine + placebo vs Risperidone + paroxetine-WMD = -0.7 (-1.805,0.405) Depression_mood-Change in MADRS at 12 weeks: Paroxetine + placebo vs Risperidone + placebo-SMD = 0.479(-0.656, 1.614) Depression_mood-Change in MADRS at 12 weeks: Paroxetine + placebo vs Risperidone + paroxetine-SMD = 0.272(-0.792,1.336)	Monitored
Depression Risperidone (Weiser M et al., 2002) NR The Rivastigmine-Risperidone Study	NR/90/85	NR/NR/58	Dementia_global-Change in NPI-12 at 20 weeks: Rivastigmine vs Risperidone-SMD = -0.918(-1.926,0.089) Dementia_global-Change in NPI-12 at 20 weeks: Rivastigmine vs Rivastigmine + risperidone-SMD = -0.956(-1.752,-0.161) Dementia_global-Change in NPI-12 at 20 weeks: Rivastigmine vs Risperidone + rivastigmine-SMD = -0.798(-1.903,0.308)	Monitored, reported by patient

Condition, Drug Author, Year Country, Trial named	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results	Method of adverse events assessment
Personality Disorder Olanzapine (Zanarini MC et al., 2004) US	NR/45/45	2/1/1942	Personality Disorder-Change in MADRAS at 8 weeks: Fluoxetine vs Olanzapine-SMD = -0.086(-0.818,0.646) Personality Disorder-Change in MADRAS at 8 weeks: Fluoxetine vs Olanzapine + fluoxetine-SMD = -0.286(-1.059,0.487)	Monitored, elicited by investigator
Tourettes Risperidone (Bruggeman R et al., 2001) Western Europe, South Africa	NR/51/51	8/1/50	Tourettes-Change in CGI-I at 12 weeks: Pimozide vs Risperidone-SMD = 0(-0.555,0.555)	Monitored, reported by patient
Tourettes Risperidone (Gaffney GR et al., 2002) US	24/21/21	1/0/21	Tourettes-Change in CGI-S at 8 weeks: Clonidine vs Risperidone-SMD = 0(-0.895,0.895)	Monitored
Dementia, Depression and Agitation Olanzapine (Kinon BJ et al., 2005) US	NR/293/293	148/4/141	No outcomes of interest to calculate effect size.	Monitored
Depression Aripiprazole (Kasper S et al., 2003) US, Europe, other countries NOS	NR/1294/1294	NR/NR/1283	Depression_mood Follow-up time greater than 48 weeks.	Monitored, elicited by investigator, reported by patient, .
Depression Olanzapine (Corya SA et al., 2005) NR	807/483/483	NR/10/365	Insufficient statistics for effect-size calculation.	Monitored

Condition, Drug Author, Year Country, Trial named	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results	Method of adverse events assessment
Depression Olanzapine (Dunner DL et al., 2005) NR	NR/410/410	189/84/393	Depression_mood and Depression_severity not a comparison of interest.	Monitored
Depression Olanzapine (Shelton RC et al., 2005) US & Canada	946/500/500	NR/17/500	Depression_severity-Change in CGI-S at 8 weeks: Fluoxetine vs Olanzapine-WMD = 0.1(-0.146,0.346) Depression_severity-Change in CGI-S at 8 weeks: Nortriptlyline vs Olanzapine-WMD = 0(-0.306,0.306)	Monitored
Tourettes Risperidone (Gilbert DL et al., 2004) US	NR/19/19	1/1/2017	Tourettes Crossover study.	Monitored

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Autism Olanzapine (Malone RP et al., 2001) US	Haloperidol vs Olanzapine: Ataxia: 16.7%(1/6) vs 0.0%(0/6) Behavioral toxicity: 33.3%(2/6) vs 0.0%(0/6) Drowsiness: 33.3%(2/6) vs 83.3%(5/6) Dry mouth: 16.7%(1/6) vs 16.7%(1/6) Dyskinesia: 0.0%(0/6) vs 0.0%(0/6) Enuresis: 16.7%(1/6) vs 16.7%(1/6) Insomnia: 0.0%(0/6) vs 16.7%(1/6) Nausea/vomiting: 0.0%(0/6) vs 33.3%(2/6) Rash: 16.7%(1/6) vs 0.0%(0/6) Rigidity: 16.7%(1/6) vs 0.0%(0/6) Tachycardia: 16.7%(1/6) vs 0.0%(0/6) Transient mild rigidity: 16.7%(1/6) vs 0.0%(0/6) Weight gain: 83.3%(5/6) vs 100.0%(6/6) Weight loss: 16.7%(1/6) vs 0.0%(0/6) Weight change in lbs: Haloperidol-6 people (3.2 mean,4.9 SD) vs Olanzapine-6 people (9 mean,3.5 SD)	Haloperidol vs Olanzapine: Withdrawals: 0.0%(0/6) vs 0.0%(0/6) Withdrawals due to adverse events: 0.0%(0/6) vs 0.0%(0/6)
Dementia and Agitation Olanzapine (Meehan KM et al., 2002) US, Russia	Placebo vs Lorazepam 1.0 mg/d vs Olanzapine 2.5 mg/d vs Olanzapine 5.0 mg/d: Accidental injury: 0.0%(0/67) vs 4.4%(3/68) vs 1.4%(1/71) vs 3.0%(2/66) ECG abnormal: 0.0%(0/67) vs 0.0%(0/68) vs 1.4%(1/71) vs 3.0%(2/66) Headache: 0.0%(0/67) vs 1.5%(1/68) vs 2.8%(2/71) vs 3.0%(2/66) Hypertension: 1.5%(1/67) vs 2.9%(2/68) vs 0.0%(0/71) vs 3.0%(2/66) Sinus bradycardia: 3.0%(2/67) vs 0.0%(0/68) vs 0.0%(0/71) vs 0.0%(0/66) Somnolence: 3.0%(2/67) vs 10.3%(7/68) vs 4.2%(3/71) vs 3.0%(2/66) Vasodilation: 0.0%(0/67) vs 0.0%(0/68) vs 0.0%(0/71) vs 3.0%(2/66)	Placebo vs Lorazepam 1.0 mg/d vs Olanzapine 2.5 mg/d vs Olanzapine 5.0 mg/d: Withdrawals: 13.4%(9/67) vs 17.6%(12/68) vs 11.3%(8/71) vs 10.6%(7/66) Withdrawals due to adverse events: 0.0%(0/67) vs 0.0%(0/68) vs 0.0%(0/71) vs 0.0%(0/66)
Dementia and Agitation Quetiapine (Ballard C et al., 2005) UK	Placebo vs Rivastigmine vs Quetiapine: Death: 3.2%(1/31) vs 0.0%(0/31) vs 0.0%(0/31) Serious adverse events: 3.2%(1/31) vs 0.0%(0/31) vs 0.0%(0/31)	Placebo vs Rivastigmine vs Quetiapine: Withdrawals: 3.2%(1/31) vs 32.3%(10/31) vs 25.8%(8/31) Withdrawals due to adverse events: Not reported

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Dementia and Agitation Risperidone (Chan WC et al., 2001) China	Haloperidol vs Risperidone: Acute retention of urine: 0.0%(0/29) vs 3.4%(1/29) Constipation: 6.9%(2/29) vs 0.0%(0/29) Drug-related day-time sleepiness: 10.3%(3/29) vs 0.0%(0/29) Nausea: 0.0%(0/29) vs 3.4%(1/29) Somnolence: 3.4%(1/29) vs 0.0%(0/29)	Haloperidol vs Risperidone: Withdrawals: 3.4%(1/29) vs 6.9%(2/29) Withdrawals due to adverse events: 3.4%(1/29) vs 0.0%(0/29)
Dementia and Agitation Risperidone (De Deyn PP et al., 1999) Canada, UK, Europe	Placebo vs Haloperidol vs Risperidone: At least one adverse event: 72.8%(83/114) vs 80.0%(92/115) vs 76.5%(88/115) Somnolence: 4.4%(5/114) vs 18.3%(19/115) vs 12.2%(14/115)	Placebo vs Haloperidol vs Risperidone: Withdrawals: 35.1%(40/114) vs 29.6%(34/115) vs 40.9%(47/115) Withdrawals due to adverse events: Not reported
Dementia and Agitation Risperidone (Suh GH et al., 2004) Korea	Adverse events not reported.	Haloperidol vs Risperidone: Withdrawals: 1.7%(1/60) vs 3.3%(2/60) Withdrawals due to adverse events: 1.7%(1/60) vs 3.3%(2/60)
Depression Olanzapine (David S JBAKWP, 2002) NR	No adverse events reported.	Data not reported by intervention group.
Depression Olanzapine (McEvoy J et al.,) US, Canada, UK, Europe HGDH Study	Haloperidol vs Olanzapine: Akathisia: 30.3%(39.996/132) vs 13.0%(17.03/131) Dystonia: 13.0%(17.16/132) vs 0.0%(0/131) Emotional liability: 5.3%(6.996/132) vs 7.6%(9.956/131) Epistaxis: 0.0%(0/132) vs 4.6%(6.026/131) Extrapyramidal syndrome: 15.2%(20.064/132) vs 4.6%(6.026/131) Increased appetite: 6.1%(8.052/132) vs 16.8%(22.008/131) Joint disorder: 12.1%(15.972/132) vs 3.1%(4.061/131) Nervousness: 38.6%(50.952/132) vs 20.6%(26.986/131) Vomiting: 12.9%(17.028/132) vs 7.6%(9.956/131) Weight gain: 18.9%(24.948/132) vs 43.5%(56.985/131) Weight change in kg: Haloperidol-132 people (4.12 mean, SD NR) vs Olanzapine-131 people (10.47 mean, SD NR)	Haloperidol vs Olanzapine: Withdrawals: 91.1%(119/132) vs 78.6%(103/131) Withdrawals due to adverse events: 13.6%(18/132) vs 5.3%(7/131)

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Depression Olanzapine (Shelton RC et al., 2001)' (Tohen M et al., 1999) US	No adverse events reported. Weight change in kg: Fluoxetine-10 people (0.88 mean,1.33 SD) vs Olanzapine-8 people (6.07 mean,2.57 SD) vs Olanazpine + Fluoxetine-10 people (6.67 mean,4.54 SD)	Fluoxetine vs Olanzapine vs Olanazpine + Fluoxetine: Withdrawals: 30.0%(3/10) vs 25.0%(2/8) vs 10.0%(1/10) Withdrawals due to adverse events: 0.0%(0/10) vs 12.5%(1/8) vs 0.0%(0/10)
Depression Olanzapine (Street JS et al., 2000)' (Street JS et al., 2000)' (Satterlee WG et al., 1995) NR	No adverse events reported.	Haloperidol vs Olanzapine: Withdrawals: Not reported Withdrawals due to adverse events: Not reported
Depression Olanzapine (Svestka J SO, 2000) Czech Republic	Amitriptyline vs Olanzapine: Hyperprolactinemia: 5.0%(1/20) vs 30.0%(6/20) Tachycardia: 50.0%(10/20) vs 20.0%(4/20) Undesirable effects: 90.0%(18/20) vs 60.0%(12/20)	Amitriptyline vs Olanzapine: Withdrawals: Not reported Withdrawals due to adverse events: Not reported

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Depression Olanzapine (Tohen M et al., 2002) US	Divalproex vs Olanzapine: Agitation: 11.1%(14/126) vs 11.2%(14/125) Asthenia: 13.5%(17/126) vs 16.0%(20/125) Constipation: 11.9%(15/126) vs 14.4%(18/125) Decreased platelet count: 8.0%(10.08/126) vs 0.0%(0/125) Diarrhea: 13.5%(17/126) vs 6.4%(8/125) Dizziness: 11.9%(15/126) vs 16.0%(20/125) Dry mouth: 6.3%(8/126) vs 33.6%(42/125) Dyspepsia: 11.1%(14/126) vs 14.4%(18/125) Headache: 23.0%(29/126) vs 22.4%(28/125) Increased ALT/SGPT values: 0.0%(0/126) vs 5.1%(6.375/125) Increased appetite: 2.4%(3/126) vs 12.0%(15/125) Nausea: 28.6%(36/126) vs 10.4%(13/125) Neck rigidity: 1.6%(2/126) vs 7.2%(9/125) Nervousness: 16.7%(21/126) vs 10.4%(13/125) Pain: 14.3%(18/126) vs 13.6%(17/125) Sleep disorder: 0.8%(1/126) vs 5.6%(7/125) Somnolence: 20.6%(26/126) vs 39.2%(49/125) Speech disorder: 0.8%(1/126) vs 8.0%(10/125) Tongue edema: 0.0%(0/126) vs 4.8%(6/125) Tremor: 3.2%(4/126) vs 9.6%(12/125) Vomiting: 14.3%(18/126) vs 8.0%(10/125) Weight gain: 7.9%(10/126) vs 12.0%(15/125) Weight change in kg: Divalproex-126 people (0.9 mean, 2.5 SD) vs Olanzapine-125 people (2.5 mean,2.5 SD)	Divalproex vs Olanzapine: Withdrawals: 22.2%(28/126) vs 23.2%(29/125) Withdrawals due to adverse events: 7.1%(9/126) vs 9.6%(12/125)
Depression Olanzapine (Tohen M et al., 2005) Canada, Europe, Australia/NZ, South Africa HGHT Study	Lithium vs Olanzapine: Anxiety: 4.7%(10/214) vs 5.5%(12/217) Death: 0.9%(2/214) vs 0.0%(0/217) Depression not otherwise specified: 11.7%(25/214) vs 20.7%(45/217) Headache not otherwise specified: 5.1%(11/214) vs 4.1%(9/217) Hypersomnia: 0.0%(0/214) vs 2.8%(6/217) Insomnia: 22.4%(48/214) vs 7.8%(17/217) Nausea: 3.7%(8/214) vs 0.5%(1/217) Weight decrease: 5.1%(11/214) vs 3.2%(7/217) Weight increase: 4.7%(10/214) vs 6.5%(14/217) Worsening of mania: 20.6%(44/214) vs 7.8%(17/217) Weight change in kg: Lithium-214 people (-1.4 kg mean, SD) vs Olanzapine-217 people (1.8 kg mean, SD)	Lithium vs Olanzapine: Withdrawals: 67.3%(144/214) vs 53.5%(116/217) Withdrawals due to adverse events: 25.7%(55/214) vs 18.9%(41/217)

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Depression Olanzapine (Tollefson GD et al., 1997) US & Europe	Haloperidol vs Olanzapine: Acute dyskinesia: 8.0%(51/636) vs 2.8%(37/1306) Akathisia: 35.5%(226/636) vs 14.2%(186/1306) Ataxia: 3.1%(20/636) vs 1.7%(22/1306) Blurred vision: 15.1%(96/636) vs 10.6%(139/1306) Chills: 7.5%(48/636) vs 4.3%(56/1306) Conversion symptoms: 2.4%(15/636) vs 1.0%(13/1306) Decreased appetite: 18.1%(115/636) vs 11.4%(149/1306) Difficulty falling asleep: 28.8%(18.3/636) vs 22.9%(299/1306) Difficulty with micturition: 6.1%(39/636) vs 3.6%(47/1306) Drowsiness: 31.3%(199/636) vs 26.0%(339/1306) Dry mouth: 16.2%(103/636) vs 22.2%(290/1306) Early awakening: 24.1%(153/636) vs 15.9%(208/1306) Excessive appetite: 12.4%(79/636) vs 24.0%(313/1306) Heaviness in extremities: 16.4%(104/636) vs 11.5%(150/1306) Hot flashes: 5.7%(36/636) vs 3.4%(45/1306) Hypersalivation: 19.5%(124/636) vs 8.7%(113/1306) Hypertonia: 21.1%(134/636) vs 8.4%(110/1306) Hypokinesia: 13.5%(86/636) vs 5.1%(67/1306) Hypotonia: 4.6%(29/636) vs 2.7%(35/1306) Increased dreams/nightmares: 17.3%(110/636) vs 13.0%(170/1306) Increased perspiration: 13.2%(84/636) vs 6.8%(89/1306) Interrupted sleep: 30.3%(193/636) vs 19.0%(248/1306) Nausea: 13.7%(87/636) vs 10.1%(132/1306) Palpitations: 9.9%(63/636) vs 6.6%(86/1306) Shortened sleep: 24.8%(158/636) vs 15.1%(197/1306) Tremor: 26.3%(167/636) vs 16.5%(216/1306) Vomiting: 9.0%(57/636) vs 5.1%(67/1306) Weight change in kg: Haloperidol-636 people (0.02 mean,2.79 SD) vs Olanzapine-1306 people (1.88 mean,3.54 SD)	Haloperidol vs Olanzapine: Withdrawals: 53.2%(351/660) vs 33.6%(448/ 1336) Withdrawals due to adverse events: 7.3%(48/660) vs 4.5%(60/1336)

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Depression Olanzapine & Risperidone (Gareri P et al., 2004) Western Europe	Promazine vs Risperidone vs Olanzapine: Abdominal pain: 0.0%(0/20) vs 4.0%(0.8/20) vs 0.0%(0/20) Akathisia: 0.0%(0/20) vs 0.0%(0/20) vs 4.0%(0.8/20) Arterial hypotension: 35.0%(7/20) vs 20.0%(4/20) vs 0.0%(0/20) Asthenia: 0.0%(0/20) vs 8.0%(1.6/20) vs 0.0%(0/20) Confusion: 15.0%(3/20) vs 0.0%(0/20) vs 0.0%(0/20) Constipation: 35.0%(7/20) vs 8.0%(1.6/20) vs 16.0%(3.2/20) Dizziness: 0.0%(0/20) vs 0.0%(0/20) vs 16.0%(3.2/20) Drowsiness: 10.0%(2/20) vs 20.0%(4/20) vs 32.0%(6.4/20) Dyspepsia: 0.0%(0/20) vs 12.0%(2.4/20) vs 0.0%(0/20) EPS: 20.0%(4/20) vs 8.0%(1.6/20) vs 0.0%(0/20) Hyperglycemia (glycemic decompensation): 0.0%(0/20) vs 0.0%(0/20) vs 4.0%(1/20) Increased libido and disinhibition: 0.0%(0/20) vs 4.0%(0.8/20) vs 0.0%(0/20) Insomnia: 0.0%(0/20) vs 4.0%(0.8/20) vs 0.0%(0/20) Nausea (sickness): 5.0%(1/20) vs 0.0%(0/20) vs 0.0%(0/20) Postural hypotension: 0.0%(0/20) vs 0.0%(0/20) vs 8.0%(1.6/20) Sinus tachycardia: 25.0%(5/20) vs 8.0%(1.6/20) vs 0.0%(0/20) Weight gain: 0.0%(0/20) vs 0.0%(0/20) vs 32.0%(6.4/20) Xerostomy: 30.0%(6/20) vs 0.0%(0/20) vs 0.0%(0/20)	Promazine vs Risperidone vs Olanzapine: Withdrawals: Not reported Withdrawals due to adverse events: 0.0%(0/20) vs 5.0%(1/20) vs 0.0%(0/20)
Depression Quetiapine (Altamura AC et al., 2003) Western Europe	Other mood stabilizers (lithium, valproate, gabapentin) vs Quetiapine: Constipation: 0.0%(0/14) vs 14.3%(2/14) Sedation: 0.0%(0/14) vs 14.3%(2/14) Weight gain: 14.3%(2/14) vs 0.0%(0/14) Weight change in kg: Other mood stabilizers (lithium, valproate, gabapentin)-14 people (1.79 mean, 1.31 SD) vs Quetiapine-14 people (1.08 mean, 1.26 SD)	Other mood stabilizers (lithium, valproate, gabapentin) vs Quetiapine: Withdrawals: .%(0/14) vs .%(0/14) Withdrawals due to adverse events: 0.0%(0/14) vs 0.0%(0/14)

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Depression Risperidone (Muller-Siecheneder F et al., 1998) Western Europe	Haloperidol + Amitriptyline vs Risperidone: Abdominal pain: 3.3%(2/61) vs 0.0%(0/62) Abnormal hepatic function: 16.4%(10/61) vs 4.8%(3/62) Agitation: 1.6%(1/61) vs 3.2%(2/62) Akathisia, tremor: 0.0%(0/61) vs 3.2%(2/62) Constipation: 11.5%(7/61) vs 8.1%(5/62) Dizziness: 1.6%(1/61) vs 3.2%(2/62) Dry mouth: 9.8%(6/61) vs 6.5%(4/62) Dysphagia: 0.0%(0/61) vs 3.2%(2/62) Dystonia, abdominal pain, constipation: 3.3%(2/61) vs 0.0%(0/62) Fatigue: 3.3%(2/61) vs 6.5%(4/62) Hyperprolactinemia: 3.3%(2/61) vs 1.6%(1/62) Hypotension: 6.6%(4/61) vs 0.0%(0/62) Nausea and/or vomiting: 3.3%(2/61) vs 6.5%(4/62) Speech disorder: 1.6%(1/61) vs 1.6%(1/62) Suicidal ideations: 3.3%(2/61) vs 1.6%(1/62) Tachycardia: 3.3%(2/61) vs 1.6%(1/62)	Haloperidol + Amitriptyline vs Risperidone: Withdrawals: 21.3%(13/61) vs 32.3%(20/62) Withdrawals due to adverse events: 11.5%(7/61) vs 21.0%(13/62)

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Depression Risperidone (Shelton RC et al., 2004) US	Paroxetine + placebo vs Risperidone + placebo vs Risperidone + paroxetine: Agitation: 0.0%(0/10) vs 0.0%(0/10) vs 10.0%(1/10) Anxiety: 0.0%(0/10) vs 10.0%(1/10) vs 0.0%(0/10) Appetite decrease: 10.0%(1/10) vs 0.0%(0/10) vs 0.0%(0/10) Appetite increase: 20.0%(2/10) vs 20.0%(2/10) vs 20.0%(2/10) Blurred vision: 0.0%(0/10) vs 0.0%(0/10) vs 10.0%(1/10) Constipation: 0.0%(0/10) vs 10.0%(1/10) vs 0.0%(0/10) Depression increased: 0.0%(0/10) vs 0.0%(0/10) vs 10.0%(1/10) Dermatitis: 0.0%(0/10) vs 10.0%(1/10) vs 0.0%(0/10) Diaphoresis: 10.0%(1/10) vs 10.0%(1/10) vs 0.0%(0/10) Diarrhea: 30.0%(3/10) vs 20.0%(2/10) vs 10.0%(1/10) Dizziness: 10.0%(1/10) vs 0.0%(0/10) vs 10.0%(1/10) Dreaming increased: 0.0%(0/10) vs 10.0%(1/10) vs 0.0%(0/10) Dry mouth: 30.0%(3/10) vs 10.0%(1/10) vs 10.0%(1/10) Edema: 0.0%(0/10) vs 10.0%(1/10) vs 0.0%(0/10) Fatigue: 20.0%(2/10) vs 20.0%(2/10) vs 10.0%(1/10) GI distress: 20.0%(2/10) vs 20.0%(2/10) vs 20.0%(2/10) Hair loss: 10.0%(1/10) vs 0.0%(0/10) vs 0.0%(0/10) Headache: 10.0%(1/10) vs 10.0%(1/10) vs 0.0%(0/10) Insomnia: 20.0%(2/10) vs 0.0%(0/10) vs 10.0%(1/10) Joint pain: 0.0%(0/10) vs 10.0%(1/10) vs 0.0%(0/10) Memory problems: 0.0%(0/10) vs 0.0%(0/10) vs 10.0%(1/10) Myoclonus: 0.0%(0/10) vs 10.0%(1/10) vs 0.0%(0/10) Nausea: 20.0%(2/10) vs 0.0%(0/10) vs 0.0%(0/10) Paresthesias: 0.0%(0/10) vs 0.0%(0/10) vs 10.0%(1/10) Salivation increased: 0.0%(0/10) vs 0.0%(0/10) vs 10.0%(1/10) Sexual dysfunction: 20.0%(2/10) vs 0.0%(0/10) vs 30.0%(3/10) Somnolence: 20.0%(2/10) vs 50.0%(5/10) vs 20.0%(2/10) Spaciness: 10.0%(1/10) vs 0.0%(0/10) vs 0.0%(0/10) Tremor: 10.0%(1/10) vs 10.0%(1/10) vs 10.0%(1/10) Urinary tract infection: 10.0%(1/10) vs 0.0%(0/10) vs 0.0%(0/10) Weight gain: 10.0%(1/10) vs 10.0%(1/10) vs 40.0%(4/10)	Paroxetine + placebo vs Risperidone + placebo vs Risperidone + paroxetine: Withdrawals: 20.0%(2/10) vs 50.0%(5/10) vs 40.0%(4/10) Withdrawals due to adverse events: 10.0%(1/10) vs 10.0%(1/10) vs 30.0%(3/10)

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Depression Risperidone (Weiser M et al., 2002) NR The Rivastigmine-Risperidone Study	Rivastigmine vs Risperidone vs Rivastigmine + risperidone vs Risperidone + rivastigmine: At least one adverse event: 79.0%(11.06/14) vs 92.0%(11.96/13) vs 87.0%(40.89/47) vs 94.0%(15.04/16) Abdominal pain: 14.0%(1.96/14) vs 0.0%(0/13) vs 6.0%(2.82/47) vs 6.0%(0.96/16) Anorexia: 0.0%(0/14) vs 0.0%(0/13) vs 9.0%(4.23/47) vs 19.0%(3.04/16) Diarrhea: 21.0%(2.94/14) vs 8.0%(1.04/13) vs 13.0%(6.11/47) vs 0.0%(0/16) General weakness: 14.0%(1.96/14) vs 8.0%(1.04/13) vs 21.0%(9.87/47) vs 44.0%(7.04/16) Nausea: 14.0%(1.96/14) vs 8.0%(1.04/13) vs 17.0%(7.99/47) vs 6.0%(0.96/16) Parkinsonism: 0.0%(0/14) vs 15.0%(1.95/13) vs 6.0%(2.82/47) vs 0.0%(0/16) Restlessness: 7.0%(0.98/14) vs 8.0%(1.04/13) vs 11.0%(5.17/47) vs 13.0%(2.08/16) Somnolence/drowsiness: 0.0%(0/14) vs 31.0%(4.03/13) vs 26.0%(12.22/47) vs 31.0%(4.96/16) Vomiting: 21.0%(2.94/14) vs 0.0%(0/13) vs 21.0%(9.87/47) vs 6.0%(0.96/16) Weight loss: 0.0%(0/14) vs 0.0%(0/13) vs 9.0%(4.23/47) vs 13.0%(2.08/16)	Rivastigmine vs Risperidone vs Rivastigmine + risperidone vs Risperidone + rivastigmine: Withdrawals: 30.0%(4.2/14) vs 30.0%(3.9/13) vs 30.0%(14.1/47) vs 62.0%(9.92/16) Withdrawals due to adverse events: 12.0%(1.68/14) vs 15.0%(1.95/13) vs 13.0%(6.11/47) vs 50.0%(8/16)
Personality Disorder Olanzapine (Zanarini MC et al., 2004) US	Fluoxetine vs Olanzapine vs Olanzapine + fluoxetine: Dizziness and headaches: 0.0%(0/14) vs 0.0%(0/16) vs 6.7%(1/15) Mild akathisia: 35.7%(5/14) vs 25.0%(4/16) vs 33.3%(5/15) Mild sedation: 21.4%(3/14) vs 75.0%(12/16) vs 46.7%(7/15) Other serious movement disorders: 0.0%(0/14) vs 0.0%(0/16) vs 0.0%(0/15) Suicide attempt: 7.1%(1/14) vs 0.0%(0/16) vs 0.0%(0/15) Tardive dyskinesia: 0.0%(0/14) vs 0.0%(0/16) vs 0.0%(0/15) Weight change in kg: Fluoxetine-14 people (0.4 mean,2.3 SD) vs Olanzapine-16 people (2.9 mean,2.6 SD) vs Olanzapine + Fluoxetine-15 people (1.4 mean,1.1 SD)	Fluoxetine vs Olanzapine vs Olanzapine + fluoxetine: Withdrawals: 7.1%(1/14) vs 0.0%(0/16) vs 13.3%(2/15) Withdrawals due to adverse events: 0.0%(0/14) vs 0.0%(0/16) vs 6.7%(1/15)

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Tourettes Risperidone (Bruggeman R et al., 2001) Western Europe, South Africa	Pimozide vs Risperidone: Depression: 25.0%(6/24) vs 30.8%(8/26) EPS-like adverse events: 33.3%(8/24) vs 15.4%(4/26) Fatigue: 37.5%(9/24) vs 38.5%(10/26) Headache: 8.3%(2/24) vs 19.2%(5/26) Hyperkinesia: 20.8%(5/24) vs 7.7%(2/26) Injuries: 25.0%(6/24) vs 3.8%(1/26) Insomnia: 29.2%(7/24) vs 3.8%(1/26) Somnolence: 41.7%(10/24) vs 46.2%(12/26) Weight gain: 83.3%(20/24) vs 84.6%(22/26) Weight gain & <18 years: 29.2%(7/24) vs 38.5%(10/26) Weight gain & ≥ 18 years: 54.2%(13/24) vs 46.2%(12/26) Weight change in kg: Pimozide-24 people (2.9 mean,1.8-4.1 RANGE) vs Risperidone-26 people (3.9 mean,3.0-4.9 RANGE)	Pimozide vs Risperidone: Withdrawals: 16.7%(4/24) vs 19.2%(5/26) Withdrawals due to adverse events: 8.3%(2/24) vs 15.4%(4/26)
Tourettes Risperidone (Gaffney GR et al., 2002) US	Clonidine vs Risperidone: At least one clinically significant adverse event: 58.0%(6.96/12) vs 33.0%(2.97/9) Dizziness: 17.0%(2/12) vs 11.0%(1/9) Drug-induced parkinsonism: 0.0%(0/12) vs 0.0%(0/9) Dry mouth: 8.0%(1/12) vs 0.0%(0/9) Sedation: 42.0%(5/12) vs 11.0%(1/9) Stiffness: 8.0%(1/12) vs 22.0%(2/9) Weight change in kg: Clonidine-12 people (Mean 0.1, SD 5.9) vs Risperidone-9 people (2.1 mean, SD 2.3)	Clonidine vs Risperidone: Withdrawals: 8.3%(1/12) vs 0.0%(0/9) Withdrawals due to adverse events: 0.0%(0/12) vs 0.0%(0/9)
Dementia, Depression and Agitation Olanzapine (Kinon BJ et al., 2005) US	Typical antipsychotics vs Olanzapine: Anemia: 4.2%(6/143) vs 10.7%(16/150) Apathy: 11.2%(16/143) vs 3.3%(5/150) Cardiovascular effects: 4.3%(6/143) vs 3.4%(5/149) Death: 16.1%(23/143) vs 14.8%(22/149) Skin ulcer: 11.9%(17/143) vs 3.3%(5/150) Weight loss: 23.1%(33/143) vs 11.3%(17/150)	Typical antipsychotics vs Olanzapine: Withdrawals: 55.2%(79/143) vs 46.0%(69/150) Withdrawals due to adverse events: 20.0%(29/143) vs 17.0%(26/150)

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Depression Aripiprazole (Kasper S et al., 2003) US, Europe, other countries NOS	Haloperidol vs Aripiprazole: Agitation: 7.0%(30/431) vs 6.0%(53/859) Akathisia: 25.0%(108/431) vs 13.0%(111/859) Anxiety: 12.0%(50/431) vs 13.0%(108/859) Any AE: 87.0%(377/431) vs 78.0%(671/859) Extrapyramidal syndrome: 30.0%(130/431) vs 10.0%(84/859) Headache: 9.0%(38/431) vs 8.0%(65/859) Insomnia: 20.0%(88/431) vs 22.0%(185/859) Psychosis: 16.0%(70/431) vs 18.0%(156/859) Somnolence: 7.0%(32/431) vs 5.0%(43/859) Tremor: 10.0%(41/431) vs 4.0%(34/859) Weight gain: 3.0%(14/431) vs 5.0%(44/859)	Haloperidol vs Aripiprazole: Withdrawals: (NR/431) vs (NR/859) Withdrawals due to adverse events: 32.0%(138/431) vs 24.8%(213/859)
Depression Olanzapine (Corya SA et al., 2005) NR	Fluoxetine vs Venlafaxine vs Olanzapine vs Olanzapine/Flouxetine 1/5 vs Olanzapine/Flouxetine: Asthenia: 8.0%(5/60) vs 8.0%(5/59) vs 18.0%(11/62) vs 8.0%(4.7/59) vs 12.0%(29/243) Death: 0.0%(0/60) vs 0.0%(0/59) vs 0.0%(0/62) vs 0.0%(0/59) vs 0.4%(1/243) Dizziness: 10.0%(6/60) vs 5.0%(3/59) vs 10.0%(6.2/62) vs 22.0%(13/59) vs 14.0%(34/243) Dry mouth: 7.0%(4/60) vs 5.0%(3/59) vs 16.0%(10/62) vs 7.0%(4/59) vs 13.0%(32/243) Extrapyramidal symtoms: (NR/60) vs (NR/59) vs (NR/62) vs (NR/59) vs (NR/243) Headache: 17.0%(10/60) vs 17.0%(10/59) vs 10.0%(6/62) vs 24.0%(14/59) vs 10.0%(24/243) Increased appetite: 7.0%(4/60) vs 5.0%(3/59) vs 16.0%(10/62) vs 14.0%(8/59) vs 16.0%(39/243) Peripheral edema: 0.0%(0/60) vs 2.0%(1/59) vs 8.0%(5/62) vs 5.0%(3/59) vs 11.0%(27/243) Somnolence: 5.0%(3/60) vs 8.0%(5/59) vs 18.0%(11/62) vs 8.0%(5/59) vs 22.0%(53/243) Weight gain: 13.0%(8/60) vs 5.0%(3/59) vs 26.0%(16/62) vs 19.0%(11/59) vs 25.0%(61/243)	Fluoxetine vs Venlafaxine vs Olanzapine vs Olanzapine/Flouxetine 1/5 vs Olanzapine/Flouxetine: Withdrawals: 18.3%(11/60) vs 22.0%(13/59) vs 25.8%(16/62) vs 20.3%(12/59) vs 23.0%(56/243) Withdrawals due to adverse events: 5.0%(3/60) vs 1.7%(1/59) vs 8.1%(5/62) vs 3.4%(2/59) vs 11.9%(29/243)

Condition, Drug Author, Year Country, Trial named	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Depression Olanzapine (Dunner DL et al., 2005) NR	Lamotrigine vs Olanzapine/Flouxetine: Anxiety: 6.9%(14/205) vs 7.3%(15/205) Arthralgia: 5.9%(12/205) vs 1.5%(3/205) Back pain: 5.9%(12/205) vs 5.4%(11/205) Constipation: 3.9%(8/205) vs 5.4%(11/205) Death: 0.5%(1/205) vs 0.0%(0/205) Diarrhea: 5.9%(12/205) vs 5.9%(12/205) Disturbance in attention: 1.0%(2/205) vs 5.4%(11/205) Dizziness: 9.3%(19/205) vs 14.6%(30/205) Dry mouth: 5.9%(12/205) vs 17.1%(35/205) Fatigue: 6.9%(14/205) vs 9.3%(19/205) Headache: 10.8%(22/205) vs 12.7%(26/205) Increased appetite: 9.3%(19/205) vs 19.5%(40/205) Insomnia: 14.7%(30/205) vs 5.9%(12/205) Irritability: 7.4%(15/205) vs 2.9%(5.9/205) Lethargy: 1.5%(3/205) vs 5.9%(12/205) Nausea: 11.3%(23/205) vs 7.8%(16/205) Peripheral edema: 0.0%(0/205) vs 5.4%(11/205) Rash: 8.8%(18/205) vs 5.4%(11/205) Sedation: 2.9%(6/205) vs 14.1%(29/205) Somnolence: 9.3%(19/205) vs 21.0%(43/205) Tremor: 1.5%(3/205) vs 10.7%(22/205) Upper respiratory infection: 3.4%(7/205) vs 5.4%(11/205) Weight gain: 2.9%(6/205) vs 22.4%(46/205)	Lamotrigine vs Olanzapine/Flouxetine: Withdrawals: 41.4%(85/205) vs 50.7%(104/205) Withdrawals due to adverse events: 13.7%(28/205) vs 18.0%(37/205)
Depression Olanzapine (Shelton RC et al., 2005) US & Canada	Fluoxetine vs Nortriptyline vs Olanzapine vs Olanzapine/Fluxetine: Akathisia: (NR/142) vs (NR/68) vs (NR/144) vs (NR/146) Asthenia: (NR/142) vs (NR/68) vs (NR/144) vs (NR/146) Cardiovascular effects: (NR/142) vs (NR/68) vs (NR/144) vs (NR/146) Dyskinesia: (NR/142) vs (NR/68) vs (NR/144) vs (NR/146) Headache: (NR/142) vs (NR/68) vs (NR/144) vs (NR/146) Increased appetite: (NR/142) vs (NR/68) vs (NR/144) vs (NR/146) Insomnia: (NR/142) vs (NR/68) vs (NR/144) vs (NR/146) Nausea: (NR/142) vs (NR/68) vs (NR/144) vs (NR/146) Nervousness: (NR/142) vs (NR/68) vs (NR/144) vs (NR/146) Parkinsonian symptoms: (NR/142) vs (NR/68) vs (NR/144) vs (NR/146) Somnolence: (NR/142) vs (NR/68) vs (NR/144) vs (NR/146) Tremor: 2.1%(3/142) vs (NR/68) vs 4.9%(7/144) vs 11.6%(17/146) Weight gain: 0.0%(0/142) vs 0.0%(0/68) vs 4.3%(6/144) vs 7.8%(11/146)	Fluoxetine vs Nortriptyline vs Olanzapine vs Olanzapine/Fluxetine: Withdrawals: (NR/142) vs (NR/68) vs (NR/144) vs (NR/146) Withdrawals due to adverse events: 2.8%(4/142) vs 2.9%(2/68) vs 9.7%(14/144) vs 6.8%(10/146)

Condition, Drug **Author, Year** **Country, Trial named**	**Adverse events reported**	**Total withdrawals** **Withdrawals due to adverse events**
Tourettes Risperidone (Gilbert DL et al., 2004) US	Adverse events not reported before crossover.	Pimozide vs Pimozide vs Risperidone vs Risperidone: Withdrawals: 0.0%(0/7) vs 0.0%(0/7) vs 8.3%(1/12) vs 8.3%(1/12) Withdrawals due to adverse events: 0.0%(0/7) vs 0.0%(0/7) vs 0.0%(0/12) vs 0.0%(0/12)

Acronyms in Evidence Table:

CCT	Clinical control trial
kg	kilograms
lbs	pounds
ND	Not described
NOS	Not otherwise specified
NR	Not reported
RCT	Randomized control trial
RR	Risk ratio
SMD	Standard mean difference
WMD	Weighted mean difference

Outcomes:

ABC	Aberrant Behavior Checklist
ACES	Agitation-Calmness Evaluation Scale
ADAS-cog	Alzheimer's Disease Assessment Scale
ADHDRS	DuPaul Attention Deficit Hyperactivity Scale
ADL	Activities of Daily Life
AIAQ	Anger, Irritability, and Assault Questionnaire
ASI	Addiction Severity Index
BABS	Brown Assessment of Beliefs Scale
BAI	Beck Anxiety Index
BDHI	Buss-Durkee Hostility Index
BDI	Beck Depression Index
BDS	Blessed Dementia Scale
BEHAVE-AD	Behavioral Pathology in Alzheimer's Disease Rating Scale
BPRS	Brief Psychiatric Rating Scale
BRMES	Bech-Rafaelsen Melancholia Scale
CAPS	Clinician Administered PTSD Scale
CDSS	Calgary Depression Scale for Schizophrenia
CES-D	Center for Epidemiologic Studies Depression Scale
CGI	Clinical Global Impression Scale
CMAI	Cohen-Mansfield Agitation Inventory
CM-PNB	Cohen-Mansfield Physically Non-Aggressive Behavior
CPRS	Children's Psychiatric Rating Scale
CSDD	Cornell Scale for Depression in Dementia
CY-BOCS	Children's Yale-Brown Obsessive-Compulsive Scale
DCM	Dementia Care Mapping
DES	Dissociative Experiences Scale
DTS	Davidson Trauma Scale
E-BEHAVE-AD	Empirical Behavioral Pathology in Alzheimer's Disease Rating Scale
FAST	Functional Assessment Staging Rating Scale
GAF	Global Assessment of Functioning Scale
HAM-A	Hamilton Rating Scale for Anxiety
HAM-D/HDRS	Hamilton Rating Scale for Depression
IGT	Iowa Gambling Task
MADRS	Montgomery-Asberg Depression Rating Scale
MDRS	Mattis Dementia Rating Scale
MMSE	Mini-Mental State Examination
M-NCAS	Modified Strain in Nursing Care Assessment

MOSES	Multidimentional Observational Scale for Elderly Subjects
MOVES	Motor Tic, Obsessions, and Compulsions, Vocal Tic Evaluation Survey
N-CBRF	Nisonger Child Behavior Rating Scale
NIMH-OC	National Institute of Mental Health Obsessive-Compulsive Scale
NPI	Neuropsychiatric Inventory
NPI/NH	Neuropsychiatric Inventory/Nursing Home
NPI-Q	Neuropsychiatric Inventory Questionnaire
OAS-M	Overt Aggression Scale-Modified
PANSS	Positive and Negative Symptom Scale
PCL-M	Patient Checklist for PTSD--Military Version
PDC	Depression cluster
PDS	Progressive Deterioration Scale
PGDRS	Psychogeriatric Dependency Rating Scale
PGI	Patient Global Impressions
QLDS	Quality of Life in Depression Scale
Q-LES-Q	Quality of Life Enjoyment and Satisfaction Questionnaire
QLS	Quality of Life Scales
QUALID	Quality of Life in Late-Stage Dementia Scale
ROAS	Retrospective Overt Aggression Scale
SANS	Scale for the Assessment of Negative Symptoms
SCL-90	Symptom Checklist-90
SDS	Sheehan Disability Scale
SF-36	Medical Outcomes Study 36-Item Short-Form Health Survey
SIB	Severe Impairment Battery
SIB-Q	Self-injurious Behavior Questionnaire
SIP	Structured Interview for PTSD
SPQ	Schizotypal Personality Questionnaire
SPRINT	Short PTSD Rating Interview
STAS-AX	State-Trait Anger Expression Inventory
STAT-S	Spielberger State-Trait Anger Scale, state version
STAT-T	Spielberger State-Trait Anger Scale, trait version
TOP-8	Treatment Outcome PTSD Scale
TSSS	Tourette's Syndrome Severity Scale
VAS	Visual Analog Scale
Y-BOCS	Yale-Brown Obsessive-Compulsive Scale
YGTSS	Yale Global Tic Severity Scale
YMRS	Young Mania Rating Scale

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C3: Evidence Tables – Placebo Control Trials

Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)	Run-in period/Randomization Method Wash-out period/Randomization Method
Autism Risperidone (McCracken JT et al., 2002) US RUPP Autism Study	Design: RCT Setting: Multi-center Jadad: 4	Inclusion criteria: Age 5-17, Weight ≥ 15 kg, Mental age ≥ 18 mos, Behavioral disturbances, CGI ≥ moderate severity, ABC Irritability subscale ≥ 18, Exclusion criteria: Medically significant disorders, DSM-IV Axis I disorder, not including primary condition studied, Psychotropic medication for behavioral disturbances	Placebo-2.4 mg/day average final dose Risperidone-1.8 mg/day average final dose Duration: 2.0 months	None 2-4 week washout period for all psychotropics
Autism Risperidone (Shea S et al., 2004) Canada RIS-CAN-23 Study	Design: RCT Setting: Multi-center Jadad: 5	Inclusion criteria: Healthy, Age 5-12, CARS ≥ 30 with or without mental retardation, DSM-IV Axis I diagnosis of PDD Exclusion criteria: Psychotic disorder, Medically significant disorders, Abnormal laboratory results, Seizure disorder, Allergic or toxic reactions to antipsychotic medications, Tardive dyskinesia, Neuroleptic malignant syndrome, Alcohol or substance abuse, Schizophrenia or other psychotic disorders, HIV, Risperidone used in last 3 mos, Previously unresponsive or intolerant to Risperidone	Placebo-dosage not reported Risperidone-1.48 mg/day average final dose Duration: 2.0 months	None None
Dementia and Agitation Olanzapine (De Deyn PP et al., 2004) Europe, Australia/NZ, South Africa F1D-MC-HGIV Study	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: Age ≥ 40, Hospitalized/ institutionalized, Psychosis/psychotic features, MMSE = 5-26 Exclusion criteria: DSM-IV Axis I disorder, not including primary condition studied	Placebo-dosage not reported Olanzapine-1.0 mg/day fixed single dose Olanzapine-2.5 mg/day fixed single dose Olanzapine-5.0 mg/day fixed titration schedule Olanzapine-7.5 mg/day fixed titration schedule Duration: 2.5 months	14 wk of Placebo for randomization not described None

Condition, Drug Author, Year Country, Trial named	**Study design Setting Quality (Jadad Score)**	**Eligibility criteria**	**Interventions (drug, dose, duration)**	**Run-in period/Randomization Method Wash-out period/Randomization Method**
Dementia and Agitation Olanzapine (Street JS et al., 2000) US HGEU Study	Design: RCT Setting: Multi-center Jadad: 5	Inclusion criteria: NPI/NH ≥ 3 Exclusion criteria: DSM-IV Axis I disorder, not including primary condition studied, Neurological conditions, excluding Alzheimers or vascular dementia, contributing to psychosis or dementia, MMSE > 24, Bedridden, Anticholinergic medications, Mood stabilizers, Antipsychotics other than the ones studied, Tricyclic antid	Placebo-dosage not reported Olanzapine-5 mg/day fixed single dose Olanzapine-10 mg/day fixed titration schedule Olanzapine-15 mg/day fixed titration schedule Duration: 1.5 months	3-14 dy of Placebo for non-placebo responders None
Dementia and Agitation Olanzapine & Risperidone (Ruths S et al., 2004) Western Europe	Design: RCT Setting: Single center Jadad: 4	Inclusion criteria: Nursing home resident, Age ≥ 65, Risperidone, olanzapine or haloperidol treatment ≥ 3 months, Resident ≥3 months before enrollment Exclusion criteria: Psychotic disorder, Mental retardation, Terminal illness, Recent major changes in health status	Continued tx w/ risperidone, olanzapine, or halperidol Withdrawal from risperidone, olanzapine, or halperidol Duration: 1.0 month	3-44 mo of Haloperidol, Risperidone, Olanzapine for patients who met study criteria None
Dementia and Agitation Quetiapine (Zhong X et al., 2004) US	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: NR Exclusion criteria: NR	Placebo-dosage not reported Quetiapine-100 mg/day fixed titration schedule Quetiapine-200 mg/day fixed titration schedule Duration: 2.5 months	None None
Dementia and Agitation Risperidone (Ballard CG et al., 2004) UK	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: Neuroleptics ≥ 3 months (median prescription time > 1 yr), Age >65, Clinical Dementia Rating Scale ≥1 Exclusion criteria: NPI > 7	Placebo-dosage not reported Active tx (risperidone, thioridazine, haloperidol, chlorpromazine, or trifluoperazine Duration: 3.0 months	None None

Condition, Drug Author, Year Country, Trial named	**Study design Setting Quality (Jadad Score)**	**Eligibility criteria**	**Interventions (drug, dose, duration)**	**Run-in period/Randomization Method Wash-out period/Randomization Method**
Dementia and Agitation Risperidone (Brodaty H et al., 2003) Australia/New Zealand	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: Age ≥ 55, FAST ≥ 4, MMSE ≤ 23, CMAI score of ≥ 4 on at least 1 aggressive item or a score of 3 on at least 2 aggressive items, or a score of 2 on at least 3 aggressive items, or 2 aggressive items occurring at a frequency of 2 and 1 at a frequency of 3, Nursing home resident, Resident ≥ 1 month prior to enrollment Exclusion criteria: Neurological or medical conditions diminishing cognitive function, Dementia other than primary condition, Major depressive disorder, Psychotic disorder, Tardive dyskinesia, Medically significant disorders, Abnormal laboratory results, Depot neuroleptic within 2 treatment cycles	Placebo-1.06 mg/day average final dose Risperidone-0.95 mg/day average final dose Duration: 3.0 months	None 7 dy of Psychotropics, Placebo for patients who completed the wash-out period
Dementia and Agitation Risperidone (Katz IR et al., 1999) US The Risperidone Study	Design: RCT Setting: Multi-center Jadad: 4	Inclusion criteria: Age ≥ 55, FAST ≥ 4, MMSE ≤ 23, BEHAVE-AD ≥ 8, BEHAVE-AD global rating ≥ 1 Exclusion criteria: Untreated reversible causes of dementia, Neurological or medical conditions diminishing cognitive function, HIV dementia, Substance induced dementia, Delirium, Amnestic disorder, Psychiatric diagnosis for psychotic disturbances	Placebo-dosage not reported Risperidone-0.5 mg/day in divided doses, Risperidone-1 mg/day fixed titration schedule in divided doses Risperidone-2 mg/day fixed titration schedule in divided doses Duration: 3.0 months	None 3-7 dy of Placebo for randomization not described
Dementia and Agitation Risperidone (Meguro K et al., 2004) Japan	Design: RCT Setting: Single center Jadad: 1	Inclusion criteria: Wandering behavior or aggressiveness > 4 in 7 consecutive days Exclusion criteria: Cerebrovascular disease, Parkinsons disease	Placebo-dosage not reported Risperidone- 1 mg/day fixed single dose Duration: 1.0 month	None None

Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)	Run-in period/Randomization Method Wash-out period/Randomization Method
Dementia and Agitation Risperidone (Mertens C, 1993) Western Europe	Design: CCT Setting: NR Jadad: 3	Inclusion criteria: Male or female, Age > 65, CDR = 1, 2, or 3 Exclusion criteria: Neurological or medical conditions diminishing cognitive function, Neurologic disorder, not including primary conditioned studied, Psychiatric disorder, not including primary conditioned studied	Placebo Risperidone-2 mg/day average final dose Duration: 0.9 month	1 wk of Placebo for randomization not described None
Depression Olanzapine (Howanitz E et al., 2001) NR	Design: RCT Setting: NR Jadad: 2	Inclusion criteria: NR Exclusion criteria: NR	Placebo-dosage not reported Olanzapine-6.25 mg/day average final dose Duration: 1.5 months	None None
Depression Olanzapine (Kinrys G et al., 2002) US	Design: RCT Setting: NR Jadad: 3	Inclusion criteria: HAM-A = 50% reduction, CGI ≥ 4 Exclusion criteria: NR	Placebo-dosage not reported Olanzapine-9.4 mg/day average final dose Duration: 1.5 months	6 wk of Fluoxetine for symptomatic patients None
Depression Olanzapine (Rothschild AJ et al., 2004) (Corya S et al., 2002) US The HGGA Study	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: Age ≥ 18, HAM-D ≥ 20 Exclusion criteria: Psychotic disorder, Pregnant, Lactating	Placebo-dosage not reported Olanzapine-11.9 mg/day average final dose Olanzapine-12.4 mg/day average final dose, Fluoxetine- 23.5 mg/day average final dose Duration: 2.0 months	None None
Depression Olanzapine (Shi L et al., 2004) US, Australia/NZ, Europe, Colombia	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: Age ≥ 18, MADRS ≥ 20, At least 1 manic or mixed episode requiring treatment with mood stabilizer or antipsychotic Exclusion criteria: Alcohol or substance abuse or dependency, Suicidal or violent, Medically significant disorders	Placebo-dosage not reported Olanzapine-9.7 mg/day average final dose Olanzapine-7.4 mg/day average final dose, Fluoxetine- 25 or 50 mg Duration: 2.0 months	None 2-14 dy of Psychotropics, except benzodiazepines or anticholinergics for patients who completed the wash-out period

Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)	Run-in period/Randomization Method Wash-out period/Randomization Method
Depression Olanzapine (Tohen M et al., 2003) US, Australia/NZ, Europe, Colombia	Design: RCT Setting: Multi-center Jadad: 4	Inclusion criteria: Age ≥ 18, MADRS ≥ 20, At least 1 manic or mixed episode requiring treatment with mood stabilizer or antipsychotic Exclusion criteria: Alcohol or substance abuse or dependency, Suicidal or violent, Medically significant disorders	Placebo-dosage not reported Olanzapine-9.7 mg/day average final dose Olanzapine-7.4 mg/day average final dose, Fluoxetine- 39.3 mg/day average final dose Duration: 2.0 months	None 2-14 dy of Psychotropics, except benzodiazepines or anticholinergics for patients who completed the wash-out period
Depression Olanzapine (Tohen M et al., 2000) US The Olanzapine HGGW Study	Design: RCT Setting: Multi-center Jadad: 4	Inclusion criteria: YMRS ≥ 20 Exclusion criteria: Medically significant disorders, Alcohol or substance abuse or dependency, Suicidal or violent	Placebo-dosage not reported Olanzapine-16.4 mg/day average final dose Duration: 1.0 month	None 997 dy of Psychotropics for randomization not described
Depression Olanzapine (Tohen M et al., 1999) US The Olanzapine HGEH Study	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: Age 18-65, YMRS ≥ 20 Exclusion criteria: Medically significant disorders, Alcohol or substance abuse or dependency, Suicidal or violent	Placebo-dosage not reported Olanzapine-14.9 mg/day average final dose Duration: 0.8 month	None 2-4 dy of All medications except benzodiazepines for randomization not described
Depression Olanzapine (Tohen M et al., 2003) US	Design: RCT Setting: NR Jadad: 2	Inclusion criteria: YMRS ≤ 12, HAM-21 ≤ 8 Exclusion criteria: NR	Placebo-dosage not reported Olanzapine-5-20 mg/day ' Duration: 13.0 months	None None
Depression Olanzapine (Tollefson GD et al., 1999) US Collaborative Crossover Study	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: Age ≥ 18, Clozapine treatment within 4 wks Exclusion criteria: Alcohol or substance abuse or dependency, Suicidal or violent, Previous exposure to study drug, Medically significant disorders	Placebo-dosage not reported Olanzapine-10 mg/day fixed single dose Duration: 0.2 month	None None

Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)	Run-in period/Randomization Method Wash-out period/Randomization Method
Dementia-Agitation Olanzapine & Risperidone (van Reekum R et al., 2002) Canada	Design: RCT Setting: Multi-center Jadad: 5	Inclusion criteria: Hospitalized/institutionalized, Antipsychotic treatment ≥ 6 months Exclusion criteria: Schizophrenia, Delirium, Resistant to antipsychotic treatment, Antipsychotic use for nausea, BEHAVE-AD ≥ 3 at screening, 1 week before study, or within 2 weeks pretrial period	Withdrawal from risperidone, olanzapine, halperidol, thiroidazine, or loxapine Continued tx w/ risperidone, olanzapine, halperidol, thiroidazine, or loxapine Duration: 6.0 months	1.5-1.8 yr of Risperidone, Olanzapine, Haloperidol, Anticonvulsants for patients who met study criteria None
Depression Quetiapine (Calabrese J et al., 2004) US	Design: RCT Setting: NR Jadad: 2	Inclusion criteria: HAM-D ≥ 20, YMRS ≤ 12 Exclusion criteria: DSM-IV Axis I disorder, not including primary condition studied	Placebo-dosage not reported Quetiapine-300 mg/day fixed titration schedule Quetiapine-600 mg/day fixed titration schedule Duration: 2.0 months	None None
Dementia and Agitation Risperidone (Mintzer J et al., 2004) US	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: MMSE = 5-23, Age ≥ 55, BEHAVE-AD Psychosis Subscale ≥ 2, Able to ambulate, walk with assistance or use wheelchair independently Exclusion criteria: Medically significant disorders, Abnormal laboratory results, Epilepsy, Neurological or medical conditions diminishing cognitive function or that cause psychosis, Cancer, except for non-melanoma of the skin, Recent depot neuroleptic injections, Change in medications in preceding 30 dys	Placebo-53.1 mg mean modal dose Risperidone-1.2 mg mean modal dose Duration: 2.0 months	None 7 dys of Psychotropics for randomization not described
Depression Risperidone (Gharabawi GM et al., 2004) International ARISe-RD Study	Design: RCT Setting: Multi-center Jadad: 4	Inclusion criteria: Age 18-85, HAM-D ≤ 7, CGI score = 1 or 2, Achieved symptomatic remission following ≥ wks of RIS augmentation Exclusion criteria: Pregnant, lactating, psychiatric history, DSM-IV diagnosis confounded by various things, including being medically unstable, testing positive on urine drug screen, impaired hepatic or renal function, history failure of citalopram or any antidepressant with risperidone augmentation, etc.	Citalopram-mean modal dose 53.1 mg/day + Placebo Citalopram-53.1 mg/day + Risperidone-1.2 mg/day mean modal dose Duration: 6.0 months	4-6 wk of Citalopram monotherapy, then Risperidone augmentation 4-6 wk in citalopram non-responders None

Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)	Run-in period/Randomization Method Wash-out period/Randomization Method
Depression Ziprasidone (Daniels DG et al., 1999) US & Canada The Ziprasidone Study	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: Age ≥ 18, Hospitalized/institutionalized, PANSS ≥ 60, PANSS with score ≥ 4 on at least 2 items on positive symptoms subscale, CGI ≥ 3, Exclusion criteria: Resistant to antipsychotic treatment, Hospitalized > 4 weeks, Alcohol or substance abuse or dependency, Mental retardation, Organic mental disorder, Brief reactive psychosis, Depot neuroleptic within 4 weeks, Suicidal or violent	Placebo-dosage not reported Ziprasidone-80 mg/day fixed single dose Ziprasidone-160 mg/day fixed titration schedule Duration: 1.5 months	None 3 dy of Neuroleptics, Antidepressants, Sedatives, Anxiolytics, Hypnotics, Anticholinergics, Beta-adrenoceptor antagonists for patients who completed the wash-out period
Depression Ziprasidone (Keck P Jr et al., 1998) US The Ziprasidone Study	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: Age 18-64, Hospitalized/institutionalized, 1 year duration primary condition, BPRS ≥ 37, BPRS ≥ 4 on 2 or more of core items, Exclusion criteria: Nursing home/residential center resident, Resistant to antipsychotic treatment, Alcohol or substance abuse or dependency, Residual schizophrenia, Mental retardation, Organic mental disorder, Brief reactive psychosis, Suicidal or violent	Placebo-dosage not reported Ziprasidone-40 mg/day fixed single dose Ziprasidone-120 mg/day fixed single dose Duration: 1.0 month	None 4-7 dy of Placebo, Antidepressants, Anticholinergics, Thymoleptics, Anxiolytics, Hypnotics for patients who completed the wash-out period
Depression and PTSD Risperidone (Bartzokis G et al., 2004) US	Design: RCT Setting: Single center Jadad: 3	Inclusion criteria: Proof of military service, CAPS ≥ 65 Exclusion criteria: Alcohol or substance abuse or dependency, Suicidal or violent, Medically significant disorders, Neurological or medical conditions diminishing cognitive function, Antipsychotic medications, Seizure disorder or epilepsy or risk, Change in antidepressant regimen within 6 wks prior to study entry	Placebo-dosage not reported Risperidone-3 mg/day average final dose Duration: 4.0 months	None None
PTSD Risperidone (Padala PR et al., 2005) US	Design: RCT Setting: NR Jadad: 2	Inclusion criteria: Level of understanding to perform all tests and examinations Exclusion criteria: Bipolar disorder, Schizophrenia, Medically significant disorders, Abnormal laboratory results, Suicidal or violent, Alcohol or substance abuse or dependency, Previous exposure to study drug, Antipsychotics other than the ones studied, Previous exposure to risperidone, Pregnancy/nursing, Use of psychotropics	Placebo-dosage not reported Risperidone-2.62 mg/day average final dose Duration: 3.0 months	None 2 wk of Psychotropics for randomization not described

Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)	Run-in period/Randomization Method Wash-out period/Randomization Method
PTSD Risperidone (Reich DB et al., 2004) US	Design: RCT Setting: Single Center Jadad: 2	Inclusion criteria: Understand English, Able to give informed consent, Level of understanding to perform all tests and examinations, CAPS-1 ≥ 50, PTSD related to childhood physical, sexual, emotional or verbal abuse, Exclusion criteria: Medically significant disorders, Alcohol or substance abuse or dependency, Psychotic disorder, Organic mental disorder, Antipsychotics other than the ones studied, Mood stabilizers, Risperidone treatment of 1 week or more, Suicidal or violent, Pregnancy/nursing, Entry into individual psychotherapy within 3 mos of study, and entry into group therapy within 1 mo of study	Placebo-dosage not reported Risperidone-1.41 mg/day average final dose Duration: 2.0 months	None None
OCD Olanzapine (Bystritsky A et al., 2004) US	Design: RCT Setting: Single center Jadad: 3	Inclusion criteria: Age 18-65 Exclusion criteria: DSM-IV Axis I disorder, not including primary condition studied, DSM-IV Axis II disorder, not including primary condition studied, Neurological conditions, excluding Alzheimers or vascular dementia, contributing to psychosis or dementia, Pregnant, Medically significant disorders, HAM-D > 20, Bizarre psychosis	Placebo-16.9 mg/day average final dose Olanzapine-11.2 mg/day average final dose Duration: 1.5 months	None None
OCD Risperidone (Buchsbaum MS, 2003) NR	Design: CCT Setting: NR Jadad: 1	Inclusion criteria: Refractory to SRI therapy Exclusion criteria: NR	Placebo-dosage not reported Risperidone-dosage not reported Duration: 2.0 months	None None
OCD Risperidone (Erzegovesi S et al., 2005) Western Europe	Design: RCT Setting: Single center Jadad: 4	Inclusion criteria: Age 18-65, 1 year duration primary condition, Drug-free within 3 weeks, Drug-free for at least 3 wks prior to study entry Exclusion criteria: Antiobsessional medications, Psychiatric disorders except for panic disorder and tic disorders, Pregnant, Lactating, Seizure disorder or epilepsy or risk, Medical conditions contraindicating use of fluvoxamine, Contraindication to risperidone	Placebo-dosage not reported Risperidone-0.5 mg/day fixed single dose Duration: 1.5 months	12 wk of Fluvoxamine for responders separated from non-responders None

Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)	Run-in period/Randomization Method Wash-out period/Randomization Method
OCD Risperidone (Hollander E et al., 2003) US	Design: RCT Setting: NR Jadad: 4	Inclusion criteria: CGI ≥ 3, SRI therapy ≥ 12 weeks, ≥2 SRI trials of adequate dose and duration Exclusion criteria: Medically significant disorders, Schizophrenia and schizoaffective disorder, Bipolar disorder	Placebo-2.75 mg/day average final dose Risperidone-2.25 mg/day average final dose Duration: 2.0 months	None None
PTSD Olanzapine (Butterfield MI et al., 2001) US	Design: RCT Setting: NR Jadad: 3	Inclusion criteria: Age 18-70, Understand English, Able to give informed consent Exclusion criteria: Bipolar disorder, Psychotic disorder, Mental retardation, Alcohol or substance abuse or dependency, Suicidal or violent	Placebo-13.9 mg/day average final dose Olanzapine-14.1 mg/day average final dose Duration: 2.5 months	None None
PTSD Olanzapine (Stein MB et al., 2002) US	Design: RCT Setting: VA Healthcare S Jadad: 3	Inclusion criteria: Refractory to SRI therapy Exclusion criteria: NR	Placebo-20.00 mg/day average final dose Olanzapine-15.00 mg/day average final dose Duration: 2.0 months	Variable weeks of SSRIs for patients minimally responsive to SSRIs None
PTSD Risperidone (Hamner MB et al., 2003) US	Design: RCT Setting: Single center Jadad: 4	Inclusion criteria: Age ≥ 18, Psychosis/psychotic features, PANSS ≥ 60, PANSS with score ≥ 4 on at least 1 item on positive symptoms subscale, Exclusion criteria: Toxic reactions to antipsychotic medications, Medically significant disorders, Alcohol or substance abuse or dependency, Schizophrenia, Bipolar disorder, Suicidal or violent, Risperidone hypersensitivity	Placebo-dosage not reported Risperidone-2.5 mg/day average final dose Duration: 1.3 months	1 wk of Placebo for non-placebo responders Prior to run-in antipsychotics or thymoleptics (carbamazepine, valproic acid and lithium) had medications reduced or discontinued
PTSD Risperidone (Monnelly EP et al., 2003) US	Design: RCT Setting: Single center Jadad: 4	Inclusion criteria: PCL-M ≥ 20 on cluster D subscale Exclusion criteria: Schizophrenia, Bipolar disorder with psychotic features, Organic mental disorder, Antipsychotic medications, Alcohol/substance dependency in remission	Placebo-0.62 mg/day average final dose Risperidone-0.57 mg/day average final dose Duration: 1.5 months	None None
Personality Disorder Olanzapine (Bogenschutz MP et al., 2004) US	Design: RCT Setting: Single center Jadad: 3	Inclusion criteria: Age 18-60 Exclusion criteria: Psychotropic medications, Pregnant, Bipolar disorder, Psychotic disorder, Major depressive disorder, Alcohol or substance abuse or dependency, Suicidal or violent, Neurological disorder	Placebo-10.2 mg/day average final dose Olanzapine-6.9 mg/day average final dose Duration: 3.0 months	None None

Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)	Run-in period/Randomization Method Wash-out period/Randomization Method
Personality Disorder Olanzapine (Zanarini MC et al., 2001) US	Design: RCT Setting: NR Jadad: 5	Inclusion criteria: Age 18-40 Exclusion criteria: Previous exposure to study drug, Medically significant disorders, Seizure disorder or epilepsy or risk, Psychotropic medications, Alcohol or substance abuse or dependency, Suicidal or violent, Pregnant, Lactating	Placebo-dosage not reported Olanzapine-5.33 mg/day average final dose Duration: 6.0 months	None None
Personality Disorder Risperidone (Koenigsberg HW et al., 2003) US	Design: RCT Setting: Multi-center Jadad: 4	Inclusion criteria: Healthy, Age 18-60 Exclusion criteria: Alcohol or substance abuse or dependency, Use psychotropic medications within 2 wks	Placebo-dosage not reported Risperidone-0.25-2 mg/day flexible dose Duration: 2.3 months	2 wk of Placebo for randomization not described None
Tourettes Ziprasidone (Sallee FR et al., 2000) US	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: Age 7-17, Severe tic symptoms requiring medication treatment, Healthy, Free of psychotropic medications within 4 weeks Exclusion criteria: Abnormal laboratory results, Neuroleptic malignant syndrome, Atypical antipsychotics sensitivity, Major depressive disorder, Pervasive developmental disorder, Autism, Mental retardation, Eating disorders	Placebo-dosage not reported Ziprasidone-28.2 mg/day average final dose Duration: 1.8 months	None None
Dementia and Agitation Aripiprazole (Breder C et al., 2004) NR	Design: RCT Setting: Multi-center Jadad: 1	Inclusion criteria: Psychosis/psychotic features, Nursing home resident, NPI or NPI/NH ≥ 6 sum of hallucinations and delusional items, Age 55-95, MMSE = 6-22 Exclusion criteria: NR	Placebo - dosage not reported Aripiprazole - 2 mg/day fixed single dose Aripiprazole - 5 mg/day fixed single dose Aripiprazole - 10 mg/day fixed titration schedule Duration: 2.5 months	None ≥ 7 dy of psychotropics for patients who completed the wash-out period

Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)	Run-in period/Randomization Method Wash-out period/Randomization Method
Dementia and Agitation Aripiprazole (De Deyn P et al., 2005) NR	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: NPI or NPI/NH ≥ 6 sum of hallucinations and delusional items, Age 55-95, Noninstitutionalized, Delusions or hallucinations ≥ 1 month, MMSE = 6-24 Exclusion criteria: Bipolar disorder, Schizophrenia, Delirium, Amnestic disorder, Schizoaffective disorder, Mood disorders with psychotic features, Psychotic features accounted better by disease other than the one studied or by effects of a substance, Refractory to neuroleptics	Placebo - dosage not reported Aripiprazole - 10 mg/day average final dose Duration: 2.5 months	None 7 wk of psychotropics for patients who completed the wash-out period
Dementia and Agitation Aripiprazole (Streim JE et al., 2004) US	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: Delusions or hallucinations ≥ 1 month, Nursing home resident, Age 55-95, MMSE = 6-22, NPI or NPI/NH ≥ 6 sum of hallucinations and delusional items Exclusion criteria: NR	Placebo - dosage not reported Aripiprazole - 8.6 mg/day average final dose Duration: 2.5 months	None None
Depression Aripiprazole (McQuade R et al., 2004) NR	Design: RCT Setting: NR Jadad: 2	Inclusion criteria: Recent manic episode, but did not participate in a trial of study drug, Recently completed trial of study drug, YMRS ≤ 10, MADRS ≤ 13 Exclusion criteria: NR	Placebo - dosage not reported Aripiprazole - 24.3 mg/day average final dose Duration: 6.5 months	6-18 wk of Aripiprazole for randomization not described None
Depression Olanzapine (Kennedy J et al., 2005) US	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: Age ≥ 40 Exclusion criteria: DSM-IV Axis I disorder, not including primary condition studied, Neurologic disorder, not including primary conditioned studied, NPI > 1 on delusions, hallucinations, agitation/aggression or dysphoria items, Score ≥ 1 on cholinesterase inhibitor use, antioxidant or herbal supplement items ≤ 4 week	Placebo - dosage not reported Olanzapine - 2.5-7.5 mg/day flexible dose Duration: 6.5 months	None 10-18 dy of medications to treat Alzheimers for randomization not described
Depression and Personality Disorder Olanzapine (Soler J et al., 2005) Western Europe	Design: RCT Setting: Single center Jadad: 2	Inclusion criteria: CGI ≥ 4, Age 18-45 Exclusion criteria: DSM-IV Axis I disorder, not including primary condition studied, Psychotherapy, Sexually active females of child bearing age not using an effective contraceptive method	Placebo - dosage not reported Olanzapine - 883 mg/day average final dose Duration: 3.0 months	None None

Condition, Drug Author, Year Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)	Run-in period/Randomization Method Wash-out period/Randomization Method
Tourettes Risperidone (Scahill L et al., 2003) US	Design: RCT Setting: Single center Jadad: 3	Inclusion criteria: Age 7-65 Exclusion criteria: Major depressive disorder, Psychosis/psychotic features, Anxiety disorder, Wechsler Intelligence Scale age approximate IQ < 70, Previous adequate trial of risperidone, Medically significant disorders, Y-BOCS or CY-BOCS > 15, Psychotropic medications	Placebo - 3.3 mg/day fixed titration schedule Risperidone - 2.5 mg/day fixed titration schedule Duration: 2.0 months	None 7-14 wk of placebo for patients who completed the wash-out period

Condition, Drug Author, Year Country, Trial named	**Allowed other medications**	**Method of outcome assessment Timing of assessment**	**Age mean/ Age range Gender Ethnicity**	**Screened/ Eligible/ Enrolled**
Autism Risperidone (McCracken JT et al., 2002) US RUPP Autism Study	Anticonvulsant agent for seizure control if no dose change in 4 wks and no seizures for at least 6 mos.	Assessed at baseline and 8 weeks: ABC, CGI	9/5-17 81% male Caucasian, African-American, Hispanic, Asian, NOS	270/101/ 101
Autism Risperidone (Shea S et al., 2004) Canada RIS-CAN-23 Study	Anticholinergic medications, Anti-asthmatics, A single anticonvulsant and medications for sleep or anxiety if doses of each had been stable for at least 30 days	Assessed at baseline and 8 weeks: ABC, N-CBRF, CGI, VAS	7.5 77% male Caucasian, African-American, NOS	NR/80/79
Dementia and Agitation Olanzapine (De Deyn PP et al., 2004) Europe, Australia/NZ, South Africa F1D-MC-HGIV Study	Benzodiazepines, Sedative/ hypnotics	Assessed at baseline and 10 weeks: NPI-NH, CGI, BPRS, MMSE, SIB	77/NR 25% male Caucasian, NOS	NR/652/ NR
Dementia and Agitation Olanzapine (Street JS et al., 2000) US HGEU Study	Benzodiazepines	Assessed at baseline and 6 weeks: NPI-NH, BPRS, MMSE	83/61-97 39% male Caucasian, African-American, Hispanic, NOS	288/206/ 206
Dementia and Agitation Olanzapine & Risperidone (Ruths S et al., 2004) Western Europe	Antidepressants, sedative/ Hypnotic, Anxiolytics, Anticholinergic medications, Narcotic analgesics	Assessed at baseline and 4 weeks: NPI-Q, Sleep disorders	83/NR 20% male NR	51/30/30
Dementia and Agitation Quetiapine (Zhong X et al., 2004) US	NR	Assessed at baseline and 10 weeks: PANSS, CGI	83/NR NR NR	NR/333/ NR
Dementia and Agitation Risperidone (Ballard CG et al., 2004) UK	NR	Assessed at baseline and 3 months: NPI, DCM	83/NR 19% male NR	NR/100/ 100

Condition, Drug **Author, Year** **Country, Trial named**	**Allowed other medications**	**Method of outcome assessment** **Timing of assessment**	**Age mean/** **Age range** **Gender** **Ethnicity**	**Screened/** **Eligible/** **Enrolled**
Dementia and Agitation Risperidone (Brodaty H et al., 2003) Australia/New Zealand	Anti-EPS medications, Benzodiazepines, Tricyclic antidepressants, anticholinergic medications, short-acting sedative/hypnotic agents, and narcotic analgesics	Assessed at baseline and 12 weeks: CMAI, BEHAVE-AD, FAST, MMSE, CGI	83/NR 28% male NR	384/345/ 345
Dementia and Agitation Risperidone (Katz IR et al., 1999) US The Risperidone Study	Benztropine, lorzepam, chloral hydrate	Assessed at baseline and 12 weeks: BEHAVE-AD, CMAI, CGI, MMSE	83/NR 32% male Caucasian, NOS	729/625/ 625
Dementia and Agitation Risperidone (Meguro K et al., 2004) Japan	Acetyl- cholinesterase inhibitors	Assessed at baseline and 1 months: Sleep disorders, Wandering behavior	78/68-90 21% male NR	NR/34/34
Dementia and Agitation Risperidone (Mertens C, 1993) Western Europe	NR	Assessed at baseline and 4 weeks: BEHAVE-AD, CGI, MMSE, VAS, ADL	NR/65-88 31% male NR	NR/39/39
Depression Olanzapine (Howanitz E et al., 2001) NR	NR	Assessed at baseline and 6 weeks: NPI, BPRS, ADAS-cog	73/NR NR NR	NR/16/16
Depression Olanzapine (Kinrys G et al., 2002) US	Fluoxetine	Assessed at baseline and 6 weeks: HAM_D_HDRS, HAM_A, CGI	NR/NR NR NR	NR/14/14
Depression Olanzapine (Rothschild AJ et al., 2004) (Corya S et al., 2002) US The HGGA Study	NR	Assessed at baseline and 8 weeks: HAM_D_HDRS, HAM_A, BPRS, CGI	41/NR 48% male Caucasian, NOS	NR/124/ 124

Condition, Drug Author, Year Country, Trial named	**Allowed other medications**	**Method of outcome assessment Timing of assessment**	**Age mean/ Age range Gender Ethnicity**	**Screened/ Eligible/ Enrolled**
Depression Olanzapine (Shi L et al., 2004) US, Australia/NZ, Europe, Colombia	Benzodiazepines	Assessed at baseline and 8 weeks: SF-36, QLDS	40/NR 35% male Caucasian, NOS	1072/833/833
Depression Olanzapine (Tohen M et al., 2003) US, Australia/NZ, Europe, Colombia	Benzodiazepines	Assessed at baseline and 8 weeks: MADRS, HAM_A, CGI, YMRS	42/NR 37% male Caucasian, NOS	1072/833/833
Depression Olanzapine (Tohen M et al., 2000) US The Olanzapine HGGW Study	Benzodiazepines	Assessed at baseline and 4 weeks: YMRS, HAM_D_HDRS, CGI, PANSS	39/NR 50% male Caucasian, NOS	NR/115/ 115
Depression Olanzapine (Tohen M et al., 1999) US The Olanzapine HGEH Study	Anticholinergic medications, Benzodiazepines	Assessed at baseline and 3 weeks: YMRS, HAM_D_HDRS, PANSS, CGI, SF-36	40/NR 52% male Caucasian, NOS	NR/139/ 139
Depression Olanzapine (Tohen M et al., 2003) US	NR	Assessed at baseline and 52 weeks: HAM_D_HDRS, YMRS	NR/NR NR NR	NR/361/ 361
Depression Olanzapine (Tollefson GD et al., 1999) US Collaborative Crossover Study	Anti-EPS medications, Benzodiazepines, Clozapine	Assessed at baseline and 997 day: CGI, PANSS, BPRS, MADRS, MMSE	39/NR 71% male Caucasian, African-American, Hispanic	115/106/ 106
Dementia-Agitation Olanzapine & Risperidone (van Reekum R et al., 2002) Canada	Lorazepam if needed	Assessed at baseline and 6 months: BEHAVE-AD, NPI, ROAS, MMSE, MDRS, BDS, CGI	84/NR 50% male NR	NR/34/34

Condition, Drug Author, Year Country, Trial named	**Allowed other medications**	**Method of outcome assessment Timing of assessment**	**Age mean/ Age range Gender Ethnicity**	**Screened/ Eligible/ Enrolled**
Depression Quetiapine (Calabrese J et al., 2004) US	NR	Assessed at baseline and 8 weeks: HAM_D_HDRS, MADRS, Q-LES-Q, CGI, Sleep disorders	37/NR 43% male NR	832/542/542
Dementia and Agitation Risperidone (Mintzer J et al., 2004) US	Lorazepam permitted	Assessed at baseline and 8 weeks: BEHAVE-AD, CGI	83/NR 23% male Caucasian, African-American, Hispanic, Asian, NOS	NR/473/ 473
Depression Risperidone (Gharabawi GM et al., 2004) International ARISe-RD Study	Zolpidem, lorazepam, zopiclone, zaleplon, benztropine	Assessed at baseline and 24 weeks: CGI, HAM_D_HDRS	48/NR 36% male Caucasian, NOS	489/241/ 241
Depression Ziprasidone (Daniels DG et al., 1999) US & Canada The Ziprasidone Study	Lorazepam	Assessed at baseline and 6 weeks: PANSS, CGI, BPRS, MADRS	37/18-67 71% male Caucasian, African-American, Asian, NOS	440/302/302
Depression Ziprasidone (Keck P Jr et al., 1998) US The Ziprasidone Study	Anti-EPS medications, Beta-blockers, Lorazepam	Assessed at baseline and 4 weeks: BPRS, CGI, SANS	39/19-76 79% male Caucasian, African-American, Asian, NOS	203/139/139
Depression and PTSD Risperidone (Bartzokis G et al., 2004) US	Antidepressants, Anxiolytics, Sedative/hypnotics	Assessed at baseline and 16 weeks: HAM_D_HDRS, HAM_A, PANSS, CAPS	52/38-63 100% male Caucasian, African-American, Asian, Native American	73/65/65

Condition, Drug Author, Year Country, Trial named	**Allowed other medications**	**Method of outcome assessment Timing of assessment**	**Age mean/ Age range Gender Ethnicity**	**Screened/ Eligible/ Enrolled**
PTSD Risperidone (Padala PR et al., 2005) US	Diphenhydramine 25-50 mg/dy PRN	Assessed at baseline and 10 weeks: TOP8, HAM_A, CAPS, CGI, HAM_D_HDRS	41/NR 0% male Caucasian, African-American, NOS	NR/20/20
PTSD Risperidone (Reich DB et al., 2004) US	Antidepressants, Benzodiazepines permitted	Assessed at baseline and 8 weeks: CAPS	27/NR 0% male Caucasian, African-American, Asian	NR/21/21
OCD Olanzapine (Bystritsky A et al., 2004) US	SRIs	Assessed at baseline and 6 weeks: YBOCS, HAM_D_HDRS, HAM_A, CGI	41/18-65 50% male NR	NR/26/26
OCD Risperidone (Buchsbaum MS, 2003) NR	NR	Assessed at baseline and 8 weeks: CGI .	NR/NR NR NR	NR/16/16
OCD Risperidone (Erzegovesi S et al., 2005) Western Europe	Fluvoxamine, Previously established benzodiazepines used as hypnotics	Assessed at baseline and 6 weeks: YBOCS, NIMH-OC, HAM_D_HDRS, CGI	37/NR 53% male NR	NR/45/45
OCD Risperidone (Hollander E et al., 2003) US	SRIs	Assessed at baseline and 8 weeks: YBOCS, HAM_D_HDRS, CGI	39/NR 56% male NR	NR/16/16
PTSD Olanzapine (Butterfield MI et al., 2001) US	NR	Assessed at baseline and 10 weeks: SIP, SPRINT, TOP8, DTS, SDS, CGI	43/26-73 7% male Caucasian, African-American	NR/15/15

Condition, Drug Author, Year Country, Trial named	Allowed other medications	Method of outcome assessment Timing of assessment	Age mean/ Age range Gender Ethnicity	Screened/ Eligible/ Enrolled
PTSD Olanzapine (Stein MB et al., 2002) US	SRIs	Assessed at baseline and 8 weeks: CAPS, CES-D, Pittsburg Sleep, CGI	53/34-69 100% male NR	NR/21/19
PTSD Risperidone (Hamner MB et al., 2003) US	Antidepressants, Benzodiazepines, Chloral hydrate, Mood stabilizers	Assessed at baseline and 5 weeks: PANSS, CAPS	52/47-68 100% male Caucasian, African-American	NR/40/40
PTSD Risperidone (Monnelly EP et al., 2003) US	Antidepressants, Benzodiazepines, Buspirone, Mood stabilizers	Assessed at baseline and 6 weeks: OAS-M, PCL-M, BDHI, STAT-T, STAS-AX, BDI, BAI, DES, STAT-S	51/NR 100% male Caucasian, African-American, Hispanic	NR/16/16
Personality Disorder Olanzapine (Bogenschutz MP et al., 2004) US	NR	Assessed at baseline and 12 weeks: CGI, OAS-M, AIAQ, HAM_D_HDRS, HAM_A, SCL_90, ASI	33/18-54 38% male Caucasian, Hispanic, Asian, NOS	NR/40/40
Personality Disorder Olanzapine (Zanarini MC et al., 2001) US	NR	Assessed at baseline and 24 weeks: SCL_90, HAM_D_HDRS, DES, PANSS, GAF	27/NR 0% male Caucasian, NOS	30/28/28
Personality Disorder Risperidone (Koenigsberg HW et al., 2003) US	NR	Assessed at baseline and 9 weeks: PANSS, HAM_D_HDRS, CGI, SPQ	41/NR 83% male Caucasian, African-American, Hispanic	NR/25/25
Tourettes Ziprasidone (Sallee FR et al., 2000) US	NR	Assessed at baseline and 56 day: Yale Global Tic, CGI, Goetz Videotaping Scale, CY-BOCS	12/7-16 79% male NR	29/28/28

Condition, Drug Author, Year Country, Trial named	**Allowed other medications**	**Method of outcome assessment Timing of assessment**	**Age mean/ Age range Gender Ethnicity**	**Screened/ Eligible/ Enrolled**
Dementia and Agitation Aripiprazole (Breder C et al., 2004) NR	Antidepressants, Cognition enhancers at stable doses, zolpidem, lorazepam as long as it was not within 12 hours of baseline and double-blind study evaluations	Assessed at baseline and 10 weeks: BPRS, NPI-NH, CGI, CMAI, Extrapyramidel side effects	83 / 56-97 21% male NR	NR/487/487
Dementia and Agitation Aripiprazole (De Deyn P et al., 2005) NR	Sedative/hypnotics, Acetylcholinesterase inhibitors, Rivastigmine, Tacrine, Antidepressants, Benztropine	Assessed at baseline and 10 weeks: NPI, BPRS, CGI, MMSE, Extrapyramidel side effects	82 / NR 28% male Caucasian, NOS	NR/208/208
Dementia and Agitation Aripiprazole (Streim JE et al., 2004) US	Antidepressants, Cognition enhancers at stable doses, zolpidem, lorazepam	Assessed at baseline and 10 weeks: BPRS, CGI, NPI-NH, CMAI, CSDD, Extrapyramidel side effects	83 / 59-96 24% male NR	NR/256/256
Depression Aripiprazole (McQuade R et al., 2004) NR	Not reported	Assessed at baseline and 26 weeks: YMRS, MADRS, Extrapyramidel side effects	NR / NR NR NR	567/161/161
Depression Olanzapine (Kennedy J et al., 2005) US	Benzodiazepines, Hypnotics	Assessed at baseline and 26 weeks: NPI, MMSE, ADAS-cog, Extrapyramidel side effects, CIBIC	78 / NR 44% male Caucasian, NOS	446/268/268
Depression and Personality Disorder Olanzapine (Soler J et al., 2005) Western Europe	Antidepressants, Mood stabilizers, Benzodiazepines	Assessed at baseline and 12 weeks: HAM_D_HDRS, HAM_A, CGI, Dysfunctional behaviors	27 / NR 13% male NR	125/60/60
Tourettes Risperidone (Scahill L et al., 2003) US	Not reported	Assessed at baseline and 8 weeks: Yale Global Tic, TSSR, CGI, Extrapyramidel side effects	20 / 6-62 88% male NR	49/34/34

Condition, Drug Author, Year Country, Trial named	**Withdrawn/Lost to FU/ Analyzed**	**Results**	**Method of adverse events assessment**
Autism Risperidone (McCracken JT et al., 2002) US RUPP Autism Study	18/3/101	Autism-Change in ABC-I at 8 weeks: Placebo vs Risperidone-SMD = -1.24(-1.667, -0.814)	Monitored, elicited by investigator
Autism Risperidone (Shea S et al., 2004) Canada RIS-CAN-23 Study	7/0/79	Autism-Change in ABC-I at 8 weeks: Placebo vs Risperidone-SMD = -0.932(-1.403, -0.461)	Monitored

Condition, Drug Author, Year Country, Trial named	Withdrawn/Lost to FU/ Analyzed	Results	Method of adverse events assessment
Dementia and Agitation Olanzapine (De Deyn PP et al., 2004) Europe, Australia/NZ, South Africa F1D-MC-HGIV Study	NR/NR/ NR	Dementia_agitation-Change in NPI-NH (agitation) at 10 weeks: Placebo vs Olanzapine 1 mg/d-SMD = -0.142(-0.387,0.103) Dementia_agitation-Change in NPI-NH (agitation) at 10 weeks: Placebo vs Olanzapine 2.5 mg/d-SMD = -0.114 (-0.356,0.128) Dementia_agitation-Change in NPI-NH (agitation) at 10 weeks: Placebo vs Olanzapine 5 mg/d-SMD = -0.114(-0.361,0.134) Dementia_agitation-Change in NPI-NH (agitation) at 10 weeks: Placebo vs Olanzapine 7.5mg/d-SMD = -0.142(-0.387,0.103) Dementia_global-Change in NPI-NH (total) at 10 weeks: Placebo vs Olanzapine 1 mg/d-SMD = 0.042(-0.203,0.287) Dementia_global-Change in NPI-NH (total) at 10 weeks: Placebo vs Olanzapine 2.5 mg/d-SMD = -0.047 (-0.289,0.194) Dementia_global-Change in NPI-NH (total) at 10 weeks: Placebo vs Olanzapine 5 mg/d-SMD = -0.053(-0.3,0.194) Dementia_global-Change in NPI-NH (total) at 10 weeks: Placebo vs Olanzapine 7.5mg/d-SMD = -0.1(-0.345,0.145) Dementia_psychosis-Change in NPI-NH (psychosis) at 10 weeks: Placebo vs Olanzapine 1 mg/d-SMD = -0.12(-0.365,0.124) Dementia_psychosis-Change in NPI-NH (psychosis) at 10 weeks: Placebo vs Olanzapine 2.5 mg/d-SMD = -0.281(-0.524, -0.038) Dementia_psychosis-Change in NPI-NH (psychosis) at 10 weeks: Placebo vs Olanzapine 5 mg/d-SMD = -0.12(-0.368,0.127) Dementia_psychosis-Change in NPI-NH (psychosis) at 10 weeks: Placebo vs Olanzapine 7.5mg/d-SMD = -0.261(-0.506, -0.015)	Monitored, reported by patient

Condition, Drug Author, Year Country, Trial named	Withdrawn/Lost to FU/ Analyzed	Results	Method of adverse events assessment
Dementia and Agitation Olanzapine (Street JS et al., 2000) US HGEU Study	54/0/152	Dementia_agitation-Change in NPI-NH (agitation) at 6 weeks: Placebo vs Olanzapine 5 mg/d-SMD = -0.284(-0.68,0.112) Dementia_agitation-Change in NPI-NH (agitation) at 6 weeks: Placebo vs Olanzapine 10 mg/d-SMD = -0.227(-0.633,0.179) Dementia_agitation-Change in NPI-NH (agitation) at 6 weeks: Placebo vs Olanzapine 15 mg/d-SMD = -0.142(-0.542,0.258) Dementia_global-Change in NPI-NH (total) at 6 weeks: Placebo vs Olanzapine 5 mg/d-SMD = -0.463(-0.862,-0.063) Dementia_global-Change in NPI-NH (total) at 6 weeks: Placebo vs Olanzapine 10 mg/d-SMD = -0.447(-0.857, -0.037) Dementia_global-Change in NPI-NH (total) at 6 weeks: Placebo vs Olanzapine 15 mg/d-SMD = -0.131(-0.531,0.268) Dementia_psychosis-Change in NPI-NH (psychosis) at 6 weeks: Placebo vs Olanzapine 5 mg/d-SMD = -0.642(-1.046,-0.238) Dementia_psychosis-Change in NPI-NH (psychosis) at 6 weeks: Placebo vs Olanzapine 10 mg/d-SMD = -0.441(-0.851, -0.032) Dementia_psychosis-Change in NPI-NH (psychosis) at 6 weeks: Placebo vs Olanzapine 15 mg/d-SMD = -0.301(-0.702,0.1)	Monitored
Dementia and Agitation Olanzapine & Risperidone (Ruths S et al., 2004) Western Europe	0/0/30	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of follow-ups.	Monitored
Dementia and Agitation Quetiapine (Zhong X et al., 2004) US	NR/NR/NR	Insufficient statistics for effect-size calculation.	Monitored
Dementia and Agitation Risperidone (Ballard CG et al., 2004) UK	28/0/NR	Not a comparison of interest for statistical analysis.	Monitored, elicited by investigator

Condition, Drug Author, Year Country, Trial named	Withdrawn/Lost to FU/ Analyzed	Results	Method of adverse events assessment
Dementia and Agitation Risperidone (Brodaty H et al., 2003) Australia/New Zealand	101/0/236	Dementia_agitation-Change in BEHAVE-AD (aggressiveness) at 12 weeks: Placebo vs Risperidone-SMD = -0.538(-0.768, -0.308) Dementia_global-Change in BEHAVE-AD (total) at 12 weeks: Placebo vs Risperidone-SMD = -0.421(-0.682, -0.160)	Monitored, reported by patient, clinical examination
Dementia and Agitation Risperidone (Katz IR et al., 1999) US The Risperidone Study	190/0/435	Dementia_agitation-Change in BEHAVE-AD (aggressiveness) at 12 weeks: Placebo vs Risperidone 0.5mg/d-SMD = -0.351(-0.609, -0.093) Dementia_agitation-Change in BEHAVE-AD (aggressiveness) at 12 weeks: Placebo vs Risperidone 1 mg/d-SMD = -0.602(-0.872,-0.331) Dementia_agitation-Change in BEHAVE-AD (aggressiveness) at 12 weeks: Placebo vs Risperidone 2 mg/d-SMD = -0.752(-1.029,-0.475) Dementia_global-Change in BEHAVE-AD (total) at 12 weeks: Placebo vs Risperidone 0.5mg/d-SMD = -0.19(-0.446,0.066) Dementia_global-Change in BEHAVE-AD (total) at 12 weeks: Placebo vs Risperidone 1 mg/d-SMD = -0.332(-0.599,-0.065) Dementia_global-Change in BEHAVE-AD (total) at 12 weeks: Placebo vs Risperidone 2 mg/d-SMD = -0.601(-0.875,-0.327) Dementia_psychosis-Change in BEHAVE-AD (psychosis) at 12 weeks: Placebo vs Risperidone 0.5mg/d-SMD = -0.051(-0.307, 0.204) Dementia_psychosis-Change in BEHAVE-AD (psychosis) at 12 weeks: Placebo vs Risperidone 1 mg/d-SMD = -0.154(-0.419,0.111) Dementia_psychosis-Change in BEHAVE-AD (psychosis) at 12 weeks: Placebo vs Risperidone 2 mg/d-SMD = -0.385(-0.656,-0.115) Dementia_severity-Change in CGI-S at 12 weeks: Placebo vs Risperidone 1 mg/d-WMD = -0.4(-0.596,-0.204) Dementia_severity-Change in CGI-S at 12 weeks: Placebo vs Risperidone 2 mg/d-WMD = -0.5(-0.698,-0.302)	Monitored, reported by patient
Dementia and Agitation Risperidone (Meguro K et al., 2004) Japan	NR/NR/ NR	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of followups.	Monitored

Condition, Drug Author, Year Country, Trial named	Withdrawn/Lost to FU/ Analyzed	Results	Method of adverse events assessment
Dementia and Agitation Risperidone (Mertens C, 1993) Western Europe	8/0/39	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of follow-ups.	Monitored
Depression Olanzapine (Howanitz E et al., 2001) NR	2/0/14	Insufficient statistics for effect-size calculation.	Monitored
Depression Olanzapine (Kinrys G et al., 2002) US	3/0/11	Insufficient statistics for effect-size calculation.	NR
Depression Olanzapine (Rothschild AJ et al., 2004) (Corya S et al., 2002) US The HGGA Study	NR/NR/116	Depression_mood-Change in HAM-D24 at 8 weeks: Placebo vs Olanzapine-SMD = -0.282(-0.573, 0.008) Depression_mood Comparison of interest not reported. Depression_severity-Change in CGI-S at 8 weeks: Placebo vs Olanzapine-WMD = -0.2(-0.441, 0.041) Depression_severity Comparison of interest not reported.	Monitored, reported by patient
Depression Olanzapine (Shi L et al., 2004) US, Australia/NZ, Europe, Colombia	397/57/ 573	Depression_qol-Change in SF-36 at 8 weeks: Placebo vs Olanzapine-SMD = 0.234(0.061,0.407)	NR
Depression Olanzapine (Tohen M et al., 2003) US, Australia/NZ, Europe, Colombia	397/57/ 788	Depression_mood-Change in MADRS at 8 weeks: Placebo vs Olanzapine-SMD = -0.233(-0.381, -0.085) Depression_severity-Change in CGI-S at 8 weeks: Placebo vs Olanzapine-WMD = -0.3(-0.423, -0.177)	Monitored
Depression Olanzapine (Tohen M et al., 2000) US The Olanzapine HGGW Study	52/4/115	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of followups.	Monitored, reported by patient

Condition, Drug Author, Year Country, Trial named	**Withdrawn/Lost to FU/ Analyzed**	**Results**	**Method of adverse events assessment**
Depression Olanzapine (Tohen M et al., 1999) US The Olanzapine HGEH Study	NR/NR/139	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of followups.	Monitored
Depression Olanzapine (Tohen M et al., 2003) US	NR/NR/66	Insufficient statistics for effect-size calculation.	NR
Depression Olanzapine (Tollefson GD et al., 1999) US Collaborative Crossover Study	11/0/95	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of followups.	Monitored, reported by patient
Dementia-Agitation Olanzapine & Risperidone (van Reekum R et al., 2002) Canada	16/0/33	Dementia_global Not a comparison of interest for statistical analysis.	Monitored
Depression Quetiapine (Calabrese J et al., 2004) US	NR/NR/511	Depression_mood-Change in MADRS at 8 weeks: Placebo vs Quetiapine 300 mg/d-SMD = -0.829(-1.05,-0.608) Depression_mood-Change in MADRS at 8 weeks: Placebo vs Quetiapine 600 mg/d-SMD = -0.868(-1.091,-0.645)	Monitored, reported by patient
Depression Risperidone (Mintzer J et al., 2004) US	NR/NR/ 355	Dementia_psychosis-Change in BEHAVE-AD (psychosis) at 8 weeks: Placebo vs Risperidone-SMD = -0.308(-0.502, -0.114) Dementia_agitation-Change in BEHAVE-AD (aggressiveness) at 8 weeks: Placebo vs Risperidone-SMD = -0.228(-0.422, -0.035) Dementia_global-Change in BEHAVE-AD (total) at 8 weeks: Placebo vs Risperidone-SMD=-0.153(-0.346, 0.040)	Monitored
Depression Risperidone (Gharabawi GM et al., 2004) (Gharabawi GM et al., 2004) NR ARISe-RD Study	17/8/48	Insufficient statistics for effect-size calculation.	Monitored

Condition, Drug Author, Year Country, Trial named	Withdrawn/Lost to FU/ Analyzed	Results	Method of adverse events assessment
Depression Ziprasidone (Daniels DG et al., 1999) US & Canada The Ziprasidone Study	NR/NR/302	Depression_mood-Change in MADRS at 6 weeks: Placebo vs Ziprasidone 80 mg/d-SMD = -0.117 (-0.402,0.169) Depression_mood-Change in MADRS at 6 weeks: Placebo vs Ziprasidone 160 mg/d-SMD = -0.298(-0.585,-0.011) Depression_severity-Change in CGI-S at 6 weeks: Placebo vs Ziprasidone 80 mg/d-WMD = -0.3 (-0.534,-0.066) Depression_severity-Change in CGI-S at 6 weeks: Placebo vs Ziprasidone 160 mg/d-WMD = -0.6 (-0.835,-0.365)	Monitored, reported by patient, clinical observation
Depression Ziprasidone (Keck P Jr et al., 1998) US The Ziprasidone Study	62/1/139	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of followups.	Monitored, reported by patient, clinical observation
Depression and PTSD Risperidone (Bartzokis G et al., 2004) US	17/8/1948	Depression_mood-Change in HAM-D at 16 weeks: Placebo vs Risperidone-SMD = -0.447(-1.072, 0.178) PTSD_depression-Change in CAPS-TOTAL at 6 weeks: Placebo vs Risperidone-SMD = -0.441(-1.022, 0.139)	Monitored, reported by patient, .
Depression and PTSD Risperidone (Padala PR et al., 2005) US	NR/NR/15	PTSD_depression-Change in CAPS-TOTAL at 10 weeks: Placebo vs Risperidone-SMD = -1.809(-3.054, -0.564)	Monitored
Depression and PTSD Risperidone (Reich DB et al., 2004) US	NR/NR/21	PTSD-Change in CAPS-2 TOTAL at 8 weeks: Placebo vs Risperidone-SMD = -0.519(-1.398,0.361)	Monitored
OCD Olanzapine (Bystritsky A et al., 2004) US	8/0/18	OCD-Change in Y-BOCS at 6 weeks: Placebo vs Olanzapine-WMD = -5.7(-10.7,-0.7) OCD-Change in Number of Responders at 6 weeks: Placebo vs Olanzapine-RR = 13(0.8,209.4)	Monitored

Condition, Drug Author, Year Country, Trial named	Withdrawn/Lost to FU/ Analyzed	Results	Method of adverse events assessment
OCD Risperidone (Buchsbaum MS, 2003) NR	NR/NR/15	Insufficient statistics for effect-size calculation.	NR
OCD Risperidone (Erzegovesi S et al., 2005) Western Europe	1/0/39	OCD-Change in Y-BOCS at 6 weeks: Placebo vs Risperidone-WMD = 0.89 (-2.5,4.3) OCD-Change in Number of Responders at 6 weeks: Placebo vs Risperidone-RR = 2.5(0.6,9.9)	NR
OCD Risperidone (Hollander E et al., 2003) US	3/0/16	OCD-Change in Y-BOCS at 8 weeks: Placebo vs Risperidone-WMD = -4.9 (-13.9,4.096) OCD-Change in Number of Responders at 8 weeks: Placebo vs Risperidone-RR = 5.7(0.4,90.8)	Monitored, elicited by investigator
PTSD Olanzapine (Butterfield MI et al., 2001) US	4/0/11	PTSD-Change in SIP at 10 weeks: Placebo vs Olanzapine-SMD = 0.182 (-0.894,1.257)	Reported by patient
PTSD Olanzapine (Stein MB et al., 2002) US	5/2/2014	Olanzapine was associated with a greater reduction than placebo in depressive symptoms as measured by the CES-D. SMD = -.726 (-1.659, .207).	NR
PTSD Risperidone (Hamner MB et al., 2003) US	15/0/37	Rejected from meta-analysis because outcomes were measured at less than 6 weeks of followups.	Elicited by investigator
PTSD Risperidone (Monnelly EP et al., 2003) US	1/0/15	Outcome of interest for statistical analysis not reported.	NR
Personality Disorder Olanzapine (Bogenschutz MP et al., 2004) US	8/7/1935	Personality Disorder-Change in CGI-BPD at 12 weeks: Placebo vs Olanzapine-SMD = -0.667 (-1.351,0.018)	Monitored

Condition, Drug Author, Year Country, Trial named	Withdrawn/Lost to FU/ Analyzed	Results	Method of adverse events assessment
Personality Disorder Olanzapine (Zanarini MC et al., 2001) US	8/11/2028	Personality Disorder-Change in SCL90-ANXIETY at 24 weeks: Placebo vs Olanzapine-SMD = -0.32 (-1.118,0.478)	Monitored, elicited by investigator
Personality Disorder Risperidone (Koenigsberg HW et al., 2003) US	10/1/23	Personality Disorder-Change in PANSS-TOTAL at 9 weeks: Placebo vs Risperidone-SMD = -1.624(-2.595, -0.653)	NR
Tourettes Ziprasidone (Sallee FR et al., 2000) US	4/0/28	Tourettes-Change in YALE GLOBAL Tic at 8 weeks: Placebo vs Ziprasidone-SMD = -0.563(-1.346, 0.22)	Monitored, reported by patient, clinical observation
Dementia and Agitation Aripiprazole (Breder C et al., 2004) NR	NR/NR/274	Insufficient statistics for effect-size calculation.	NR
Dementia and Agitation Aripiprazole (De Deyn P et al., 2005) NR	36/0/203	Dementia_global-Change in NPI-Total at 10 weeks: Placebo vs Aripiprazole-SMD = 0.847(0.56,1.135) Dementia_psychosis-Change in NPI-Psychosis at 10 weeks: Placebo vs Aripiprazole-SMD = 0.424(0.146,0.702) Dementia_severity-Change in CGI-S at 10 weeks: Placebo vs Aripiprazole-SMD = -1.034(-1.327,-0.74)	Monitored
Dementia and Agitation Aripiprazole (Streim JE et al., 2004) US	NR/NR/249	Insufficient statistics for effect-size calculation.	NR
Depression Aripiprazole (McQuade R et al., 2004) NR	NR/NR/67	Depression_mood-Change in MADRS at 26 weeks: Placebo vs Aripiprazole-SMD = -0.298(-0.612,0.016)	Monitored
Depression Olanzapine (Kennedy J et al., 2005) US	92/3/173	Dementia_cognition-Change in ADAS-Cog at 26 weeks: Placebo vs Olanzapine-SMD = 0.145(-0.109,0.398) Dementia_psychosis-Change in NPI-Psychosis at 26 weeks: Placebo vs Olanzapine-SMD = -0.015(-0.269,0.239)	Monitored, reported by patient

Condition, Drug Author, Year Country, Trial named	**Withdrawn/Lost to FU/ Analyzed**	**Results**	**Method of adverse events assessment**
Depression and Personality Disorder Olanzapine (Soler J et al., 2005) Western Europe	NR/NR/60	Depression_mood-Change in HAM-D at 12 weeks: Placebo vs Olanzapine-SMD = -2.438(1.765,3.111) Depression_severity-Change in CGI-S at 12 weeks: Placebo vs Olanzapine-WMD = -11.87(-14.226,-9.514)	Monitored
Tourettes Risperidone (Scahill L et al., 2003) US	2/0/34	Tourettes-Change in YALE GLOBAL Tic at 8 weeks: Placebo vs Risperidone-SMD = -1.09(-1.814,-0.365)	Monitored

Condition, Drug **Author, Year** **Country, Trial named**	**Adverse events reported**	**Total withdrawals** **Withdrawals due to adverse events**
Autism Risperidone (McCracken JT et al., 2002) US RUPP Autism Study	Placebo vs Risperidone: Anxiety: 20%(10/51) vs 24%(12/49) Constipation: 12%(6/51) vs 29%(14/49) Decreased appetite: 10%(5/52) vs 6%(3/49) Diarrhea: 22%(11/51) vs 18%(9/49) Dizziness: 4%(2/51) vs 16%(8/49) Drooling: 6%(3/51) vs 27%(13/49) Drowsiness: 12%(6/51) vs 49%(24/49) Dry mouth: 10%(5/51) vs 18%(9/49) Dyskinesia: 6%(3/51) vs 12%(6/49) Earache: 8%(4/51) vs 4%(2/49) Elevated serum glutamic-pyruvic transaminase level: 2%(1/51) vs 0%(0/49) Enuresis: 29%(15/51) vs 31%(15/49) Fatigue: 27%(14/51) vs 59%(29/49) Fever in association with a documented, time-limited illness: 20%(10/51) vs 16%(8/49) Headache: 12%(6/51) vs 18%(9/49) Increased appetite (mild): 25%(13/51) vs 49%(24/49) Increased appetite (moderate): 4%(2/51) vs 24%(12/49) Increased thirst: 10%(5/51) vs 12%(6/49) Insomnia: 29%(15/51) vs 14%(7/49) Muscle rigidity: 2%(1/51) vs 10%(5/49) Nasal congestion: 39%(20/51) vs 51%(25/49) Nausea: 10%(5/51) vs 8%(4/49) Nonspecific, clinically insignificant change in cardiac conduction: 2%(1/51) vs 0%(0/49) Restlessness: 6%(3/51) vs 6%(3/49) Serum glutamic-oxaloacetic transaminase more than twice upper limit of normal range at 8 wks: 2%(1/51) vs 2%(1/49) Skin irritation: 14%(7/51) vs 22%(11/49) Sleep problems: 18%(9/51) vs 22%(11/49) Sore throat: 2%(1/51) vs 10%(5/49) Stomachache: 18%(9/51) vs 10%(5/49) Tachycardia: 2%(1/51) vs 12%(6/49) Tremor: 2%(1/51) vs 14%(7/49) Upper respiratory tract infection: 4%(2/51) vs 10%(5/49) Vomiting: 24%(12/51) vs 33%(16/49) Weight change in kg: Placebo-51 people (0.8 mean,2.2 SD) vs Risperidone-49 people (2.7 mean,2.9 SD)	Placebo vs Risperidone: Withdrawals: 35.3%(18/51) vs 6.1%(3/49) Withdrawals due to adverse events: 2.0%(1/51) vs 0.0%(0/49)

Condition, Drug **Author, Year** **Country, Trial named**	**Adverse events reported**	**Total withdrawals** **Withdrawals due to adverse events**
Autism Risperidone (Shea S et al., 2004) Canada RIS-CAN-23 Study	Placebo vs Risperidone: At least one adverse event: 79.5%(31/39) vs 100.0%(40/40) Abdominal pain: 7.7%(3/39) vs 20.0%(8/40) Abnormal gait: 2.6%(1/39) vs 0.0%(0/40) Accidental overdose: 2.6%(1/39) vs 2.5%(1/40) Aggressive reaction with impaired concentration (severe): 0.0%(0/39) vs 2.5%(1/40) Anorexia: 2.6%(1/39) vs 10.0%(4/40) Apathy: 0.0%(0/39) vs 12.5%(5/40) Ataxia: 2.6%(1/39) vs 0.0%(0/40) Constipation: 2.6%(1/39) vs 12.5%(5/40) Coughing: 10.3%(4/39) vs 15.0%(6/40) Diarrhea: 15.4%(6.006/39) vs 0.0%(0/40) Dyskinesia: 2.6%(1/39) vs 0.0%(0/40) EPS: 12.8%(5/39) vs 27.5%(11/40) Emotional liability: 15.4%(6.006/39) vs 0.0%(0/40) Extrapyramidal disorder: 0.0%(0/39) vs 5.0%(2/40) Extrapyramidal disorder due to accidental overdose (severe): 0.0%(0/39) vs 2.5%(1/40) Fatigue: 2.6%(1/39) vs 10.0%(4/40) Fever: 17.9%(7/39) vs 20.0%(8/40) Headache: 5.1%(2/39) vs 12.5%(5/40) Hyperkinesia and somnolence (severe): 0.0%(0/39) vs 2.5%(1/40) Hypertonia: 2.6%(1/39) vs 0.0%(0/40) Hypokinesia: 5.0%(2/39) vs 0.0%(0/40) Increased appetite: 10.3%(4/39) vs 22.5%(9/40) Influenza-like symptoms: 5.1%(2/39) vs 10.0%(4/40) Insomnia: 15.4%(6/39) vs 15.0%(6/40) Insomnia & sunken eyes (severe): 2.6%(1/39) vs 0.0%(0/40) Involuntary muscle contractions: 2.6%(1/39) vs 0.0%(0/40) Rhinitis: 10.3%(4/39) vs 27.5%(11/40) Saliva increased: 2.6%(1/39) vs 10.0%(4/40) Somnolence: 7.7%(3/39) vs 72.5%(29/40) Somnolence (severe): 0.0%(0/39) vs 2.5%(1/40) Tachycardia: 0.0%(0/39) vs 12.5%(5/40) Tardive dyskinesia: 2.6%(1/39) vs 0.0%(0/40) Tremor: 0.0%(0/39) vs 10%(4/40) Upper respiratory tract infection: 15.4%(6/39) vs 37.5%(15/40) Vomiting: 15.4%(6/39) vs 15.0%(6/40) Weight increase: 2.6%(1/39) vs 10.0%(4/40) Weight increase (severe): 0.0%(0/39) vs 2.5%(1/40) Weight change in kg: Placebo-39 people (1.0 mean,1.6 SD) vs Risperidone-40 people (2.7 mean,2.0 SD)	Placebo vs Risperidone: Withdrawals: 12.8%(5/39) vs 5.0%(2/40) Withdrawals due to adverse events: 2.6%(1/39) vs 2.5%(1/40)

Condition, Drug Author, Year Country, Trial named	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Dementia and Agitation Olanzapine (De Deyn PP et al., 2004) Europe, Australia/NZ, South Africa F1D-MC-HGIV Study	Data not reported by intervention group.	Placebo vs Olanzapine 1 mg/d vs Olanzapine 2.5 mg/d vs Olanzapine 5 mg/d vs Olanzapine 7.5mg/d: Withdrawals: 29.5%(38/129) vs 34.1%(44/129) vs 24.6%(33/134) vs 24.8%(31/125) vs 28.8%(38/132) Withdrawals due to adverse events: 3.9%(5/129) vs 9.3%(12/129) vs 6.7%(9/134) vs 7.2%(9/125) vs 9.8%(13/132)
Dementia and Agitation Olanzapine (Street JS et al., 2000) US HGEU Study	Placebo vs Olanzapine 5 mg/d vs Olanzapine 10 mg/d vs Olanzapine 15 mg/d: Abnormal gait: 2.1%(1/47) vs 19.6%(11/56) vs 14.0%(7/50) vs 17.0%(9/53) Accidental injury: 27.7%(13/47) vs 25.0%(14/56) vs 24.0%(12/50) vs 37.7%(20/53) Agitation: 8.5%(4/47) vs 8.9%(5/56) vs 12.0%(6/50) vs 11.3%(6/53) Anorexia: 8.5%(4/47) vs 1.8%(1/56) vs 4.0%(2/50) vs 15.1%(8/53) Cough increased: 6.4%(3/47) vs 12.5%(7/56) vs 10.0%(5/50) vs 7.5%(4/53) Ecchymosis: 14.9%(7/47) vs 8.9%(5/56) vs 12.0%(6/50) vs 15.1%(8/53) Fever: 2.1%(1/47) vs 8.9%(5/56) vs 14.0%(7/50) vs 13.2%(7/53) Nervousness: 4.3%(2/47) vs 7.1%(4/56) vs 12.0%(6/50) vs 1.9%(1/53) Pain: 10.6%(5/47) vs 14.3%(8/56) vs 12.0%(6/50) vs 24.5%(13/53) Peripheral edema: 6.4%(3/47) vs 3.6%(2/56) vs 12.0%(6/50) vs 7.5%(4/53) Somnolence: 6.4%(3/47) vs 25.0%(14/56) vs 26.0%(13/50) vs 35.8%(19/53) Weight loss: 6.4%(3/47) vs 0.0%(0/56) vs 4.0%(2/50) vs 11.3%(6/53)	Placebo vs Olanzapine 5 mg/d vs Olanzapine 10 mg/d vs Olanzapine 15 mg/d: Withdrawals: 23.4%(11/47) vs 19.6%(11/56) vs 28.0%(14/50) vs 34.0%(18/53) Withdrawals due to adverse events: 4.3%(2/47) vs 10.7%(6/56) vs 8.0%(4/50) vs 17.0%(9/53)
Dementia and Agitation Olanzapine & Risperidone (Ruths S et al., 2004) Western Europe	Data not reported by intervention group.	Placebo vs Haloperidol, Risperidone, or Olanzapine: Withdrawals: Not reported Withdrawals due to adverse events: Not reported
Dementia and Agitation Quetiapine (Zhong X et al., 2004) US	Placebo vs Quetiapine 200 mg/d vs Quetiapine 100 mg/d: Death: 1.1%(0.913/83) vs 1.7%(2.125/125) vs 0.6%(0.75/125)	Placebo vs Quetiapine 200 mg/d vs Quetiapine 100 mg/d: Withdrawals: Not reported Withdrawals due to adverse events: Not reported
Dementia and Agitation Risperidone (Ballard CG et al., 2004) UK	Placebo vs Active treatment (risperidone, thioridazine, haloperidol, trifluoperazine, chlorpromazine): Death: 7.0%(3/46) vs 6.0%(3/54)	Placebo vs Active treatment (risperidone, thioridazine, haloperidol, trifluoperazine, chlorpromazine): Withdrawals: 30.0%(14/46) vs 26.0%(14/54) Withdrawals due to adverse events: Not reported

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Dementia and Agitation Risperidone (Brodaty H et al., 2003) Australia/New Zealand	Placebo vs Risperidone: Aggressive reaction: 10.6%(18/170) vs 5.4%(9/167) Agitation: 24.7%(42/170) vs 19.8%(33/167) Cerebrovascular adverse event: 1.8%(3/170) vs 9.0%(15/167) Conjunctivitis: 10.6%(18/170) vs 12.0%(20/167) Constipation: 15.3%(26/170) vs 11.4%(19/167) Coughing: 2.9%(5/170) vs 5.4%(9/167) Death: 2.4%(4/170) vs 3.6%(6/167) Diarrhea: 12.9%(22/170) vs 3.0%(5/167) Dyskinesia: 5.3%(9/170) vs 0.6%(1/167) Edema peripheral: 3.5%(6/170) vs 7.8%(13/167) Extrapyramidal disorder: 2.9%(5/170) vs 6.0%(10/167) Falls: 27.1%(46/170) vs 25.1%(42/167) Fever: 2.4%(4/170) vs 5.4%(9/167) Gait abnormal: 1.2%(2/170) vs 6.0%(10/167) Headache: 6.5%(11/170) vs 4.8%(8/167) Infection: 7.1%(12/170) vs 3.6%(6/167) Injury: 37.1%(63/170) vs 35.9%(60/167) Life-threatening, requiring hospitalization or resulting in significant disability or incapacity.: 8.8%(15/170) vs 16.8%(28/167) Purpura: 15.9%(27/170) vs 18.0%(30/167) Rash: 5.3%(9/170) vs 7.8%(13/167) Skin disorder: 9.4%(16/170) vs 10.8%(18/167) Skin ulceration: 6.5%(11/170) vs 7.2%(12/167) Somnolence: 25.3%(43/170) vs 36.5%(61/167) Stroke: 0.0%(0/170) vs 3.0%(5/167) TIA: 0.0%(0/170) vs 0.6%(1/167) Total patients with adverse events: 92.4%(157/170) vs 94.0%(157/167) Tremor: 1.8%(3/170) vs 6.0%(10/167) Upper respiratory tract infection: 8.8%(15/170) vs 7.8%(13/167) Urinary tract infection: 14.7%(25/170) vs 23.4%(39/167) Vomiting: 7.6%(13/170) vs 8.4%(14/167)	Placebo vs Risperidone: Withdrawals: 32.9%(56/170) vs 26.9%(45/167) Withdrawals due to adverse events: 8.2%(13.94/170) vs 13.2% (22.044/167)

Condition, Drug Author, Year Country, Trial named	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Dementia and Agitation Risperidone (Katz IR et al., 1999) US The Risperidone Study	Placebo vs Risperidone 0.5mg/d vs Risperidone 1 mg/d vs Risperidone 2 mg/d: Experienced 1 or more serious adverse events during the trial or in the subsequent 30 days.: 12.9%(21/163) vs 10.7%(16/149) vs 16.2%(24/148) vs 17.6%(29/165) At least one adverse event: 84.7%(138/163) vs 83.9%(125/149) vs 81.8%(121/148) vs 88.5%(146/165) Agitation: 10.4%(17/163) vs 7.4%(11/149) vs 5.4%(8/148) vs 8.5%(14/165) Coughing: 8.0%(13/163) vs 10.7%(16/149) vs 5.4%(8/148) vs 8.5%(14/165) Death: 3.1%(5/163) vs 4.0%(6/149) vs 8.8%(13/148) vs 3.6%(6/165) Extrapyramidal disorder: 7.4%(12/163) vs 6.7%(10/149) vs 12.8%(19/148) vs 21.2%(35/165) Falls: 20.2%(33/163) vs 16.1%(24/149) vs 12.8%(19/148) vs 24.8%(41/165) Fever: 7.4%(12/163) vs 10.1%(15/149) vs 7.4%(11/148) vs 14.5%(24/165) Injury: 37.4%(61/163) vs 32.9%(49/149) vs 28.4%(42/148) vs 31.5%(52/165) Pain: 8.0%(13/163) vs 8.1%(12/149) vs 2.7%(4/148) vs 10.3%(17/165) Peripheral edema: 5.5%(9/163) vs 16.1%(24/149) vs 12.8%(19/148) vs 18.2%(30/165) Purpura: 11.7%(19/163) vs 16.8%(25/149) vs 12.2%(18/148) vs 10.3%(17/165) Rhinitis: 5.5%(9/163) vs 4.7%(7/149) vs 6.1%(9/148) vs 10.3%(17/165) Somnolence: 8.0%(13/163) vs 10.1%(15/149) vs 16.9%(25/148) vs 27.9%(46/165) Tardive dyskinesia: 0.6%(1/163) vs 0.0%(0/149) vs 0.0%(0/148) vs 0.0%(0/165) Upper respiratory tract infection: 3.7%(6/163) vs 10.1%(15/149) vs 7.4%(11/148) vs 5.5%(9/165) Urinary tract infection: 12.9%(21/163) vs 16.1%(24/149) vs 12.8%(19/148) vs 21.2%(35/165)	Placebo vs Risperidone 0.5mg/d vs Risperidone 1 mg/d vs Risperidone 2 mg/d: Withdrawals: 27.0%(44/163) vs 21.5%(32/149) vs 30.4%(45/148) vs 41.8%(69/165) Withdrawals due to adverse events: 12.3%(20/163) vs 8.1%(12/149) vs 16.2%(24/148) vs 24.2%(40/165)
Dementia and Agitation Risperidone (Meguro K et al., 2004) Japan	No adverse events reported.	Non-risperidone (no treatment) vs Risperidone: Withdrawals: Not reported Withdrawals due to adverse events: Not reported
Dementia and Agitation Risperidone (Mertens C, 1993) Western Europe	Placebo vs Risperidone: At least one adverse event: 42.1%(8/19) vs 55.0%(11/20) At least one serious adverse event: 0.0%(0/19) vs 5.0%(1/20) Abnormal ECG values: 31.6%(6/19) vs 35.0%(7/20) Death: 0.0%(0/19) vs 5.0%(1/20) No. of pts with code 4: .%(16/19) vs .%(9/20)	Placebo vs Risperidone: Withdrawals: 21.1%(4/19) vs 20.0%(4/20) Withdrawals due to adverse events: 0.0%(0/19) vs 10.0%(2/20)
Depression Olanzapine (Howanitz E et al., 2001) NR	Olanzapine vs Placebo: Occurance of one adverse event: 0.0%(0/8) vs 12.5%(1/8)	Olanzapine vs Placebo: Withdrawals: 12.5%(1/8) vs 12.5%(1/8) Withdrawals due to adverse events: Not reported

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Depression Olanzapine (Kinrys G et al., 2002) US	Adverse events not reported.	Placebo vs Olanzapine: Withdrawals: 0.0%(0/5) vs 33.3%(3/9) Withdrawals due to adverse events: 0.0%(0/5) vs 0.0%(0/9)
Depression Olanzapine (Rothschild AJ et al., 2004) (Corya S et al., 2002) US The HGGA Study	Placebo vs Olanzapine vs Olanzapine + fluoxetine: At least one adverse event: 83.3%(83.3/100) vs 79.2%(79.992/101) vs 81.0%(38.88/48) Ambylopia (blurred vision): 5.0%(5/100) vs 1.0%(1.01/101) vs 10.4%(4.992/48) Dry mouth: 8.0%(8/100) vs 24.8%(25.048/101) vs 10.4%(4.992/48) GGT increase: 0.0%(0/100) vs 0.0%(0/101) vs 4.2%(2.016/48) Insomnia: 20.0%(20/100) vs 7.9%(7.979/101) vs 10.4%(4.992/48) Peripheral edema: 0.0%(0/100) vs 6.9%(6.969/101) vs 10.4%(4.992/48) Somnolence: 5.0%(5/100) vs 18.8%(18.988/101) vs 25.0%(12/48) Vomiting: 10.0%(10/100) vs 3.0%(3.03/101) vs 2.1%(1.008/48) Weight gain: 2.0%(2/100) vs 10.9%(11.009/101) vs 4.2%(2.016/48)	Placebo vs Olanzapine vs Olanzapine + fluoxetine: Withdrawals: 59.0%(59/100) vs 55.4%(56/101) vs 50.0%(24/48) Withdrawals due to adverse events: 6.0%(6/100) vs 8.9%(9/101) vs 18.8%(9/48)
Depression Olanzapine (Shi L et al., 2004) US, Australia/NZ, Europe, Colombia	No adverse events reported.	Placebo vs Olanzapine vs Olanzapine + Fluoxetine: Withdrawals: 51.6%(191/370) vs 61.5%(232/377) vs 36.0%(31/86) Withdrawals due to adverse events: Not reported

Condition, Drug Author, Year Country, Trial named	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Depression Olanzapine (Tohen M et al., 2003) US, Australia/NZ, Europe, Colombia	Placebo vs Olanzapine vs Olanzapine + fluoxetine: 7% or greater weight gain: 0.3%(1.131/377) vs 18.7%(69.19/370) vs 19.5%(16.77/86) Asthenia: 3.2%(12.064/377) vs 9.7%(35.89/370) vs 12.8%(11.008/86) Diarrhea: 6.6%(24.882/377) vs 6.5%(24.05/370) vs 18.6%(15.996/86) Dry mouth: 6.1%(22.997/377) vs 11.1%(41.07/370) vs 16.3%(14.018/86) Headache: 18.6%(70.122/377) vs 12.4%(45.88/370) vs 14.0%(12.04/86) Increase in high supine systolic blood pressure: 1.7%(6.409/377) vs 0.6%(2.22/370) vs 4.9%(4.214/86) Increased appetite: 5.0%(18.85/377) vs 13.5%(49.95/370) vs 12.8%(11.008/86) Insomnia: 15.1%(56.927/377) vs 8.4%(31.08/370) vs 9.3%(7.998/86) Nausea: 8.8%(33.176/377) vs 4.3%(15.91/370) vs 11.6%(9.976/86) Nervousness: 8.0%(30.16/377) vs 10.5%(38.85/370) vs 9.3%(7.998/86) Orthostatic hypotension: 1.4%(5.278/377) vs 1.4%(5.18/370) vs 7.3%(6.278/86) Somnolence: 12.5%(47.125/377) vs 28.1%(103.97/370) vs 20.9%(17.974/86) Treatment-emergent QTc intervals of 470 milliseconds or greater: 0.3%(1/377) vs 0.3%(1/370) vs 0.0%(0/86) Treatment-emergent glucose elevation of 200 mg/dL or greater: 0.3%(1.131/377) vs 1.4%(5.18/370) vs 1.5%(1.29/86) Weight gain: 2.7%(10.179/377) vs 17.3%(64.01/370) vs 17.4%(14.964/86) Weight change in kg: Placebo-377 people (-0.47 mean,2.62 SD) vs Olanzapine-370 people (2.59 mean,3.24 SD) vs Olanzapine + Fluoxetine-86 people (2.79 mean,3.23 SD)	Placebo vs Olanzapine vs Olanzapine + fluoxetine: Withdrawals: 5.0%(19/377) vs 9.2%(34/370) vs 2.3%(2/86) Withdrawals due to adverse events: 61.5%(232/377) vs 51.6%(191/370) vs 36.0%(31/86)
Depression Olanzapine (Tohen M et al., 2000) US The Olanzapine HGGW Study	Placebo vs Olanzapine: Agitation: 25.0%(15/60) vs 9.1%(5/55) Anxiety: 15.0%(9/60) vs 3.6%(2/55) Asthenia: 5.0%(3/60) vs 10.9%(6/55) Constipation: 8.3%(5/60) vs 10.9%(6/55) Dizziness: 6.7%(4/60) vs 12.7%(7/55) Dry mouth: 5.0%(3/60) vs 16.4%(9/55) Dyspepsia: 5.0%(3/60) vs 12.7%(7/55) Headache: 21.7%(13/60) vs 18.2%(10/55) Hostility: 10.0%(6/60) vs 1.8%(1/55) Nervousness: 20.0%(12/60) vs 9.1%(5/55) Personality disorder: 11.7%(7/60) vs 1.8%(1/55) Somnolence: 8.3%(5/60) vs 38.2%(21/55) Weight change in kg: Placebo-60 people (0.45 mean,2.31 SD) vs Olanzapine-55 people (2.11 mean,2.83 SD)	Placebo vs Olanzapine: Withdrawals: 58.3%(35/60) vs 38.2%(21/55) Withdrawals due to adverse events: 1.7%(1/60) vs 3.6%(2/55)

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Depression Olanzapine (Tohen M et al., 1999) US The Olanzapine HGEH Study	Placebo vs Olanzapine: Agitation: 23.2%(16/69) vs 18.6%(13/70) Anxiety: 10.1%(7/69) vs 14.3%(10/70) Asthenia: 7.2%(5/69) vs 18.6%(13/70) Constipation: 2.9%(2/69) vs 11.4%(8/70) Depression: 11.6%(8/69) vs 12.9%(9/70) Dizziness: 5.8%(4/69) vs 22.9%(16/70) Dry mouth: 8.7%(6/69) vs 25.7%(18/70) Headache: 15.9%(11/69) vs 17.1%(12/70) Hostility: 11.6%(8/69) vs 8.6%(6/70) Increased ALT/SGPT values: 0.0%(0/69) vs 17.6%(12.32/70) Nervousness: 13.0%(9/69) vs 8.6%(6/70) Pain: 4.3%(3/69) vs 11.4%(8/70) Personality disorder: 11.6%(8/69) vs 7.1%(5/70) Somnolence: 17.4%(12/69) vs 32.9%(23/70) Weight gain: 1.4%(1/69) vs 11.4%(8/70) Weight change in kg: Placebo-69 people (-0.44 mean, 2.35 SD) vs Olanzapine-70 people (1.65 mean,2.54 SD)	Placebo vs Olanzapine: Withdrawals: 65.2%(45/69) vs 38.6%(27/70) Withdrawals due to adverse events: 2.9%(2/69) vs 0.0%(0/70)
Depression Olanzapine (Tohen M et al., 2003) US	No adverse events reported.	Placebo vs Olanzapine: Withdrawals: 90.4%(122.944/136) vs 76.4% (171.9/225) Withdrawals due to adverse events: Not reported
Depression Olanzapine (Tollefson GD et al., 1999) US Collaborative Crossover Study	Placebo vs Olanzapine: Delusions: 22.6%(10.17/45) vs 7.5%(3.75/50)	Placebo vs Olanzapine: Withdrawals: 26.7%(12/45) vs 32.0%(16/50) Withdrawals due to adverse events: 6.7%(3/45) vs 14.0%(7/50)
Dementia-Agitation Olanzapine & Risperidone (van Reekum R et al., 2002) Canada	Data not reported by interventions.	Placebo vs Anti-psychotics (risperidone, thioridazine, loxapine, perphenazine, olanzapine, haloperidol, nozinan): Withdrawals: 58.8%(10/17) vs 41.2%(7/17) Withdrawals due to adverse events: 58.8%(10/17) vs 41.2%(7/17)

Condition, Drug Author, Year Country, Trial named	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Depression Quetiapine (Calabrese J et al., 2004) US	Placebo vs Quetiapine 300 mg/d vs Quetiapine 600 mg/d: Constipation: 4.4%(8/181) vs 11.7%(21/181) vs 11.1%(20/180) Dizziness: 8.3%(15/181) vs 16.8%(30/181) vs 22.8%(41/180) Dry mouth: 7.8%(14/181) vs 44.1%(79/181) vs 40.6%(73/180) Mania: 4.0%(7.24/181) vs 3.0%(5.43/181) vs 2.0%(3.6/180) Sedation: 6.1%(11/181) vs 29.6%(53/181) vs 32.2%(58/180) Somnolence: 8.3%(15/181) vs 27.4%(49/181) vs 24.2%(44/180) Weight change in kg: Placebo-181 people (0.1 mean, SD NR) vs Quetiapine 300 mg/d-181 people (0.4 mean, SD NR) vs Quetiapine 600 mg/d-180 people (1.6 mean, SD NR)	Placebo vs Quetiapine 300 mg/d vs Quetiapine 600 mg/d: Withdrawals: 6.6%(12/181) vs 5.0%(9/181) vs 5.6%(10/180) Withdrawals due to adverse events: Not reported
Depression Risperidone (Mintzer J et al., 2004) US	Placebo vs Risperidone: Agitation: 6.7%(16/238) vs 8.1%(19/235) Cerebrovascular disorder: 0.4%(1/238) vs 1.7%(4/235) Death: 2.5%(6/238) vs 3.8%(9/235) EPS-related AEs: 3.4%(8/238) vs 8.5%(20/235) Edema-related AEs: 4.6%(11/238) vs 5.1%(12/235) Fall: 12.6%(30/238) vs 11.1%(26/235) Glucose-related AEs: 2.1%(5/238) vs 1.7%(4/235) Hematoma: 5.0%(12/238) vs 3.4%(8/235) Injury: 10.5%(25/238) vs 9.4%(22/235) Insomnia: 5.9%(14/238) vs 5.5%(13/235) Prolactin-related AEs: 0.0%(0/238) vs 0.0%(0/235) Somnolence: 4.6%(11/238) vs 16.2%(38/235) Stroke: 0.4%(1/238) vs 0.4%(1/235) Urinary tract infection: 10.1%(24/238) vs 9.4%(22/235)	Placebo vs Risperidone: Withdrawals: 24.8%(59/238) vs 25.1%(59/235) Withdrawals due to adverse events: 10.1% (24.038/238) vs 10.6% (24.91/235)
Depression Risperidone (Gharabawi GM et al., 2004) (Gharabawi GM et al., 2004) NR ARISe-RD Study	Placebo vs Risperidone + citalopram: Dizziness: 2.5%(3/119) vs 5.7%(7/122) Fatigue: 7.6%(9/119) vs 4.9%(6/122) Headache: 5.9%(7/119) vs 11.5%(14/122) Insomnia: 5.9%(7/119) vs 3.3%(4/122) Weight Increase: 4.2%(5/119) vs 7.4%(9/122) Weight change in kg: Placebo-119 people (-0.6 kg mean, SD NR) vs Risperidone-122 people (1.2 kg mean, SD NR)	Placebo vs Risperidone + citalopram: Withdrawals: 9.3% (11.067/119) vs 11.5% (14.03/122) Withdrawals due to adverse events: 2.5%(2.975/119) vs 4.1%(5.002/122)

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Depression Ziprasidone (Daniels DG et al., 1999) US & Canada The Ziprasidone Study	Placebo vs Ziprasidone 80 mg/d vs Ziprasidone 160 mg/d: At least one adverse event: 86.0%(79/92) vs 87.0%(92/106) vs 89.0%(93/104) Abdominal pain: 5.0%(5/92) vs 3.0%(3/106) vs 10.0%(10/104) Agitation: 11.0%(10/92) vs 10.0%(10/106) vs 9.0%(9/104) Akathisia: 7.0%(6/92) vs 14.0%(15/106) vs 13.0%(13/104) Constipation: 14.0%(13/92) vs 7.0%(7/106) vs 14.0%(14/104) Dizziness: 9.0%(8/92) vs 9.0%(10/106) vs 17.0%(18/104) Dry mouth: 4.0%(4/92) vs 4.0%(4/106) vs 13.0%(13/104) Dyspepsia: 9.0%(8/92) vs 9.0%(10/106) vs 14.0%(14/104) Dystonia: 2.2%(2.024/92) vs 0.0%(0/106) vs 3.8%(3.952/104) Extrapyramidal syndrome: 1.0%(0.92/92) vs 2.0%(2.12/106) vs 7.0%(7.28/104) Headache: 33.0%(30/92) vs 17.0%(18/106) vs 31.0%(32/104) Impotence: 0.0%(0/92) vs 0.0%(0/106) vs 1.0%(1/104) Increased appetite: 0.0%(0/92) vs 1.9%(2/106) vs 0.0%(0/104) Insomnia: 14.0%(13/92) vs 12.0%(13/106) vs 12.0%(12/104) Male sexual dysfunction: 0.0%(0/92) vs 0.0%(0/106) vs 1.0%(1/104) Nausea: 9.0%(8/92) vs 14.0%(15/106) vs 7.0%(7/104) Pain: 9.0%(8/92) vs 6.0%(6/106) vs 10.0%(10/104) Seizure: 0.0%(0/92) vs 0.0%(0/106) vs 0.0%(0/104) Severe EPS: 0.0%(0/92) vs 0.0%(0/106) vs 1.0%(1/104) Severe adverse evens: 11.0%(10/92) vs 8.0%(8/106) vs 8.0%(8/104) Somnolence: 5.0%(5/92) vs 19.0%(20/106) vs 19.0%(20/104) Tachycardia & orthostatic hypotension: 0.0%(0/92) vs 2.0%(2.12/106) vs 1.0%(1.04/104) Vomiting: 15.0%(14/92) vs 11.0%(12/106) vs 6.0%(6/104) Weight change in kg: Placebo-92 people (0.0 mean, SD NR) vs Ziprasidone 80 mg/day-106 people (1.0 mean, SD NR) vs Ziprasidone 160 mg/day-104 people (0.0 mean, SD NR)	Placebo vs Ziprasidone 80 mg/d vs Ziprasidone 160 mg/d: Withdrawals: 50.0%(46/92) vs 48.0% (50.88/106) vs 28.0% (29.12/104) Withdrawals due to adverse events: 1.1%(1/92) vs 1.8%(2/106) vs 7.7%(8/104)

Condition, Drug Author, Year Country, Trial named	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Depression Ziprasidone (Keck P Jr et al., 1998) US The Ziprasidone Study	Placebo vs Ziprasidone 40 mg/d vs Ziprasidone 120 mg/d: At least one adverse event: 75.0%(36/48) vs 75.0%(33/44) vs 81.0%(36/47) Abdominal pain: 8.3%(4/48) vs 11.4%(5/44) vs 2.1%(1/47) Abnormal laboratory test (elevated hepatic transaminase): 0.0%(0/48) vs 0.0%(0/44) vs 2.1%(1/47) Agitation: 12.5%(6/48) vs 0.0%(0/44) vs 6.4%(3/47) Akathisia: 6.3%(3/48) vs 6.8%(3/44) vs 2.1%(1/47) Asthenia: 0.0%(0/48) vs 2.3%(1/44) vs 4.3%(2/47) Asthma: 2.1%(1/48) vs 4.5%(2/44) vs 2.1%(1/47) Back pain: 0.0%(0/48) vs 4.5%(2/44) vs 4.3%(2/47) Cogwheel rigidity: 0.0%(0/48) vs 0.0%(0/44) vs 4.3%(2/47) Constipation: 4.2%(2/48) vs 6.8%(3/44) vs 10.6%(5/47) Diarrhea: 0.0%(0/48) vs 0.0%(0/44) vs 4.3%(2/47) Dizziness: 2.1%(1/48) vs 4.5%(2/44) vs 2.1%(1/47) Dyspepsia: 6.3%(3/48) vs 11.4%(5/44) vs 6.4%(3/47) EPS: 2.1%(1/48) vs 2.3%(1/44) vs 6.4%(3/47) Headache: 20.8%(10/48) vs 18.2%(8/44) vs 21.3%(10/47) Hypertonia: 2.1%(1/48) vs 2.3%(1/44) vs 4.3%(2/47) Insomnia: 4.2%(2/48) vs 2.3%(1/44) vs 0.0%(0/47) Nausea: 4.2%(2/48) vs 6.8%(3/44) vs 6.4%(3/47) Pain: 8.3%(4/48) vs 9.1%(4/44) vs 4.3%(2/47) Peripheral edema: 0.0%(0/48) vs 0.0%(0/44) vs 4.3%(2/47) Pharyngitis: 2.1%(1/48) vs 4.5%(2/44) vs 4.3%(2/47) Rash: 0.0%(0/48) vs 6.8%(3/44) vs 2.1%(1/47) Respiratory disorder: 2.1%(1/48) vs 6.8%(3/44) vs 4.3%(2/47) Serious adverse events: 0.0%(0/48) vs 11.4%(5/44) vs 6.4%(3/47) Skin hypertrophy: 0.0%(0/48) vs 4.5%(2/44) vs 2.1%(1/47) Somnolence: 8.3%(4/48) vs 6.8%(3/44) vs 8.5%(4/47) Tremor: 0.0%(0/48) vs 0.0%(0/44) vs 6.4%(3/47) Vomiting: 4.2%(2/48) vs 4.5%(2/44) vs 2.1%(1/47)	Placebo vs Ziprasidone 40 mg/d vs Ziprasidone 120 mg/d: Withdrawals: 50.0%(24/48) vs 36.0%(16/44) vs 49.0%(23/47) Withdrawals due to adverse events: 0.0%(0/48) vs 2.0%(1/44) vs 9.0%(4/47)
Depression and PTSD Risperidone (Bartzokis G et al., 2004) US	No adverse events reported.	Placebo vs Risperidone: Withdrawals: 18.8%(6/32) vs 33.3%(11/33) Withdrawals due to adverse events: 6.3%(2/32) vs 9.1%(3/33)
Depression and PTSD Risperidone (Padala PR et al., 2005) US	No adverse events reported.	Placebo vs Risperidone: Withdrawals: Not reported Withdrawals due to adverse events: Not reported

Condition, Drug Author, Year Country, Trial named	**Adverse events reported**	**Total withdrawals Withdrawals due to adverse events**
Depression and PTSD Risperidone (Reich DB et al., 2004) US	Placebo vs Risperidone: At least one adverse event: 11.1%(1/9) vs 33.3%(4/12) Weight change in kg: Placebo-9people (1.4 kg mean, SD) vs Risperidone-12 people (1.1 kg mean, SD)	Placebo vs Risperidone: Withdrawals: 22.2%(2/9) vs 25.0%(3/12) Withdrawals due to adverse events: 0.0%(0/9) vs 8.3%(1/12)
OCD Olanzapine (Bystritsky A et al., 2004) US	No adverse events reported.	Placebo vs Olanzapine: Withdrawals: 46.2%(6/13) vs 15.4%(2/13) Withdrawals due to adverse events: 0.0%(0/13) vs 15.4%(2/13)
OCD Risperidone (Buchsbaum MS, 2003) NR	Sample size not reported by group	Placebo vs Risperidone: Withdrawals: Not reported Withdrawals due to adverse events: Not reported
OCD Risperidone (Erzegovesi S et al., 2005) Western Europe	Placebo vs Risperidone: Mild increasing of appetite: 0.0%(0/19) vs 15.0%(3/20) Transient sedation: 0.0%(0/19) vs 35.0%(7/20)	Placebo vs Risperidone: Withdrawals: Not reported Withdrawals due to adverse events: not broken down by group
OCD Risperidone (Hollander E et al., 2003) US	Placebo vs Risperidone: At least one adverse event: 33.3%(2/6) vs 40.0%(4/10) Dizziness: 0.0%(0/6) vs 10.0%(1/10) Dry mouth: 16.7%(1/6) vs 20.0%(2/10) Sedation: 0.0%(0/6) vs 30.0%(3/10) Sexual dysfunction: 16.7%(1/6) vs 0.0%(0/10)	Placebo vs Risperidone: Withdrawals: 33.3%(2/6) vs 10.0%(1/10) Withdrawals due to adverse events: 0.0%(0/6) vs 0.0%(0/10)
PTSD Olanzapine (Butterfield MI et al., 2001) US	No adverse events reported. Weight change in lbs: Placebo-5 people (0.9 mean,0.06 SD) vs Olanzapine-10 people (11.5 mean,4.43 SD)	Placebo vs Olanzapine: Withdrawals: Not reported Withdrawals due to adverse events: Not reported
PTSD Olanzapine (Stein MB et al., 2002) US	Placebo vs Olanzepine: Somnolence: 0.0%(0/9) vs 20.0%(2/10) Weight change in lbs: Placebo-9 people (Mean NR , SD NR) vs Olanzapine-10 people (13 mean, SD)	Placebo vs Olanzepine: Withdrawals: 22.2%(2/9) vs 30.0%(3/10) Withdrawals due to adverse events: 0.0%(0/9) vs 20.0%(2/10)
PTSD Risperidone (Hamner MB et al., 2003) US	Placebo vs Risperidone: Mild akathisia: 0.0%(0/18) vs 5.3%(1/19) Mild nausea and diarrhea: 0.0%(0/18) vs 5.3%(1/19)	Placebo vs Risperidone: Withdrawals: 33.3%(6/18) vs 47.4%(9/19) Withdrawals due to adverse events: 0.0%(0/18) vs 0.0%(0/19)

Condition, Drug Author, Year Country, Trial named	Adverse events reported	Total withdrawals Withdrawals due to adverse events
PTSD Risperidone (Monnelly EP et al., 2003) US	Placebo vs Risperidone: Mild adverse events: 25.0%(2/8) vs 50.0%(4/8) Moderate adverse events: 12.5%(1/8) vs 0.0%(0/8) Urinary retention: 0.0%(0/8) vs 12.5%(1/8)	Placebo vs Risperidone: Withdrawals: 0.0%(0/8) vs 12.5%(1/8) Withdrawals due to adverse events: 0.0%(0/8) vs 12.5%(1/8)
Personality Disorder Olanzapine (Bogenschutz MP et al., 2004) US	Olanzapine vs Placebo: Sedation: 10.0%(2/20) vs 0.0%(0/20) Weight gain: 10.0%(2/20) vs 0.0%(0/20) Weight change in kg: Placebo-20 people (0.08 mean,4.8 SD) vs Olanzapine-20 people (3.71 mean,3.4 SD)	Olanzapine vs Placebo: Withdrawals: 50.0%(10/20) vs 35.0%(7/20) Withdrawals due to adverse events: 20.0%(4/20) vs 0.0%(0/20)
Personality Disorder Olanzapine (Zanarini MC et al., 2001) US	Placebo vs Olanzapine: Constipation: 0.0%(0/9) vs 31.6%(6/19) Mild rigidity: 0.0%(0/9) vs 5.3%(1/19) Perceived weight gain: 0.0%(0/9) vs 47.4%(9/19) Sedation: 33.3%(3/9) vs 42.1%(8/19) Self mutilative acts: 0.0%(0/9) vs 0.0%(0/19) Serious movement disorders: 0.0%(0/9) vs 0.0%(0/19) Suicidal acts: 0.0%(0/9) vs 0.0%(0/19) Tardive dyskinesia: 0.0%(0/9) vs 0.0%(0/19) Weight change in kg: Placebo-9 people (-0.78 mean,2.59 SD) vs Olanzapine-19 people (1.29 mean,2.56 SD)	Placebo vs Olanzapine: Withdrawals: 88.9%(8/9) vs 57.9%(11/19) Withdrawals due to adverse events: 0.0%(0/9) vs 31.6%(6/19)
Personality Disorder Risperidone (Koenigsberg HW et al., 2003) US	Placebo vs Risperidone: At least one adverse event: 50.0%(5/10) vs 46.7%(7/15)	Placebo vs Risperidone: Withdrawals: 30.0%(3/10) vs 46.7%(7/15) Withdrawals due to adverse events: 10.0%(1/10) vs 33.3%(5/15)
Tourettes Ziprasidone (Sallee FR et al., 2000) US	Placebo vs Ziprasidone: At least one adverse event: 58.3%(7/12) vs 100.0%(16/16) Akathisia: 0.0%(0/12) vs 6.3%(1/16) Increase in sedation score above baseline values on at least one visit: 45.0%(5/12) vs 69.0%(11/16) Increases in serum prolacin concentrations greater than 1.1 times the upper limit of normal: 0.0%(0/12) vs 31.3%(5/16) Mild gynecomastia: 0.0%(0/12) vs 6.3%(1/16) Somnolence: 0.0%(0/12) vs 6.3%(1/16) Weight change in kg: Placebo-12 people (0.8 mean,2.3 SD) vs Ziprasidone-16 people (0.7 mean,1.5 SD)	Placebo vs Ziprasidone: Withdrawals: 25.0%(3/12) vs 6.3%(1/16) Withdrawals due to adverse events: 0.0%(0/12) vs 6.3%(1/16)

Condition, Drug Author, Year Country, Trial named	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Dementia and Agitation Aripiprazole (Breder C et al., 2004) NR	Placebo vs Aripiprazole vs Aripiprazole vs Aripiprazole: Accidental injury: 18.0%(22/121) vs 30.0%(35/118) vs 24.0%(29/122) vs 23.0%(29/126) Agitation: 16.0%(19/121) vs 12.0%(14/118) vs 7.0%(9/122) vs 11.0%(14/126) Anorexia: 11.0%(13/121) vs 8.0%(9/118) vs 5.0%(6/122) vs 6.0%(8/126) Asthenia: 4.0%(5/121) vs 6.0%(7/118) vs 9.0%(11/122) vs 6.0%(8/126) Death: 3.0%(4/121) vs (NR/118) vs (NR/122) vs (NR/126) EPS-related AEs: 6.0%(7/121) vs 8.0%(9/118) vs 7.0%(9/122) vs 7.0%(9/126) Ecchymosis: 10.0%(12/121) vs 9.0%(11/118) vs 5.0%(6/122) vs 8.0%(10/126) Edema peripheral: 8.0%(10/121) vs 10.0%(12/118) vs 6.0%(7/122) vs 10.0%(13/126) Extremity pain: 6.0%(7/121) vs 7.0%(8/118) vs 9.0%(11/122) vs 10.0%(13/126) Skin ulcer: 7.0%(9/121) vs 10.0%(12/118) vs 12.0%(15/122) vs 11.0%(14/126) Somnolence: 3.0%(4/121) vs 3.0%(4/118) vs 10.0%(12/122) vs 9.0%(11/126) Urinary incontinence: 2.0%(2/121) vs 2.0%(2/118) vs 10.0%(12/122) vs 6.0%(8/126) Urinary tract infection: 14.0%(17/121) vs 15.0%(18/118) vs 17.0%(21/122) vs 22.0%(28/126) Vomiting: 7.0%(9/121) vs 11.0%(13/118) vs 8.0%(10/122) vs 7.0%(9/126)	Placebo vs Aripiprazole vs Aripiprazole vs Aripiprazole: Withdrawals: (NR/121) vs (NR/118) vs (NR/122) vs (NR/126) Withdrawals due to adverse events: 3.0%(16/121) vs 8.0%(9/118) vs 18.0%(22/122) vs 25.0%(31/126)
Dementia and Agitation Aripiprazole (De Deyn P et al., 2005) NR	Placebo vs Aripiprazole: Bronchitis: 3.0%(3.1/102) vs 6.0%(6.4/106) Death: 0.0%(0/102) vs 3.8%(4/106) EPS-related AEs: 3.9%(4/102) vs 4.7%(5/106) Fractures: 2.0%(2/102) vs 4.7%(5/106) Hypertension: 5.0%(5/102) vs 4.0%(4/106) Increased QTc Interval: 1.0%(1/102) vs 1.9%(2/106) Increased lactate dehydrogenase: 1.0%(1/102) vs 0.0%(0/106) Mild transient cerebral ischemia: 1.0%(1/102) vs 0.9%(1/106) Somnolence: 1.0%(1/102) vs 8.0%(9/106) Urinary tract infection: 12.0%(12/102) vs 8.0%(9/106) Weight gain: 3.0%(3/102) vs 5.0%(5/106)	Placebo vs Aripiprazole: Withdrawals: 17.6%(18/102) vs 17.0%(18/106) Withdrawals due to adverse events: 6.9%(7/102) vs 9.4%(10/106)
Dementia and Agitation Aripiprazole (Streim JE et al., 2004) US	Placebo vs Aripiprazole: Accidental injury: 30.0%(38/125) vs 21.0%(28/131) Asthenia: 7.0%(9/125) vs 12.0%(16/131) Death: 2.4%(3/125) vs 2.3%(3/131) ECG abnormalities: (NR/125) vs (NR/131) EPS-related AEs: 4.0%(5/125) vs 5.0%(7/131) Ecchymosis: 13.0%(16/125) vs 12.0%(16/131) Hypotension and syncope: 5.0%(6/125) vs 3.0%(4/131) Rash: 12.0%(15/125) vs 10.0%(13/131) Somnolence: 4.0%(5/125) vs 14.0%(18/131) Urinary tract infection: 11.0%(14/125) vs 14.0%(18/131) Vomiting: 8.0%(10/125) vs 10.0%(13/131)	Placebo vs Aripiprazole: Withdrawals: (NR/125) vs (NR/131) Withdrawals due to adverse events: 9.0%(11/125) vs 12.0%(16/131)

Condition, Drug Author, Year Country, Trial named	Adverse events reported	Total withdrawals Withdrawals due to adverse events
Depression Aripiprazole (McQuade R et al., 2004) NR	Placebo vs Aripiprazole: Agitation: 11.0%(9/83) vs 7.0%(6/78) Akathisia: 1.2%(1/83) vs 6.5%(5/78) Anxiety: 16.0%(13/83) vs 18.0%(14/78) Depression: 14.0%(12/83) vs 11.0%(9/78) EPS: 1.2%(1/83) vs 0.0%(0/78) Headache: 17.0%(14/83) vs 8.0%(6/78) Insomnia: 20.0%(17/83) vs 16.0%(12/78) Nervousness: 5.0%(4/83) vs 10.0%(8/78) Reaction Manic: 13.0%(11/83) vs 6.0%(5/78) Somnolence: 7.2%(6/83) vs 5.2%(4/78)	Placebo vs Aripiprazole: Withdrawals: (NR/83) vs (NR/78) Withdrawals due to adverse events: 1.0%(1/83) vs 6.0%(5/78)
Depression Olanzapine (Kennedy J et al., 2005) US	Placebo vs Olanzapine: Abnormal gait: 3.3%(3/90) vs 6.7%(12/178) Accidental injury: 6.7%(6/90) vs 11.8%(21/178) Agitation: 5.7%(5/90) vs 8.4%(15/178) Amnesia: 2.2%(2/90) vs 5.6%(10/178) Anxiety: 5.7%(5/90) vs 5.6%(10/178) Asthenia: 5.7%(5/90) vs 10.1%(18/178) Cerebrovascular adverse events: 1.1%(1/90) vs 1.7%(3/178) Confusion: 2.2%(2/90) vs 6.2%(11/178) Constipation: 1.1%(1/90) vs 6.2%(11/178) Death: 1.1%(1/90) vs 0.6%(1/178) Delusions: 1.1%(1/90) vs 5.6%(10/178) Depression: 2.2%(2/90) vs 6.7%(12/178) Diarrhea: 5.7%(5/90) vs 7.3%(13/178) Dizziness: 7.8%(7/90) vs 8.4%(15/178) Extrapyramidal symptoms: (NR/90) vs (NR/178) Flu syndrome: 1.1%(1/90) vs 9.6%(17/178) Insomnia: 3.3%(3/90) vs 6.2%(11/178) Osteoporosis: 3.3%(3/90) vs 0.0%(0/178) Pain: 5.7%(5/90) vs 5.1%(9/178) Peripheral edema: 1.1%(1/90) vs 7.3%(13/178) Somnolence: 4.4%(4/90) vs 16.9%(30/178) Surgical procedure: 5.7%(5/90) vs 9.0%(16/178) Treatment-emergent central anticholinergic-like events: 10.0%(9/90) vs 22.5%(40/178) Treatment-emergent peripheral anticholinergic-like events: 3.3%(3/90) vs 11.2%(20/178) Urinary tract infection: 5.7%(5/90) vs 5.6%(10/178) Weight gain: 1.1%(1/90) vs 7.3%(13/178)	Placebo vs Olanzapine: Withdrawals: 26.7%(24/90) vs 38.2%(68/178) Withdrawals due to adverse events: 4.4%(4/90) vs 12.4%(22/178)
Depression and Personality Disorder Olanzapine (Soler J et al., 2005) Western Europe	1625 Placebo vs Olanzapine: Increased cholesterol: (NR/30) vs (NR/30) Movement disorders: (NR/30) vs (NR/30) Secondary effects: (NR/30) vs (NR/30) Weight gain: (NR/30) vs (NR/30)	Placebo vs Placebo vs Olanzapine vs Olanzapine: Withdrawals: (NR/30) vs (NR/30) vs (NR/30) vs (NR/30)

Condition, Drug **Author, Year** **Country, Trial named**	**Adverse events reported**	**Total withdrawals** **Withdrawals due to adverse events**
Tourettes Risperidone (Scahill L et al., 2003) US	Placebo vs Risperidone: Blurred vision: 0.0%(0/18) vs 12.5%(2/16) Constipation: 5.5%(1/18) vs 0.0%(0/16) Decreased appetite: 5.5%(1/18) vs 6.5%(1/16) Erectle difficulties: 0.0%(0/18) vs 13.0%(2/16) Fatigue: 5.5%(1/18) vs 37.5%(6/16) Foggy thinking: 0.0%(0/18) vs 12.5%(2/16) Headache: 17.0%(3/18) vs 0.0%(0/16) Increased appetite: 0.0%(0/18) vs 44.0%(7/16) Insomnia: 5.5%(1/18) vs 6.5%(1/16) Nausea/Vomiting: 0.0%(0/18) vs 6.5%(1/16) Sedation: 5.5%(1/18) vs 19.0%(3/16) Social phobia: 0.0%(0/18) vs 13.0%(2/16)	Placebo vs Risperidone: Withdrawals: 5.6%(1/18) vs 6.3%(1/16) Withdrawals due to adverse events: (NR/18) vs (NR/16)

Acronyms in Evidence Table:

CCT	Clinical control trial
kg	kilograms
lbs	pounds
ND	Not described
NOS	Not otherwise specified
NR	Not reported
RCT	Randomized control trial
RR	Risk ratio
SMD	Standard mean difference
WMD	Weighted mean difference

Outcomes:

ABC	Aberrant Behavior Checklist
ACES	Agitation-Calmness Evaluation Scale
ADAS-cog	Alzheimer's Disease Assessment Scale
ADHDRS	DuPaul Attention Deficit Hyperactivity Scale
ADL	Activities of Daily Life
AIAQ	Anger, Irritability, and Assault Questionnaire
ASI	Addiction Severity Index
BABS	Brown Assessment of Beliefs Scale
BAI	Beck Anxiety Index
BDHI	Buss-Durkee Hostility Index
BDI	Beck Depression Index
BDS	Blessed Dementia Scale
BEHAVE-AD	Behavioral Pathology in Alzheimer's Disease Rating Scale
BPRS	Brief Psychiatric Rating Scale
BRMES	Bech-Rafaelsen Melancholia Scale
CAPS	Clinician Administered PTSD Scale
CDSS	Calgary Depression Scale for Schizophrenia
CES-D	Center for Epidemiologic Studies Depression Scale
CGI	Clinical Global Impression Scale
CMAI	Cohen-Mansfield Agitation Inventory
CM-PNB	Cohen-Mansfield Physically Non-Aggressive Behavior
CPRS	Children's Psychiatric Rating Scale
CSDD	Cornell Scale for Depression in Dementia
CY-BOCS	Children's Yale-Brown Obsessive-Compulsive Scale
DCM	Dementia Care Mapping
DES	Dissociative Experiences Scale
DTS	Davidson Trauma Scale
E-BEHAVE-AD	Empirical Behavioral Pathology in Alzheimer's Disease Rating Scale
FAST	Functional Assessment Staging Rating Scale
GAF	Global Assessment of Functioning Scale
HAM-A	Hamilton Rating Scale for Anxiety
HAM-D/HDRS	Hamilton Rating Scale for Depression
IGT	Iowa Gambling Task
MADRS	Montgomery-Asberg Depression Rating Scale
MDRS	Mattis Dementia Rating Scale
MMSE	Mini-Mental State Examination
M-NCAS	Modified Strain in Nursing Care Assessment

MOSES	Multidimentional Observational Scale for Elderly Subjects
MOVES	Motor Tic, Obsessions, and Compulsions, Vocal Tic Evaluation Survey
N-CBRF	Nisonger Child Behavior Rating Scale
NIMH-OC	National Institute of Mental Health Obsessive-Compulsive Scale
NPI	Neuropsychiatric Inventory
NPI/NH	Neuropsychiatric Inventory/Nursing Home
NPI-Q	Neuropsychiatric Inventory Questionnaire
OAS-M	Overt Aggression Scale-Modified
PANSS	Positive and Negative Symptom Scale
PCL-M	Patient Checklist for PTSD--Military Version
PDC	Depression cluster
PDS	Progressive Deterioration Scale
PGDRS	Psychogeriatric Dependency Rating Scale
PGI	Patient Global Impressions
QLDS	Quality of Life in Depression Scale
Q-LES-Q	Quality of Life Enjoyment and Satisfaction Questionnaire
QLS	Quality of Life Scales
QUALID	Quality of Life in Late-Stage Dementia Scale
ROAS	Retrospective Overt Aggression Scale
SANS	Scale for the Assessment of Negative Symptoms
SCL-90	Symptom Checklist-90
SDS	Sheehan Disability Scale
SF-36	Medical Outcomes Study 36-Item Short-Form Health Survey
SIB	Severe Impairment Battery
SIB-Q	Self-injurious Behavior Questionnaire
SIP	Structured Interview for PTSD
SPQ	Schizotypal Personality Questionnaire
SPRINT	Short PTSD Rating Interview
STAS-AX	State-Trait Anger Expression Inventory
STAT-S	Spielberger State-Trait Anger Scale, state version
STAT-T	Spielberger State-Trait Anger Scale, trait version
TOP-8	Treatment Outcome PTSD Scale
TSSS	Tourette's Syndrome Severity Scale
VAS	Visual Analog Scale
Y-BOCS	Yale-Brown Obsessive-Compulsive Scale
YGTSS	Yale Global Tic Severity Scale
YMRS	Young Mania Rating Scale

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C4: Evidence Tables – Augmentation Trials

Condition, Drug Author, Year, Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)	Run-in period/ Randomization Method Wash-out period/ Randomization Method	Allowed other medications	Method of outcome assessment Timing of assessment	Age mean/ Age range Gender Ethnicity
Depression Olanzapine (Tohen M et al., 2002) US & Canada	Design: RCT Setting: Multi-center Jadad: 3	Inclusion criteria: Previous depressed, manic, or mixed episode, YMRS ≥ 16, Treatment = lithium or valproate at therapeutic level Exclusion criteria: NR	Lithium-dosage not reported or Valproate-dosage not reported Olanzapine-10.4 mg/day average final dose, Lithium or Valproate Duration: 1.5 months	None 2-7 dy of Concomitant medication except lithium or valproate for randomization not described	Benzodiazepines	Assessed at baseline and 6 weeks: YMRS, HAM_D_HDRS, PANSS, CGI	41/NR 48% male Caucasian, NOS
Depression Quetiapine (Yargic LI et al., 2004) Turkey	Design: RCT Setting: Multi-center Jadad: 2	Inclusion criteria: HAM-D Items 10 and 11 ≥ 2, HAM-D ≥ 26 Exclusion criteria: HAM-D Item 3 > 2, Psychotic disorder, Use psychotropic medications within 4 wks, Medically significant disorders, Abnormal laboratory results, Bipolar disorder, Alcohol or substance abuse or dependency, Pregnant	Paroxetine- 27.6 mg/day average final dose Quetiapine-60 mg/day average final dose, Paroxetine- 27.0 mg/day average final dose Duration: 2.0 months	None None	NR	Assessed at baseline and 8 weeks: HAM_D_HDRS, HAM_A, CGI	35/18-65 26% male NR
OCD Quetiapine (Atmaca M et al., 2002) Turkey	Design: RCT Setting: Single center Jadad: 2	Inclusion criteria: Y-BOCS ≥ 18, CGI-I minimal improvement Exclusion criteria: NR	SRI- varied depending on drug Quetiapine-91.1 mg/day average final dose, SRI- varied depending on drug Duration: 2.0 months	3 mo of SSRIs for patients refractory to SRI monotherapy None	NR	Assessed at baseline and 8 weeks: YBOCS, CGI	28/18-49 52% male NR

Condition, Drug Author, Year, Country, Trial named	**Study design Setting Quality (Jadad Score)**	**Eligibility criteria**	**Interventions (drug, dose, duration)**	**Run-in period/ Randomization Method Wash-out period/ Randomization Method**	**Allowed other medications**	**Method of outcome assessment Timing of assessment**	**Age mean/ Age range Gender Ethnicity**
OCD Quetiapine (Denys D et al., 2004) Western Europe	Design: RCT Setting: Single center Jadad: 4	Inclusion criteria: Age 18-65, Y-BOCS ≥ 18, Y-BOCS ≥ 12, if only obsessions or compulsions were present, Refractory to SRI therapy Exclusion criteria: Tic disorder, Tourettes disorder, Major depressive disorder, Pregnant, Organic mental disorder, Seizure disorder or epilepsy or risk, Neurological disorder, Bipolar disorder	SRI- 20 to 300 mg, depending on drug Quetiapine-150 mg/day average final dose, SRI- 20 to 300 mg, depending on drug Duration: 2.0 months	None None	NR	Assessed at baseline and 8 weeks: YBOCS, HAM_D_HDRS, HAM_A, SDS, BABS, CGI	35/18-60 25% male NR
OCD Risperidone (Cavedini P et al., 2004) Western Europe	Design: RCT Setting: Single center Jadad: 4	Inclusion criteria: NR Exclusion criteria: DSM-IV Axis I disorder, not including primary condition studied, Tic disorder, Medically significant disorders, Severe internal or neurological disease, Brain injury or head trauma, Alcohol or substance abuse or dependency	Fluvoxamine- 245 mg/day average final dose Fluvoxamine- 255 mg/day average final dose Risperidone-0.5 mg/day fixed single dose Duration: 3.0 months	None None	No other concomitant therapy, either pharmacologic or non-pharmacologic was allowed.	Assessed at baseline and 12 weeks: YBOCS, IGT	36/NR 37% male NR

Condition, Drug Author, Year, Country, Trial named	**Study design Setting Quality (Jadad Score)**	**Eligibility criteria**	**Interventions (drug, dose, duration)**	**Run-in period/ Randomization Method Wash-out period/ Randomization Method**	**Allowed other medications**	**Method of outcome assessment Timing of assessment**	**Age mean/ Age range Gender Ethnicity**
OCD Risperidone (McDougle CJ et al., 2000) US	Design: Trial + open label Setting: Single center Jadad: 4	Inclusion criteria: 1 year duration primary condition, CGI ≥ moderate severity, Refractory to SRI therapy Exclusion criteria: Non-healthy, Pregnant, Use psychotropic medications within 4 wks	Risperidone-2.2 mg/day average final dose, Clomipramine-250 mg/day average final dose, Fluvoxamine-300 mg/day average final dose Duration: 1.5 months	12 wk of SRI monotherapy for patients refractory to SRI monotherapy None	None	Assessed at baseline and 6 weeks: YBOCS, HAM_D_HDRS, HAM_A, Yale Global Tic, CGI	37/19-63 58% male Caucasian, African-American, Hispanic, Asian
OCD and Tourettes Olanzapine (Shapira NA et al., 2004) US	Design: RCT Setting: Single center Jadad: 3	Inclusion criteria: Age 14-70, 1 year duration primary condition, CGI ≥ moderate severity, Y-BOCS ≥ 19 Exclusion criteria: Major depressive disorder, Psychotic disorder, Bipolar disorder, Alcohol or substance abuse or dependency, Seizure disorder or epilepsy or risk, Encephalitis, Brain injury or head trauma, Medically significant disorders	Placebo-5.9 mg/day average final dose, Fluoxetine- 40 mg Olanzapine-6.1 mg/day average final dose, Fluoxetine- 40 mg Duration: 1.5 months	1 wk of Placebo for randomization not described None	NR	Assessed at baseline and 6 weeks: YBOCS	37/NR 41% male NR

Condition, Drug Author, Year, Country, Trial named	**Study design Setting Quality (Jadad Score)**	**Eligibility criteria**	**Interventions (drug, dose, duration)**	**Run-in period/ Randomization Method Wash-out period/ Randomization Method**	**Allowed other medications**	**Method of outcome assessment Timing of assessment**	**Age mean/ Age range Gender Ethnicity**
Depression Ziprasidone (Dunner D et al., 2003) US	Design: RCT Setting: NR Jadad: 1	Inclusion criteria: Age 21-65, MADRS ≥ 20, Resistant to antidepressant therapy, MADRS ≥ 30% reduction at week 7, CGI ≥ 4, Male or female Exclusion criteria: NR	Sertraline - 100-200 mg/day fixed titration schedule Ziprasidone - 80 or 160 mg/day fixed titration schedule, Sertraline - 100-200 mg/day fixed titration schedule Duration: 2.0 months	6 wk of Sertraline for non-placebo responders None	Not reported	Assessed at baseline and 8 weeks: MADRS, HAM_D_HDRS, CGI	44 / NR 48% male NR
OCD and Depression Quetiapine (Carey PD et al., 2005) Canada, South Africa ISRCTN83050762	Design: RCT Setting: Multi-center Jadad: 5	Inclusion criteria: Age 18-65, Y-BOCS < 25% improvement > 12 wks of SRI treatment at maximum tolerated dose, CGI-I minimal improvement, CGI = worse Exclusion criteria: Lactating, Sexually active females of child bearing age not using an effective contraceptive method, Medically significant disorders, Brain injury or head trauma, Co-existing Axis -I disorder unless deemed to be secondary to OCD, Brain Surgery, Seizure disorder or epilepsy or risk, Medications that interact with Quetiapine	Placebo - 228.57 mg/day average final dose, Fluvoxamine 100-300 mg/day flexible dose, Fluoxetine 20-300 mg/day flexible dose, Paroxetine 60-300 mg/day flexible dose, Citalopram 50-300 mg/day flexible dose Quetiapine - 168.75 mg/day average final dose, Fluvoxamine 25-300 mg/day flexible dose, Fluoxetine 20-300 mg/day flexible dose, Paroxetine 50-300 mg/day flexible dose, Citalopram 60-300 mg/day flexible dose, Clomipramine 100-300 mg/day flexible dose, Sert Duration: 1.5 months	6-12 wk of SSRIs for patients refractory to SRI None	Not reported	Assessed at baseline and 6 weeks: YBOCS, CGI, MADRS, SDS, Yale Global Tic	33 / NR 46% male NR

Condition, Drug Author, Year, Country, Trial named	**Study design Setting Quality (Jadad Score)**	**Eligibility criteria**	**Interventions (drug, dose, duration)**	**Run-in period/ Randomization Method Wash-out period/ Randomization Method**	**Allowed other medications**	**Method of outcome assessment Timing of assessment**	**Age mean/ Age range Gender Ethnicity**
OCD and Depression Quetiapine (Fineberg NA et al., 2005) UK	Design: RCT Setting: NR Jadad: 3	Inclusion criteria: Y-BOCS < 25% improvement > 12 wks of SRI treatment at maximum tolerated dose, Y-BOCS ≥ 18 Exclusion criteria: DSM-IV Axis I disorder, not including primary condition studied, DSM-IV Axis I disorder, not including primary condition studied or depression with MADRS < 30, Tourettes disorder, Resistant to antipsychotic treatment	Placebo - dosage not reported, Paroxetine 40-60 mg/day flexible dose, Citalopram 60-80 mg/day flexible dose, Sertraline 200 mg/day average final dose Quetiapine - 215 mg/day average final dose, Paroxetine 60 mg/day average final dose, Sertraline 75-200 mg/day flexible dose Duration: 4.0 months	None None	Not reported	Assessed at baseline and 16 weeks: YBOCS, Yale Global Tic, CGI, MADRS, NIMH-OC, Extrapyramidel side effects, SDS	38 / NR 43% male NR

Condition, Drug Author, Year, Country, Trial named	Study design Setting Quality (Jadad Score)	Eligibility criteria	Interventions (drug, dose, duration)	Run-in period/ Randomization Method Wash-out period/ Randomization Method	Allowed other medications	Method of outcome assessment Timing of assessment	Age mean/ Age range Gender Ethnicity
OCD and Depression Risperidone (Li X et al., 2005) US	Design: CCT, Crossover Setting: Single center Jadad: 2	Inclusion criteria: Y-BOCS ≥ 10 on items 1-5, Y-BOCS ≥ 16 Exclusion criteria: DSM-IV Axis I disorder, not including primary condition studied, SADS-L (Schedule for Affective Disorders and Schizophrenia - Lifetime version) Criteria, Major motor disorder, Vocal tics	Placebo - dosage not reported, Fluoxetine or Paroxitine = 40/mg/day, Fluvoxamine = 200 mg/day, or Sertraline = 100mg/day - therapeutic doses for at least 12 weeks Haloperidol - 2 mg/day fixed single dose, Fluoxetine or Paroxitine = 40/mg/day, Fluvoxamine = 200 mg/day, or Sertraline = 100mg/day - therapeutic doses for at least 12 weeks Risperidone - 1 mg/day fixed single dose, Fluoxetine or Paroxitine = 40/mg/day, Fluvoxamine = 200 mg/day, or Sertraline = 100mg/day - therapeutic doses for at leas Duration: 2.3 months	1 wk of placebo for randomization not described 1 wk of placebo for randomization not described	Antihistamine, Benztropine	Assessed at baseline and 2 weeks: YBOCS, SCL_90, HAM_D_HDRS, POMS, SNST, HVLT-R, CPT	34 / 19-56 44% male NR

Condition, Drug Author, Year, Country, Trial named	Screened/Eligible/ Enrolled	Withdrawn/Lost to FU/ Analyzed	Results	Methods of adverse events assessment
Depression Olanzapine (Tohen M et al., 2002) US & Canada	501/344/344	94/8/334	Outcome of interested for statistical analysis not reported.	Monitored
Depression Quetiapine (Yargic LI et al., 2004) Turkey	NR/120/NR	17/NR/84	Depression_mood-Change in HAM-D at 8 weeks: Paroxetine vs Paroxetine + quetiapine-SMD = -0.223 (-0.595,0.149)	Elicited by investigator, reported by patient
OCD Quetiapine (Atmaca M et al., 2002) Turkey	52/27/27	0/0/27	OCD-Change in Y-BOCS at 8 weeks: SRI + placebo vs SRI + quetiapine-WMD = -8(-10.876, -5.124) OCD-Change in Number of Responders at 8 weeks: SRI + placebo vs SRI + quetiapine-RR = 19.6(1.263115, 304.1371) OCD_severity-Change in CGI-S at 8 weeks: SRI + placebo vs SRI + quetiapine-WMD = -1.34 (-2.209,-0.471)	Monitored, reported by patient

Condition, Drug Author, Year, Country, Trial named	Screened/Eligible/ Enrolled	Withdrawn/Lost to FU/ Analyzed	Results	Methods of adverse events assessment
OCD Quetiapine (Denys D et al., 2004) Western Europe	NR/40/40	1/0/40	OCD-Change in Y-BOCS at 8 weeks: SRI + placebo vs SRI + quetiapine-WMD = -5.4 (-9.342,-1.458) OCD-Change in Number of Responders at 8 weeks: SRI + placebo vs SRI + quetiapine-RR = 4(0.9,16.5) OCD_improvement-Change in CGI-I at 8 weeks: SRI + placebo vs SRI + quetiapine-WMD = -0.85 (-1.411,-0.289)	Elicited by investigator, reported by patient, clinical observation and exam

Condition, Drug Author, Year, Country, Trial named	Screened/Eligible/ Enrolled	Withdrawn/Lost to FU/ Analyzed	Results	Methods of adverse events assessment
OCD Risperidone (Cavedini P et al., 2004) Western Europe	NR/30/30	NR/NR/NR	OCD-Change in Y-BOCS at 12 weeks: Fluvoxamine + placebo (good IGT+) vs Fluvoxamine + risperidone (bad IGT)- WMD = -0.4 (-6.305,5.505) OCD-Change in Y-BOCS at 12 weeks: Fluvoxamine + placebo (bad IGT+) vs Fluvoxamine + risperidone (bad IGT)- WMD = -7.9 (-14.842,-0.958) OCD – Change in severity Fluv + placebo (good IGT) vs. Fluv + risperidone (bad IGT): RR=0.889, (0.612, 1.290) Fluv + placebo (bad IGT) vs. Fluv + risperidone (bad IGT): RR=8.0, (1.214, 52.692)	NR

Condition, Drug Author, Year, Country, Trial named	Screened/Eligible/ Enrolled	Withdrawn/Lost to FU/ Analyzed	Results	Methods of adverse events assessment
OCD Risperidone (McDougle CJ et al., 2000) US	70/36/36	3/0/33	OCD-Change in Y-BOCS at 6 weeks: Placebo + SRI vs Risperidone + SRI-WMD = -6.29 (-10.777,-1.803) OCD-Change in Number of Responders at 6 weeks: Placebo + SRI vs Risperidone + SRI-RR = 16(1.0,254.1) OCD_improvement-Change in CGI-I at 6 weeks: Placebo + SRI vs Risperidone + SRI-WMD = -0.8 (-2.065,0.465)	Monitored
OCD and Tourettes Olanzapine (Shapira NA et al., 2004) US	74/44/44	4/3/1944	OCD-Change in Y-BOCS at 6 weeks: Fluoxetine + placebo vs Fluoxetine + olanzapine-WMD = -1.9(-5.033,1.233) OCD-Change in Number of Responders at 6 weeks: Fluoxetine + placebo vs Fluoxetine + olanzapine-RR = 1(0.5,2.0)	NR

Condition, Drug Author, Year, Country, Trial named	Screened/Eligible/ Enrolled	Withdrawn/Lost to FU/ Analyzed	Results	Methods of adverse events assessment
Depression Ziprasidone (Dunner D et al., 2003) US	90/64/64	NR/NR/60	Depression_improvement-Change in CGI-I at 8 weeks: Sertraline vs Sertraline + Ziprasidone-WMD = -0.625(-1.006,-0.244) Depression_mood-Change in MADRS at 8 weeks: Sertraline vs Sertraline + Ziprasidone-SMD = -0.444(-0.807,-0.082) Depression_severity-Change in CGI-S at 8 weeks: Sertraline vs Sertraline + Ziprasidone-WMD = -0.62(-0.988,-0.252)	Monitored

Condition, Drug Author, Year, Country, Trial named	Screened/Eligible/ Enrolled	Withdrawn/Lost to FU/ Analyzed	Results	Methods of adverse events assessment
OCD and Depression Quetiapine (Carey PD et al., 2005) Canada, South Africa ISRCTN83050762	NR/42/42	2/0/41	Depression_mood-Change in MADRS at 6 weeks: Placebo vs Quetiapine-SMD = 0.71(0.077,1.342) Depression_severity-Change in CGI-S at 6 weeks: Placebo vs Quetiapine-WMD = -3.61(-6.968,-0.252) OCD-Change in Y-BOCs at 6 weeks: Placebo vs Quetiapine-SMD = -0.146(-0.759,0.467) OCD-Change in Number of Responders at 6 weeks: Placebo vs Quetiapine-RR = 1.28(0.609,2.691)	Monitored

Condition, Drug Author, Year, Country, Trial named	Screened/Eligible/ Enrolled	Withdrawn/Lost to FU/ Analyzed	Results	Methods of adverse events assessment
OCD and Depression Quetiapine (Fineberg NA et al., 2005) UK	NR/21/21	4/0/21	Depression_mood-Change in MADRS at 16 weeks: Placebo vs Quetiapine-SMD = -1.06(-1.98,-0.14) Depression_severity-Change in CGI-S at 16 weeks: Placebo vs Quetiapine-WMD = -0.4(-1.302,0.502) OCD-Change in Y-BOCs at 16 weeks: Placebo vs Quetiapine-SMD = 0.615(-0.264,1.493) OCD-Change in Number of Responders at 16 weeks: Placebo vs Quetiapine-RR = 2.727(0.336,22.158)	Monitored
OCD and Depression Risperidone (Li X et al., 2005) US	27/16/16	NR/NR/NR	OCD Crossover study.	Monitored

Condition, Drug **Author, Year, Country, Trial named**	**Adverse events reported**	**Total withdrawals** **Withdrawals due to adverse events**
Depression Olanzapine (Tohen M et al., 2002) US & Canada	Lithium or valproate vs Olanzapine + (lithium or valproate): Asthenia: 13.0%(14.95/115) vs 18.3%(41.907/229) Depression: 17.4%(20.01/115) vs 17.9%(40.991/229) Diarrhea: 14.8%(17.02/115) vs 11.8%(27.022/229) Dizziness: 7.0%(8.05/115) vs 13.5%(30.915/229) Dry mouth: 7.8%(8.97/115) vs 31.9%(73.051/229) Headache: 18.3%(21.045/115) vs 15.7%(35.953/229) Increased appetite: 7.8%(8.97/115) vs 23.6%(54.044/229) Nervousness: 14.8%(17.02/115) vs 10.5%(24.045/229) Somnolence: 27.0%(31.05/115) vs 51.5%(117.935/229) Speech disorder: 0.9%(1.035/115) vs 6.6%(15.114/229) Thirst: 6.1%(7.015/115) vs 10.0%(22.9/229) Tremor: 13.0%(14.95/115) vs 23.1%(52.899/229) Weight gain: 7.0%(8.05/115) vs 26.2%(59.998/229) Weight change in kg: Monotherapy, Full Sample-115 people (0.23 mean,2.48 SD) vs Monotherapy, Lithium-41 people (Mean NR , SD NR) vs Monotherapy, Valproate-73 people (Mean NR , SD NR) vs Olanzapine Cotherapy, Full Sample-229 people (3.08 mean,3.04 SD) vs Olanzapine Cotherapy, Lithium-74 people (Mean NR , SD NR) vs Olanzapine Cotherapy, Valproate-145 people (Mean NR , SD NR)	Lithium or valproate vs Olanzapine + (lithium or valproate): Withdrawals: 28.7%(33/115) vs 30.1%(69/229) Withdrawals due to adverse events: 1.7%(2/115) vs 10.9%(25/229)
Depression Quetiapine (Yargic LI et al., 2004) Turkey	Paroxetine + quetiapine vs Paroxetine: Increased anxiety: 2.0%(1.16/58) vs 13.3%(7.182/54) Increased appetite: 20.4%(11.832/58) vs 2.4%(1.296/54) Insomnia: 0.0%(0/58) vs 31.0%(16.74/54)	Paroxetine + quetiapine vs Paroxetine: Withdrawals: 19.0%(11/58) vs 31.5%(17/54) Withdrawals due to adverse events: 3.4%(2/58) vs 16.7%(9/54)
OCD Quetiapine (Atmaca M et al., 2002) Turkey	SRI + placebo vs SRI + quetiapine: At least one adverse event: 30.8%(4/13) vs 64.3%(9/14) Dizziness: 0.0%(0/13) vs 7.1%(1/14) Headache: 7.7%(1/13) vs 0.0%(0/14) Nausea: 0.0%(0/13) vs 42.9%(6/14) Nervousness: 7.7%(1/13) vs 0.0%(0/14) Sedation: 15.4%(2/13) vs 21.4%(3/14) Weight change in kg: SRI + Placebo-13 people (1.6 mean,1.3 SD) vs SRI + Quetiapine-14 people (1.9 mean,1.8 SD)	SRI + placebo vs SRI + quetiapine: Withdrawals: 0.0%(0/13) vs 0.0%(0/14) Withdrawals due to adverse events: 0.0%(0/13) vs 0.0%(0/14)

Condition, Drug **Author, Year, Country, Trial named**	**Adverse events reported**	**Total withdrawals** **Withdrawals due to adverse events**
OCD Quetiapine (Denys D et al., 2004) Western Europe	SRI + placebo vs SRI + quetiapine: At least 2 or 3 adverse events: 100.0%(20/20) vs 100.0%(20/20) Asthenia: 0.0%(0/20) vs 10.0%(2/20) Change in mood: 15.0%(3/20) vs 10.0%(2/20) Diarrhea: 10.0%(2/20) vs 0.0%(0/20) Dizziness: 0.0%(0/20) vs 30.0%(6/20) Dry mouth: 40.0%(8/20) vs 55.0%(11/20) Increased appetite: 0.0%(0/20) vs 20.0%(4/20) Muscular pain: 0.0%(0/20) vs 10.0%(2/20) Nightmares: 0.0%(0/20) vs 10.0%(2/20) Palpitations: 10.0%(2/20) vs 0.0%(0/20) Problems with concentration: 0.0%(0/20) vs 15.0%(3/20) Somnolence: 35.0%(7/20) vs 95.0%(19/20) Sweating: 30.0%(6/20) vs 10.0%(2/20) Weight gain: 0.0%(0/20) vs 30.0%(6/20)	SRI + placebo vs SRI + quetiapine: Withdrawals: 0.0%(0/20) vs 5.0%(1/20) Withdrawals due to adverse events: 0.0%(0/20) vs 0.0%(0/20)
OCD Risperidone (Cavedini P et al., 2004) Western Europe	No adverse events reported.	Fluvoxamine + Placebo vs Fluvoxamine + Placebo vs Fluvoxamine + Risperidone: Withdrawals: Not reported Withdrawals due to adverse events: Not reported
OCD Risperidone (McDougle CJ et al., 2000) US	Placebo + SRI vs Risperidone + SRI: At least one adverse event: 100.0%(15/16) vs 90.0%(18/20) Blurred vision: 12.5%(2/16) vs 0.0%(0/20) Constipation: 0.0%(0/16) vs 5.0%(1/20) Diaphoresis: 25.0%(4/16) vs 5.0%(1/20) Diarrhea: 6.3%(1/16) vs 0.0%(0/20) Dry mouth: 31.3%(5/16) vs 25.0%(5/20) Headache: 31.3%(5/16) vs 0.0%(0/20) Increased appetite: 18.8%(3/16) vs 30.0%(6/20) Insomnia: 6.3%(1/16) vs 5.0%(1/20) Lightheadedness: 25.0%(4/16) vs 5.0%(1/20) Muscle stiffness: 6.3%(1/16) vs 0.0%(0/20) Palpitations: 6.3%(1/16) vs 0.0%(0/20) Restlessness: 37.5%(6/16) vs 30.0%(6/20) Sedation: 50.0%(8/16) vs 85.0%(17/20) Tinnitus: 6.3%(1/16) vs 10.0%(2/20) Urinary urgency: 0.0%(0/16) vs 5.0%(1/20)	Placebo + SRI vs Risperidone + SRI: Withdrawals: 6.3%(1/16) vs 10.0%(2/20) Withdrawals due to adverse events: 0.0%(0/16) vs 5.0%(1/20)

Condition, Drug **Author, Year, Country, Trial named**	**Adverse events reported**	**Total withdrawals** **Withdrawals due to adverse events**
OCD and Tourettes Olanzapine (Shapira NA et al., 2004) US	No adverse events reported. Weight change in kg: Fluoxetine + placebo-22 people (0.5 mean,1.8 SD) vs Fluoxetine + Olanzapine-22 people (2.8 mean,3.1 SD)	Fluoxetine + Placebo vs Fluoxetine + Olanzapine: Withdrawals: 9.1%(2/22) vs 22.7%(5/22) Withdrawals due to adverse events: 9.1%(2/22) vs 9.1%(2/22)
Depression Ziprasidone (Dunner D et al., 2003) US	Sertraline vs Ziprasidone: Abnormal ejaculation: 5.0%(1/21) vs 0.0%(0/43) Abnormal thinking: 0.0%(0/21) vs 9.3%(4/43) Abnormal vision: 0.0%(0/21) vs 11.6%(5/43) Agitation: 0.0%(0/21) vs 20.9%(9/43) Anxiety: 10.0%(2/21) vs 0.0%(0/43) Asthenia: 0.0%(0/21) vs 20.9%(9/43) Back pain: 0.0%(0/21) vs 4.7%(2/43) Constipation: 0.0%(0/21) vs 9.3%(4/43) Dizziness: 0.0%(0/21) vs 18.6%(8/43) Dry Mouth: 0.0%(0/21) vs 14.0%(6/43) Headache: 5.0%(1/21) vs 16.3%(7/43) Insomnia: 5.0%(1/21) vs 30.2%(13/43) Nausea: 0.0%(0/21) vs 11.6%(5/43) Neck pain: 0.0%(0/21) vs 4.7%(2/43) Respiratory tract infection: 0.0%(0/21) vs 11.6%(5/43) Somnolence: 10.0%(2/21) vs 18.6%(8/43) Tooth disorder: 0.0%(0/21) vs 7.0%(3/43) Tremor: 5.0%(1/21) vs 16.3%(7/43)	Sertraline vs Ziprasidone: Withdrawals: (NR/21) vs (NR/43) Withdrawals due to adverse events: (NR/21) vs (NR/43)
OCD and Depression Quetiapine (Carey PD et al., 2005) Canada, South Africa ISRCTN83050762	Placebo vs Quetiapine: Abdominal tenderness: 0.0%(0/21) vs 5.0%(1/21) Delayed ejaculation: 0.0%(0/21) vs 5.0%(1/21) Dizziness: 14.3%(3/21) vs 5.0%(1/21) Dry Mouth: 0.0%(0/21) vs 15.0%(3/21) Fatigue: 19.0%(4/21) vs 15.0%(3/21) Headache: 38.0%(8/21) vs 15.0%(3/21) Impared concentration: 0.0%(0/21) vs 10.0%(2/21) Increased appetite: 9.5%(2/21) vs 5.0%(1/21) Irritability: 4.7%(1/21) vs 10.0%(2/21) Memory difficulties: 0.0%(0/21) vs 5.0%(1/21) Muscle aches: 0.0%(0/21) vs 5.0%(1/21) Nausea: 9.5%(2/21) vs 5.0%(1/21) Sedation: 33.3%(7/21) vs 75.0%(15/21) Slurred speech: 0.0%(0/21) vs 5.0%(1/21) Weight gain: 0.0%(0/21) vs 5.0%(1/21) Worsening mood: 4.7%(1/21) vs 5.0%(1/21)	Placebo vs Quetiapine: Withdrawals: 0.0%(0/21) vs 9.5%(2/21) Withdrawals due to adverse events: 0.0%(0/21) vs 9.5%(2/21)

Condition, Drug **Author, Year, Country, Trial named**	**Adverse events reported**	**Total withdrawals** **Withdrawals due to adverse events**
OCD and Depression Quetiapine (Fineberg NA et al., 2005) UK	Placebo vs Quetiapine: Drowsiness: (NR/10) vs 72.7%(8/11) Dry Mouth: (NR/10) vs 54.5%(6/11) Fatigue: (NR/10) vs 9.1%(1/11) Headache: (NR/10) vs 54.5%(6/11) Restless limbs: (NR/10) vs 36.4%(4/11) Stiffness: (NR/10) vs 45.5%(5/11)	Placebo vs Quetiapine: Withdrawals: 10.0%(1/10) vs 27.3%(3/11) Withdrawals due to adverse events: 0.0%(0/10) vs 9.1%(1/11)
OCD and Depression Risperidone (Li X et al., 2005) US	Adverse events not reported before crossover.	Placebo vs Placebo vs Haloperidol vs Haloperidol vs Risperidone vs Risperidone: Withdrawals: (NR/6) vs (NR/6) vs (NR/5) vs (NR/5) vs (NR/5) vs (NR/5) Withdrawals due to adverse events: (NR/6) vs (NR/6) vs (NR/5) vs (NR/5) vs (NR/5) vs (NR/5)

Acronyms in Evidence Table:

CCT	Clinical control trial
kg	kilograms
lbs	pounds
ND	Not described
NOS	Not otherwise specified
NR	Not reported
RCT	Randomized control trial
RR	Risk ratio
SMD	Standard mean difference
WMD	Weighted mean difference

Outcomes:

ABC	Aberrant Behavior Checklist
ACES	Agitation-Calmness Evaluation Scale
ADAS-cog	Alzheimer's Disease Assessment Scale
ADHDRS	DuPaul Attention Deficit Hyperactivity Scale
ADL	Activities of Daily Life
AIAQ	Anger, Irritability, and Assault Questionnaire
ASI	Addiction Severity Index
BABS	Brown Assessment of Beliefs Scale
BAI	Beck Anxiety Index
BDHI	Buss-Durkee Hostility Index
BDI	Beck Depression Index
BDS	Blessed Dementia Scale
BEHAVE-AD	Behavioral Pathology in Alzheimer's Disease Rating Scale
BPRS	Brief Psychiatric Rating Scale
BRMES	Bech-Rafaelsen Melancholia Scale
CAPS	Clinician Administered PTSD Scale
CDSS	Calgary Depression Scale for Schizophrenia
CES-D	Center for Epidemiologic Studies Depression Scale
CGI	Clinical Global Impression Scale
CMAI	Cohen-Mansfield Agitation Inventory
CM-PNB	Cohen-Mansfield Physically Non-Aggressive Behavior
CPRS	Children's Psychiatric Rating Scale
CSDD	Cornell Scale for Depression in Dementia
CY-BOCS	Children's Yale-Brown Obsessive-Compulsive Scale
DCM	Dementia Care Mapping
DES	Dissociative Experiences Scale
DTS	Davidson Trauma Scale
E-BEHAVE-AD	Empirical Behavioral Pathology in Alzheimer's Disease Rating Scale
FAST	Functional Assessment Staging Rating Scale
GAF	Global Assessment of Functioning Scale
HAM-A	Hamilton Rating Scale for Anxiety
HAM-D/HDRS	Hamilton Rating Scale for Depression
IGT	Iowa Gambling Task
MADRS	Montgomery-Asberg Depression Rating Scale
MDRS	Mattis Dementia Rating Scale
MMSE	Mini-Mental State Examination
M-NCAS	Modified Strain in Nursing Care Assessment

MOSES	Multidimentional Observational Scale for Elderly Subjects
MOVES	Motor Tic, Obsessions, and Compulsions, Vocal Tic Evaluation Survey
N-CBRF	Nisonger Child Behavior Rating Scale
NIMH-OC	National Institute of Mental Health Obsessive-Compulsive Scale
NPI	Neuropsychiatric Inventory
NPI/NH	Neuropsychiatric Inventory/Nursing Home
NPI-Q	Neuropsychiatric Inventory Questionnaire
OAS-M	Overt Aggression Scale-Modified
PANSS	Positive and Negative Symptom Scale
PCL-M	Patient Checklist for PTSD--Military Version
PDC	Depression cluster
PDS	Progressive Deterioration Scale
PGDRS	Psychogeriatric Dependency Rating Scale
PGI	Patient Global Impressions
QLDS	Quality of Life in Depression Scale
Q-LES-Q	Quality of Life Enjoyment and Satisfaction Questionnaire
QLS	Quality of Life Scales
QUALID	Quality of Life in Late-Stage Dementia Scale
ROAS	Retrospective Overt Aggression Scale
SANS	Scale for the Assessment of Negative Symptoms
SCL-90	Symptom Checklist-90
SDS	Sheehan Disability Scale
SF-36	Medical Outcomes Study 36-Item Short-Form Health Survey
SIB	Severe Impairment Battery
SIB-Q	Self-injurious Behavior Questionnaire
SIP	Structured Interview for PTSD
SPQ	Schizotypal Personality Questionnaire
SPRINT	Short PTSD Rating Interview
STAS-AX	State-Trait Anger Expression Inventory
STAT-S	Spielberger State-Trait Anger Scale, state version
STAT-T	Spielberger State-Trait Anger Scale, trait version
TOP-8	Treatment Outcome PTSD Scale
TSSS	Tourette's Syndrome Severity Scale
VAS	Visual Analog Scale
Y-BOCS	Yale-Brown Obsessive-Compulsive Scale
YGTSS	Yale Global Tic Severity Scale
YMRS	Young Mania Rating Scale

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C5: Quality Tables – Head to Head Trials

Study	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?	Attrition, crossovers, adherence, contamination	Loss to follow-up: differential/high
(Fontaine CS et al., 2003)	Method NR	Method NR	Yes	Yes	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Herz LR et al., 2002)	Yes	Yes	NR	Yes	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Mullen J et al., 2001)	Method NR	Method NR	Yes	Yes	No	No	No	Yes/NR /NR /NR	No
(Deberdt WG et al., 2005)	Method NR	Method NR	Yes	Yes	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Levitt A et al., 2004)	Method NR	Method NR	Yes	Yes	Yes, but not described	Yes, but not described	Yes, but not described	NR /NR /NR /NR	NR
(Mulsant BH et al., 2004)	Method NR	Method NR	Yes	Yes	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Tollefson GD et al., 1999)	Method NR	Method NR	Yes	Yes	Yes, but not described	Yes, but not described	Yes, but not described	Yes/NR /Yes/NR	No
(Kinon BJ et al., 2005)	Method NR	Method NR	Yes	Yes	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Simpson GM et al., 2004)	Method NR	Method NR	Yes	Yes	NR	Yes	Yes	Yes/NR /NR /NR	NR

Study	Intention-to-treat analysis	Post-randomization exclusions	Quality rating (Jadad score)	Number screened/Eligible/ Enrolled	Exclusion criteria
(Fontaine CS et al., 2003)	Yes	No	3	NR/47/39	Neuroleptic malignant syndrome, Atypical antipsychotics sensitivity, Major depressive disorder, Schizophrenia, Bipolar disorder, Antihypertensive drug treatment, Antibiotic treatment, Antiparkinsonian drug treatment
(Herz LR et al., 2002)	Yes	No	3	NR/29/29	NR
(Mullen J et al., 2001)	No	No	1	NR/728/728	Under 18 years old, Medically significant disorders, Clozapine treatment, Clozapine unresponsiveness, Previous drug-induced agranulocytosis, Pregnant, Lactating, Participation in previous quetiapine trial, Participation in previous clinical trial within 4 months, Risperidone treatment within 4 months
(Deberdt WG et al., 2005)	Yes	No	2	NR/494/494	Frontotemporal dementia, Lewy body dementia, MMSE > 24, Parkinsons disease, Picks disease
(Levitt A et al., 2004)	Yes	No	3	NR/43/43	Suicidal, current Axis 1 DSM IV diagnosis other than anxiety disorder, substance abuse in past 3 months, pregnant, lactating or certain other medications
(Mulsant BH et al., 2004)	Yes	No	2	NR/86/86	Psychosis before dementia onset, Delirium, Inability to swallow oral medication or unable to cooperate with study
(Tollefson GD et al., 1999)	No	No	2	NR/339/339	NR
(Kinon BJ et al., 2005)	No	No	2	NR/394/NR	Previous sensitivity or unresponsiveness to stuffy drug
(Simpson GM et al., 2004)	Yes	No	4	367/269/269	Pregnant, Hospitalized ≥ 2 wks, Abnormal laboratory results, DSM-IV Axis I disorder, not including primary condition studied, Depot neuroleptic within 1 treatment cycle, Resistant to antipsychotic treatment, Suicidal or violent, Olanzapine > 14 days life time exposure or olanzapine daily dose >10 m

Study	Run-in/Randomization Method Washout/Randomization Method	Class naïve patients only	Control group standard of care	Funding	Relevance
(Fontaine CS et al., 2003)	NR Washout period reported	No	Yes	Source: Industry Role: described	Yes
(Herz LR et al., 2002)	NR NR	NR	No - Placebo	Source: NR Role: NR	Yes
(Mullen J et al., 2001)	NR NR	No	Yes	Source: Industry Role: NR	Yes
(Deberdt WG et al., 2005)	NR Washout period reported	NR	Yes	Source: Industry Role: NR	Yes
(Levitt A et al., 2004)	NR NR	NR	Yes	Source: Industry Role: NR	Yes
(Mulsant BH et al., 2004)	Run-in period reported Washout period reported	NR	Yes	Source: Industry Role: described	Yes
(Tollefson GD et al., 1999)	NR NR	NR	Yes	Source: Industry Role: NR	Yes
(Kinon BJ et al., 2005)	NR NR	NR	Yes	Source: Industry Role: NR	Yes
(Simpson GM et al., 2004)	NR Washout period reported	NR	Yes	Source: Industry Role: NR	Yes

Acronyms in Evidence Table:

CCT	Clinical control trial
kg	kilograms
lbs	pounds
ND	Not described
NOS	Not otherwise specified
NR	Not reported
RCT	Randomized control trial
RR	Risk ratio
SMD	Standard mean difference
WMD	Weighted mean difference

Outcomes:

ABC	Aberrant Behavior Checklist
ACES	Agitation-Calmness Evaluation Scale
ADAS-cog	Alzheimer's Disease Assessment Scale
ADHDRS	DuPaul Attention Deficit Hyperactivity Scale
ADL	Activities of Daily Life
AIAQ	Anger, Irritability, and Assault Questionnaire
ASI	Addiction Severity Index
BABS	Brown Assessment of Beliefs Scale
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HAM-D/HDRS	Hamilton Rating Scale for Depression
IGT	Iowa Gambling Task
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MMSE	Mini-Mental State Examination
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MOSES	Multidimentional Observational Scale for Elderly Subjects
MOVES	Motor Tic, Obsessions, and Compulsions, Vocal Tic Evaluation Survey
N-CBRF	Nisonger Child Behavior Rating Scale
NIMH-OC	National Institute of Mental Health Obsessive-Compulsive Scale
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NPI-Q	Neuropsychiatric Inventory Questionnaire
OAS-M	Overt Aggression Scale-Modified
PANSS	Positive and Negative Symptom Scale
PCL-M	Patient Checklist for PTSD--Military Version
PDC	Depression cluster
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PGDRS	Psychogeriatric Dependency Rating Scale
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TOP-8	Treatment Outcome PTSD Scale
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VAS	Visual Analog Scale
Y-BOCS	Yale-Brown Obsessive-Compulsive Scale
YGTSS	Yale Global Tic Severity Scale
YMRS	Young Mania Rating Scale

References

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C6: Quality Tables - Active Control Trials

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?
(Malone RP et al., 2001)	Yes	Method NR	Yes	Yes	No
(Meehan KM et al., 2002)	Method NR	Method NR	Yes	Yes	NR
(Ballard C et al., 2005)	Yes	Yes	Yes	Yes	Yes
(Chan WC et al., 2001)	Method NR	Method NR	Yes	Yes	NR
(De Deyn PP et al., 1999)	Yes	Yes	Yes	Yes	NR
(Suh GH et al., 2004)	Method NR	Yes	Yes	Yes	NR
(David S JBAKWP, 2002)	Method NR	Method NR	NR	NR	NR
(McEvoy J et al.,)	Method NR	Method NR	Yes	Yes	NR
(Shelton RC et al., 2001)	Method NR	Method NR	NR	Yes	Yes, but not described
(Street JS et al., 2000)	Not randomized	Not randomized	NR	Yes	NR
(Svestka J SO, 2000)	Method NR	Method NR	NR	Yes	NR
(Tohen M et al., 1999)	Method NR	Method NR	NR	Yes	NR
(Tohen M et al., 2002)	Method NR	Method NR	Yes	Yes	Yes
(Tohen M et al., 2005)	Method NR	Method NR	Yes	Yes	Yes
(Tollefson GD et al., 1997)	Yes	Method NR	Yes	Yes	NR
(Gareri P et al., 2004)	Method NR	Method NR	NR	Yes	Yes
(Altamura AC et al., 2003)	Method NR	Method NR	Yes	Yes	Yes
(Muller-Siecheneder F et al., 1998)	Method NR	Method NR	Yes	Yes	Yes, but not described
(Shelton RC et al., 2004)	Method NR	Method NR	Yes	Yes	NR

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?
(Weiser M et al., 2002)	Method NR	Method NR	Yes	Yes	No
(Zanarini MC et al., 2004)	Method NR	Method NR	Yes	Yes	Yes, but not described
(Bruggeman R et al., 2001)	Yes	Yes	Yes	Yes	NR
(Gaffney GR et al., 2002)	Method NR	Method NR	Yes	Yes	NR
(Kinon BJ et al., 2005)	Method NR	Method NR	Yes	Yes	Yes, but not described
(Kasper S et al., 2003)	Method NR	Method NR	Yes	Yes	NR
(Corya SA et al., 2005)	Method NR	Method NR	NR	Yes	NR
(Dunner DL et al., 2005)	Method NR	Method NR	Yes	Yes	NR
(Shelton RC et al., 2005)	Method NR	Method NR	Yes	Yes	NR
(Gilbert DL et al., 2004)	Yes	Yes	NR	Yes	NR

Author, Year	Care provider masked?	Patient masked?	Attrition, crossovers, adherence, contamination	Loss to follow-up: differential/high
(Malone RP et al., 2001)	No	No	Yes/NR /NR /NR	No
(Meehan KM et al., 2002)	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Ballard C et al., 2005)	Yes	Yes	Yes/NR /NR /NR	No
(Chan WC et al., 2001)	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(De Deyn PP et al., 1999)	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Suh GH et al., 2004)	Yes	Yes	Yes/NR /NR /NR	No
(David S JBAKWP, 2002)	No	No	NR /NR /NR /NR	NR
(McEvoy J et al.,)	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Shelton RC et al., 2001)	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Street JS et al., 2000)	NR	NR	NR /NR /NR /NR	NR
(Svestka J SO, 2000)	Yes, but not described	Yes, but not described	NR /NR /NR /NR	No
(Tohen M et al., 1999)	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Tohen M et al., 2002)	Yes	Yes	Yes/NR /NR /NR	No
(Tohen M et al., 2005)	Yes	Yes	Yes/NR /Yes/NR	No
(Tollefson GD et al., 1997)	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Gareri P et al., 2004)	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Altamura AC et al., 2003)	No	No	NR /NR /NR /NR	No
(Muller-Siecheneder F et al., 1998)	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Shelton RC et al., 2004)	Yes	Yes	Yes/NR /NR /NR	No
(Weiser M et al., 2002)	No	No	Yes/NR /NR /NR	NR

Author, Year	Care provider masked?	Patient masked?	Attrition, crossovers, adherence, contamination	Loss to follow-up: differential/high
(Zanarini MC et al., 2004)	NR	Yes, but not described	Yes/NR /NR /NR	No
(Bruggeman R et al., 2001)	Yes	Yes	Yes/NR /NR /NR	No
(Gaffney GR et al., 2002)	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Kinon BJ et al., 2005)	No	No	Yes/NR /Yes/NR	No
(Kasper S et al., 2003)	Yes, but not described	Yes, but not described	Yes/NR /Yes/NR	NR
(Corya SA et al., 2005)	Yes	Yes	Yes/NR /Yes/NR	No
(Dunner DL et al., 2005)	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	Yes
(Shelton RC et al., 2005)	Yes	Yes	Yes/NR /Yes/NR	No
(Gilbert DL et al., 2004)	Yes, but not described	Yes, but not described	Yes/Yes/NR /NR	No

Author, Year	Intention-to-treat analysis	Post-randomization exclusions	Quality rating (Jadad score)	Number screened/ Eligible/Enrolled	Exclusion criteria
(Malone RP et al., 2001)	Yes	No	3	NR/13/12	Medically significant disorders, Seizure disorder or epilepsy or risk, Neurological disorder, Psychotropic medications, Previous exposure to study drug
(Meehan KM et al., 2002)	No	No	2	331/272/272	Anticholinergic medications, Antipsychotic medications, Benzodiazepines, Neurological conditions, excluding Alzheimers or vascular dementia, contributing to psychosis or dementia, Abnormal laboratory results, Suicidal or violent
(Ballard C et al., 2005)	Yes	No	4	282/93/93	Antipsychotics treatment≥4 wks, Cholinesterase treatment≥4 wks, Previous sensitivity or unresponsiveness to stuffy drug, Severe internal or neurological disease, Medically significant disorders
(Chan WC et al., 2001)	Yes	No	3	NR/58/58	Lewy body dementia, Neurological or medical conditions diminishing cognitive function, Psychosis/psychotic features, Medically significant disorders, Abnormal laboratory results, Allergic or toxic reactions to psychotropic medications, Neuroleptic malignant syndrome
(De Deyn PP et al., 1999)	No	No	4	371/344/344	Neurological or medical conditions diminishing cognitive function, Other psychiatric disorders, Severe internal or neurological disease, Abnormal laboratory results, Depot neuroleptic within 1 treatment cycle, Allergic or toxic reactions to psychotropic medication, Participation in a clinical trial with investigational drugs during the 4 weeks preceding this trial, Other psychotropics, psychotropic herbs, history of non-affective disorder.

Author, Year	Intention-to-treat analysis	Post-randomization exclusions	Quality rating (Jadad score)	Number screened/ Eligible/Enrolled	Exclusion criteria
(Suh GH et al., 2004)	Yes	No	4	280/120/120	Neurological or medical conditions diminishing cognitive function, Psychotic disorder, Severe internal or neurological disease, Medically significant disorders, Abnormal laboratory results, Allergic or toxic reactions to antipsychotic medications, Neuroleptic malignant syndrome
(David S JBAKWP, 2002)	No	Unable to determine	2	NR/1054/NR	NR
(McEvoy J et al.,)	Yes	No	2	NR/263/263	Pregnant, Clozapine treatment, Antipsychotic treatment > 16 wks in a lifetime, Lactating, Medically significant disorders, Previous sensitivity or unresponsiveness to stuffy drug, Alcohol or substance abuse or dependency, Suicidal or violent
(Shelton RC et al., 2001)	Yes	No	2	34/33/28	Psychosis/psychotic features, Dysthymic disorder, Bipolar disorder
(Street JS et al., 2000)	No	Unable to determine	1	NR/NR/NR	NR
(Svestka J SO, 2000)	Yes	No	3	NR/40/40	NR
(Tohen M et al., 1999)	No	No	2	NR/28/NR	NR
(Tohen M et al., 2002)	Yes	No	3	330/251/251	Medically significant disorders, Alcohol or substance abuse or dependency, Atypical antipsychotics sensitivity, Sensitivity to mood stabilizer, Treatment with lithium, anticonvulsant, or antipsychotic within 24 hrs
(Tohen M et al., 2005)	Yes	No	4	543/431/431	Medically significant disorders, Alcohol or substance abuse or dependency, Depot neuroleptic within 6 weeks, Suicidal or violent, Previous sensitivity or unresponsiveness to stuffy drug
(Tollefson GD et al., 1997)	Yes	No	5	2223/1996/1996	NR
(Gareri P et al., 2004)	Yes	No	3	NR/60/60	NR
(Altamura AC et al., 2003)	Yes	No	2	NR/28/28	Abnormal laboratory results, HIV dementia
(Muller-Siecheneder F et al., 1998)	Yes	No	4	NR/123/123	Suicidal or violent, Severe internal or neurological disease, Abnormal laboratory results, Allergic or toxic reactions to psychotropic medications, Participation in previous clinical trial within 4 months, Pregnant, Lactating

Author, Year	Intention-to-treat analysis	Post-randomization exclusions	Quality rating (Jadad score)	Number screened/ Eligible/Enrolled	Exclusion criteria
(Shelton RC et al., 2004)	Yes	No	4	NR/30/30	Current psychosis, Alcohol or substance abuse or dependency, Other psychotropics, psychotropic herbs, history of non-affective disorder
(Weiser M et al., 2002)	Yes	No	1	NR/90/85	NR
(Zanarini MC et al., 2004)	Yes	No	2	NR/45/45	Fluoxetine successful treatment, Olanzapine successful treatment, Medically significant disorders, Seizure disorder or epilepsy or risk, Psychotropic medications, Alcohol or substance abuse or dependency, Suicidal or violent, Major depressive disorder
(Bruggeman R et al., 2001)	Yes	Yes	5	NR/51/51	NR
(Gaffney GR et al., 2002)	Yes	No	3	24/21/21	Seizure disorder or epilepsy or risk, Neurological disorder, Pregnant, Abnormal laboratory results
(Kinon BJ et al., 2005)	Yes	No	2	NR/293/293	Tardive dyskinesia
(Kasper S et al., 2003)	Yes	No	2	NR/1294/1294	Pregnant, Lactating, Resistant to antipsychotic treatment, Suicidal or violent, Alcohol or substance abuse or dependency, Neurological disorder, Investigational drug use≥4 wks, Psychiatric disorder, not including primary conditioned studied
(Corya SA et al., 2005)	Yes	No	3	807/483/483	Bipolar disorder, Psychotic disorder, Schizophrenia, Schizoaffective disorder, PTSD, Major depressive disorder with seasonal pattern, Dissociative disorder
(Dunner DL et al., 2005)	Yes	No	2	NR/410/410	Suicidal or violent, Alcohol or substance abuse or dependency, Previous exposure to study drug, Previous failure or responded poorly to olanzapine, antidepressants or lamotrigine, Olanzapine + antidepressants treatment, Lamotrigine treatment, YMRS≥15
(Shelton RC et al., 2005)	Yes	No	3	946/500/500	BPRS positive item score≥3, Pregnant, Lactating, ECT treatment history or requiring during study

Author, Year	Intention-to-treat analysis	Post-randomization exclusions	Quality rating (Jadad score)	Number screened/ Eligible/Enrolled	Exclusion criteria
(Gilbert DL et al., 2004)	Yes	No	5	NR/19/19	Psychotic disorder, Alcohol or substance abuse or dependency, Pervasive developmental disorder, Eating disorders, Transient tic disorder, Medically significant disorders, Abnormal laboratory results, Sexually active females of child bearing age not using an effective contraceptive method

Author, Year	Run-in/Randomization Method Washout/Randomization Method	Class naïve patients only	Control group standard of care	Funding	Relevance
(Malone RP et al., 2001)	NR NR	NR	Yes	Source: Industry Role: described	Yes
(Meehan KM et al., 2002)	NR NR	NR	No - Placebo	Source: Industry Role: NR	Yes
(Ballard C et al., 2005)	NR NR	NR	No - Placebo	Source: Industry & Private Role: described	Yes
(Chan WC et al., 2001)	NR Washout period reported	No	Yes	Source: Industry Role: NR	Yes
(De Deyn PP et al., 1999)	NR Washout period reported	No	Yes	Source: Industry Role: NR	Yes
(Suh GH et al., 2004)	NR Washout period reported	NR	Yes	Source: Industry Role: described	Yes
(David S JBAKWP, 2002)	NR NR	NR	No - Placebo	Source: NR Role: NR	Yes
(McEvoy J et al.,)	NR Washout period reported	No	Yes	Source: Industry Role: NR	Yes
(Shelton RC et al., 2001)	NR NR	NR	No - Fluoxetine (for nonresponders)	Source: Government & Industry Role: NR	Yes
(Street JS et al., 2000)	NR NR	NR	NR	Source: Industry Role: NR	Yes
(Svestka J SO, 2000)	Run-in period reported NR	NR	No - Amitriptyline	Source: NR Role: NR	Yes
(Tohen M et al., 1999)	Run-in period reported NR	NR	NR	Source: NR Role: NR	Yes
(Tohen M et al., 2002)	NR NR	NR	Yes	Source: Industry Role: NR	Yes
(Tohen M et al., 2005)	NR Washout period reported	No	Yes	Source: Industry Role: NR	Yes
(Tollefson GD et al., 1997)	NR Washout period reported	No	Yes	Source: Industry Role: NR	Yes
(Gareri P et al., 2004)	NR Washout period reported	NR	Yes	Source: Government Role: NR	Yes
(Altamura AC et al., 2003)	NR NR	NR	Yes	Source: NR Role: NR	Yes
(Muller-Siecheneder F et al., 1998)	NR Washout period reported	No	Yes	Source: Industry Role: NR	Yes
(Shelton RC et al., 2004)	NR NR	NR	Yes	Source: Government & Industry Role: described	Yes
(Weiser M et al., 2002)	NR NR	NR	Yes	Source: Industry Role: NR	Yes
(Zanarini MC et al., 2004)	NR NR	NR	NR	Source: Industry Role: NR	Yes

Author, Year	Run-in/Randomization Method Washout/Randomization Method	Class naïve patients only	Control group standard of care	Funding	Relevance
(Bruggeman R et al., 2001)	NR Washout period reported	NR	Yes	Source: Industry Role: described	Yes
(Gaffney GR et al., 2002)	Run-in period reported Washout period reported	NR	Yes	Source: Industry & Private Role: NR	Yes
(Kinon BJ et al., 2005)	Run-in period reported NR	No	Yes	Source: Industry Role: NR	Yes
(Kasper S et al., 2003)	NR Washout period reported	No	Yes	Source: Industry Role: NR	Yes
(Corya SA et al., 2005)	Run-in period reported NR	No	Yes	Source: Industry Role: NR	Yes
(Dunner DL et al., 2005)	NR NR	NR	Yes	Source: Industry Role: NR	Yes
(Shelton RC et al., 2005)	Run-in period reported Washout period reported	No	Yes	Source: Industry Role: described	Yes
(Gilbert DL et al., 2004)	Run-in period reported Washout period reported	No	Yes	Source: Government & Industry Role: NR	Yes

Acronyms in Evidence Table:

CCT	Clinical control trial
kg	kilograms
lbs	pounds
ND	Not described
NOS	Not otherwise specified
NR	Not reported
RCT	Randomized control trial
RR	Risk ratio
SMD	Standard mean difference
WMD	Weighted mean difference

Outcomes:

ABC	Aberrant Behavior Checklist
ACES	Agitation-Calmness Evaluation Scale
ADAS-cog	Alzheimer's Disease Assessment Scale
ADHDRS	DuPaul Attention Deficit Hyperactivity Scale
ADL	Activities of Daily Life
AIAQ	Anger, Irritability, and Assault Questionnaire
ASI	Addiction Severity Index
BABS	Brown Assessment of Beliefs Scale
BAI	Beck Anxiety Index
BDHI	Buss-Durkee Hostility Index
BDI	Beck Depression Index
BDS	Blessed Dementia Scale
BEHAVE-AD	Behavioral Pathology in Alzheimer's Disease Rating Scale
BPRS	Brief Psychiatric Rating Scale
BRMES	Bech-Rafaelsen Melancholia Scale
CAPS	Clinician Administered PTSD Scale
CDSS	Calgary Depression Scale for Schizophrenia
CES-D	Center for Epidemiologic Studies Depression Scale
CGI	Clinical Global Impression Scale
CMAI	Cohen-Mansfield Agitation Inventory
CM-PNB	Cohen-Mansfield Physically Non-Aggressive Behavior
CPRS	Children's Psychiatric Rating Scale
CSDD	Cornell Scale for Depression in Dementia
CY-BOCS	Children's Yale-Brown Obsessive-Compulsive Scale
DCM	Dementia Care Mapping
DES	Dissociative Experiences Scale
DTS	Davidson Trauma Scale
E-BEHAVE-AD	Empirical Behavioral Pathology in Alzheimer's Disease Rating Scale
FAST	Functional Assessment Staging Rating Scale
GAF	Global Assessment of Functioning Scale
HAM-A	Hamilton Rating Scale for Anxiety
HAM-D/HDRS	Hamilton Rating Scale for Depression
IGT	Iowa Gambling Task
MADRS	Montgomery-Asberg Depression Rating Scale
MDRS	Mattis Dementia Rating Scale
MMSE	Mini-Mental State Examination
M-NCAS	Modified Strain in Nursing Care Assessment

MOSES	Multidimentional Observational Scale for Elderly Subjects
MOVES	Motor Tic, Obsessions, and Compulsions, Vocal Tic Evaluation Survey
N-CBRF	Nisonger Child Behavior Rating Scale
NIMH-OC	National Institute of Mental Health Obsessive-Compulsive Scale
NPI	Neuropsychiatric Inventory
NPI/NH	Neuropsychiatric Inventory/Nursing Home
NPI-Q	Neuropsychiatric Inventory Questionnaire
OAS-M	Overt Aggression Scale-Modified
PANSS	Positive and Negative Symptom Scale
PCL-M	Patient Checklist for PTSD--Military Version
PDC	Depression cluster
PDS	Progressive Deterioration Scale
PGDRS	Psychogeriatric Dependency Rating Scale
PGI	Patient Global Impressions
QLDS	Quality of Life in Depression Scale
Q-LES-Q	Quality of Life Enjoyment and Satisfaction Questionnaire
QLS	Quality of Life Scales
QUALID	Quality of Life in Late-Stage Dementia Scale
ROAS	Retrospective Overt Aggression Scale
SANS	Scale for the Assessment of Negative Symptoms
SCL-90	Symptom Checklist-90
SDS	Sheehan Disability Scale
SF-36	Medical Outcomes Study 36-Item Short-Form Health Survey
SIB	Severe Impairment Battery
SIB-Q	Self-injurious Behavior Questionnaire
SIP	Structured Interview for PTSD
SPQ	Schizotypal Personality Questionnaire
SPRINT	Short PTSD Rating Interview
STAS-AX	State-Trait Anger Expression Inventory
STAT-S	Spielberger State-Trait Anger Scale, state version
STAT-T	Spielberger State-Trait Anger Scale, trait version
TOP-8	Treatment Outcome PTSD Scale
TSSS	Tourette's Syndrome Severity Scale
VAS	Visual Analog Scale
Y-BOCS	Yale-Brown Obsessive-Compulsive Scale
YGTSS	Yale Global Tic Severity Scale
YMRS	Young Mania Rating Scale

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C7: Quality Tables – Placebo Control Trials

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?
(McCracken JT et al., 2002)	Yes	Yes	Yes, except on ABC in appropriate speech score	Yes
(Shea S et al., 2004)	Yes	Yes	Yes	Yes
(De Deyn PP et al., 2004)	Method NR	Method NR	Yes	Yes
(Street JS et al., 2000)	Yes	Method NR	Yes	Yes
(Ruths S et al., 2004)	Method NR	Yes	NR	Yes
(Zhong X et al., 2004)	Method NR	Method NR	Yes	NR
(Ballard CG et al., 2004)	Method NR	Method NR	Yes	Yes
(Brodaty H et al., 2003)	Yes	Method NR	Yes	Yes
(Katz IR et al., 1999)	Method NR	Yes	Yes	Yes
(Meguro K et al., 2004)	Method NR	Method NR	Yes	Yes
(Mertens C, 1993)	Not randomized	Not randomized	Yes	Yes
(Corya S et al., 2002)	Method NR	Method NR	NR	NR
(Howanitz E et al., 2001)	Method NR	Method NR	NR	NR
(Kinrys G et al., 2002)	Method NR	Method NR	NR	Yes
(Rothschild AJ et al., 2004)	Method NR	Method NR	Yes	Yes
(Shi L et al., 2004)	Method NR	Yes	Yes	Yes
(Street JS et al., 2000)	Not randomized	Not randomized	NR	Yes
(Tohen M et al., 2003)	Method NR	Yes	Yes	Yes
(Tohen M et al., 2000)	Yes	Method NR	Yes	Yes

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?
(Tohen M et al., 1999)	Method NR	Method NR	Yes	Yes
(Tohen M et al., 2003)	Method NR	Method NR	NR	Yes
(Tollefson GD et al., 1999)	Method NR	Method NR	Yes	Yes
(van Reekum R et al., 2002)	Yes	Method NR	NR	Yes
(Calabrese J et al., 2004)	Method NR	Method NR	Yes	Yes
(Mintzer J et al., 2004)	Method NR	Method NR	Yes	Yes
(Gharabawi GM et al., 2004)	Yes	Method NR	Yes	Yes
(Daniels DG et al., 1999)	Method NR	Method NR	Yes	Yes
(Keck P Jr et al., 1998)	Method NR	Method NR	Yes	Yes
(Bartzokis G et al., 2004)	Method NR	Method NR	Yes	Yes
(Padala PR et al., 2005)	Method NR	Method NR	NR	Yes
(Reich DB et al., 2004)	Method NR	Method NR	Yes	Yes
(Bystritsky A et al., 2004)	Method NR	Method NR	Yes	Yes
(Buchsbaum MS, 2003)	Not randomized	Not randomized	NR	Yes
(Erzegovesi S et al., 2005)	Yes	Yes	Yes	Yes
(Hollander E et al., 2003)	Yes	Method NR	Yes	Yes
(Butterfield MI et al., 2001)	Method NR	Method NR	Yes	Yes
(Stein MB et al., 2002)	Method NR	Method NR	Yes	Yes
(Hamner MB et al., 2003)	Yes	Method NR	Yes	Yes
(Monnelly EP et al., 2003)	Yes	Method NR	Yes	Yes

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?
(Bogenschutz MP et al., 2004)	Method NR	Method NR	Yes	Yes
(Zanarini MC et al., 2001)	Yes	Method NR	Yes	Yes
(Koenigsberg HW et al., 2003)	Method NR	Method NR	Yes	Yes
(Sallee FR et al., 2000)	Method NR	Method NR	Yes	Yes
(Breder C et al., 2004)	Method NR	Method NR	Yes	Yes
(De Deyn P et al., 2005)	Method NR	Method NR	Yes	Yes
(Streim JE et al., 2004)	Method NR	Method NR	Yes	Yes
(McQuade R et al., 2004)	Method NR	Method NR	NR	Yes
(Kennedy J et al., 2005)	Method NR	Method NR	Yes	Yes
(Soler J et al., 2005)	Method NR	Method NR	Yes	Yes
(Scahill L et al., 2003)	Method NR	Method NR	NR	Yes

Author, Year	Outcome assessors masked?	Care provider masked?	Patient masked?	Attrition, crossovers, adherence, contamination	Loss to follow-up: differential/ high
(McCracken JT et al., 2002)	Yes	Yes	Yes, but not described	Yes/NR / Yes /NR	No
(Shea S et al., 2004)	No	No	No	Yes/NR / Yes /NR	No
(De Deyn PP et al., 2004)	NR	Yes, but not described	Yes, but not described	Yes/NR /Yes/NR	NR
(Street JS et al., 2000)	NR	Yes	Yes	Yes/NR /NR /NR	No
(Ruths S et al., 2004)	Yes	Yes	Yes	NR /NR /NR /NR	No
(Zhong X et al., 2004)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Ballard CG et al., 2004)	Yes	Yes	Yes	Yes/NR /NR /NR	No
(Brodaty H et al., 2003)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Katz IR et al., 1999)	NR	Yes	Yes	Yes/NR /NR /NR	No
(Meguro K et al., 2004)	NR	NR	NR	NR /NR /NR /NR	NR
(Mertens C, 1993)	NR	Yes	Yes	Yes/NR /NR /NR	No
(Corya S et al., 2002)	NR	Yes, but not described	Yes, but not described	NR /NR /NR /NR	NR
(Howanitz E et al., 2001)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Kinrys G et al., 2002)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Rothschild AJ et al., 2004)	NR	Yes, but not described	Yes, but not described	Yes/NR /Yes/NR	NR
(Shi L et al., 2004)	Yes	Yes	Yes	Yes/NR /NR /NR	No
(Street JS et al., 2000)	NR	NR	NR	NR /NR /NR /NR	NR
(Tohen M et al., 2003)	Yes	Yes	Yes	Yes/NR /NR /NR	No
(Tohen M et al., 2000)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No

Author, Year	Outcome assessors masked?	Care provider masked?	Patient masked?	Attrition, crossovers, adherence, contamination	Loss to follow-up: differential/ high
(Tohen M et al., 1999)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Tohen M et al., 2003)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Tollefson GD et al., 1999)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(van Reekum R et al., 2002)	NR	Yes	Yes	Yes/NR /NR /NR	No
(Calabrese J et al., 2004)	NR	Yes, but not described	Yes, but not described	NR /NR /NR /NR	NR
(Mintzer J et al., 2004)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Gharabawi GM et al., 2004)	Yes, but not described	Yes, but not described	Yes, but not described	Yes/NR /Yes/NR	No
(Daniels DG et al., 1999)	NR	Yes, but not described	Yes, but not described	NR /NR /NR /NR	NR
(Keck P Jr et al., 1998)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Bartzokis G et al., 2004)	NR	Yes, but not described	Yes, but not described	Yes/NR /Yes/NR	No
(Padala PR et al., 2005)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Reich DB et al., 2004)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Bystritsky A et al., 2004)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Buchsbaum MS, 2003)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Erzegovesi S et al., 2005)	Yes, but not described	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Hollander E et al., 2003)	Yes	Yes	Yes	Yes/NR /NR /NR	No
(Butterfield MI et al., 2001)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Stein MB et al., 2002)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Hamner MB et al., 2003)	NR	Yes	Yes	Yes/NR /NR /NR	No

Author, Year	Outcome assessors masked?	Care provider masked?	Patient masked?	Attrition, crossovers, adherence, contamination	Loss to follow-up: differential/ high
(Monnelly EP et al., 2003)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Bogenschutz MP et al., 2004)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Zanarini MC et al., 2001)	NR	Yes	Yes	Yes/NR /NR /NR	Yes
(Koenigsberg HW et al., 2003)	Yes, but not described	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Sallee FR et al., 2000)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Breder C et al., 2004)	NR	No	No	Yes/NR /NR /NR	NR
(De Deyn P et al., 2005)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	No
(Streim JE et al., 2004)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(McQuade R et al., 2004)	NR	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Kennedy J et al., 2005)	NR	Yes, but not described	Yes, but not described	Yes/NR /Yes/NR	No
(Soler J et al., 2005)	Yes, but not described	Yes, but not described	Yes, but not described	Yes/NR /NR /NR	NR
(Scahill L et al., 2003)	Yes	Yes	Yes	Yes/NR /NR /NR	No

Author, Year	Intention-to-treat analysis	Post-randomization exclusions	Quality rating (Jadad score)	Number screened/ Eligible/ Enrolled	Exclusion criteria
(McCracken JT et al., 2002)	Yes	Yes	4	270/104/104	Medically significant disorders, DSM-IV Axis I disorder, not including primary condition studied, Psychotropic medication for behavioral disturbances
(Shea S et al., 2004)	Yes	Yes	5	NR/80/79	Schizophrenia or other psychotic disorder, Risperidone use in last 3 mos, Previously unresponsive or intolerant to Risperidone, Medically significant disorders, Abnormal laboratory results, Seizure disorder, Allergic or toxic reactions to antipsychotic medications, HIV, Tardive dyskinesia, Neuroleptic malignant syndrome, Alcohol or substance abuse
(De Deyn PP et al., 2004)	No	No	2	NR/652/NR	DSM-IV Axis I disorder, not including primary condition studied
(Street JS et al., 2000)	Yes	No	5	288/206/206	DSM-IV Axis I disorder, not including primary condition studied, Neurological conditions, excluding Alzheimers or vascular dementia, contributing to psychosis or dementia, MMSE > 24, Bedridden, Anticholinergic medications, Mood stabilizers, Antipsychotics other than the ones studied, Tricyclic antidepressants
(Ruths S et al., 2004)	Yes	No	4	51/30/30	Psychotic disorder, Mental retardation, Terminal illness, Recent major changes in health status
(Zhong X et al., 2004)	No	No	2	NR/333/NR	NR
(Ballard CG et al., 2004)	No	No	3	NR/100/100	NPI > 7
(Brodaty H et al., 2003)	Yes	No	3	384/345/345	Neurological or medical conditions diminishing cognitive function, Dementia other than primary condition, Major depressive disorder, Psychotic disorder, Tardive dyskinesia, Medically significant disorders, Abnormal laboratory results, Depot neuroleptic within 2 treatment cycles
(Katz IR et al., 1999)	Yes	No	4	729/625/625	Untreated reversible causes of dementia, Neurological or medical conditions diminishing cognitive function, HIV dementia, Substance induced dementia, Delirium, Amnestic disorder, Psychosis/psychotic features
(Meguro K et al., 2004)	No	No	1	NR/34/34	Cerebrovascular disease, Parkinsons disease
(Mertens C, 1993)	Yes	No	3	NR/39/39	Neurological or medical conditions diminishing cognitive function, Neurologic disorder, not including primary conditioned studied, Psychiatric disorder, not including primary conditioned studied
(Corya S et al., 2002)	No	No	2	NR/249/NR	NR
(Howanitz E et al., 2001)	Yes	No	2	NR/16/16	NR
(Kinrys G et al., 2002)	Yes	No	3	NR/14/14	NR

Author, Year	Intention-to-treat analysis	Post-randomization exclusions	Quality rating (Jadad score)	Number screened/ Eligible/ Enrolled	Exclusion criteria
(Rothschild AJ et al., 2004)	Yes	No	2	NR/124/124	Psychotic disorder, Pregnant, Lactating
(Shi L et al., 2004)	Yes	No	3	1072/833/833	Alcohol or substance abuse or dependency, Suicidal or violent, Medically significant disorders
(Street JS et al., 2000)	No	Unable to determine	1	NR/NR/NR	NR
(Tohen M et al., 2003)	Yes	No	4	1072/833/833	Alcohol or substance abuse or dependency, Suicidal or violent, Medically significant disorders
(Tohen M et al., 2000)	Yes	No	4	NR/115/115	Medically significant disorders, Alcohol or substance abuse or dependency, Suicidal or violent
(Tohen M et al., 1999)	Yes	No	3	NR/139/139	Medically significant disorders, Alcohol or substance abuse or dependency, Suicidal or violent
(Tohen M et al., 2003)	Yes	No	2	NR/361/361	NR
(Tollefson GD et al., 1999)	Yes	No	3	115/106/106	Alcohol or substance abuse or dependency, Suicidal or violent, Previous exposure to study drug, Medically significant disorders
(van Reekum R et al., 2002)	Yes	No	5	NR/34/34	Schizophrenia, Delirium, Resistant to antipsychotic treatment, Antipsychotic use for nausea, BEHAVE-AD ≥ 3 at screening, 1 week before study, or within 2 weeks pretrial period
(Calabrese J et al., 2004)	Yes	No	2	832/542/542	DSM-IV Axis I disorder, not including primary condition studied
(Mintzer J et al., 2004)	Yes	No	2	NR/473/473	Medically significant disorders, Abnormal laboratory results, Epilepsy, Neurological or medical conditions diminishing cognitive function or that cause psychosis, Cancer, except for non-melanoma of the skin, Recent depot neuroleptic injections, Change in medications in preceding 30 dys
(Gharabawi GM et al., 2004)	Yes	No	4	489/241/241	Pregnant, lactating, psychiatric history, DSM-IV diagnosis confounded by various things, including being medically unstable, testing positive on urine drug screen, impaired hepatic or renal function, history failure of citalopram or any antidepressant with risperidone augmentation, etc.
(Daniels DG et al., 1999)	Yes	No	3	440/302/302	Resistant to antipsychotic treatment, Hospitalized > 4 weeks, Alcohol or substance abuse or dependency, Mental retardation, Organic mental disorder, Brief reactive psychosis, Depot neuroleptic within 4 weeks, Suicidal or violent
(Keck P Jr et al., 1998)	Yes	No	2	203/139/139	Nursing home/residential center resident, Resistant to antipsychotic treatment, Alcohol or substance abuse or dependency, Residual schizophrenia, Mental retardation, Organic mental disorder, Brief reactive psychosis, Suicidal or violent

Author, Year	Intention-to-treat analysis	Post-randomization exclusions	Quality rating (Jadad score)	Number screened/ Eligible/ Enrolled	Exclusion criteria
(Bartzokis et al., 2004)	Yes	No	3	73/65/65	Alcohol or substance abuse or dependency, Suicidal or violent, Medically significant disorders, Neurological or medical conditions diminishing cognitive function, Antipsychotic medications, Seizure disorder or epilepsy or risk, Change in antidepressant regimen within 6 wk prior to study entry
(Padala PR et al., 2005)	Yes	No	2	NR/20/20	Bipolar disorder, Schizophrenia, Medically significant disorders, Abnormal laboratory results, Suicidal or violent, Pregnancy, Nursing, Previous exposure to study drug, Psychotropic use, Alcohol or substance abuse or dependency, Antipsychotics other than the ones studied
(Reich DB et al., 2004)	Yes	No	2	NR/21/21	Medically significant disorders, Alcohol or substance abuse or dependency, Psychotic disorder, Organic mental disorder, Antipsychotics other than the ones studied, Mood stabilizers, Risperidone treatment of 1 week or more, Suicidal or violent, Entry into individual psychotherapy within 3 mos of study, Entry into group therapy within 1 mo of study,
(Bystritsky A et al., 2004)	Yes	No	3	NR/26/26	DSM-IV Axis I disorder, not including primary condition studied, DSM-IV Axis II disorder, not including primary condition studied, Neurological conditions, excluding Alzheimers or vascular dementia, contributing to psychosis or dementia, Pregnant, Medically significant disorders, HAM-D > 20, Bizarre psychosis
(Buchsbaum MS, 2003)	No	No	1	NR/16/16	NR
(Erzegovesi S et al., 2005)	No	No	4	NR/45/45	Antiobsessional medications, Psychiatric disorders except for panic disorder and tic disorders, Pregnant, Contraindication to risperidone, Lactating, Seizure disorder or epilepsy or risk, Medical conditions contraindicating use of fluvoxamine
(Hollander E et al., 2003)	Yes	No	4	NR/16/16	Medically significant disorders, Schizophrenia and schizoafective disorder, Bipolar disorder
(Butterfield MI et al., 2001)	Yes	No	3	NR/15/15	Bipolar disorder, Psychotic disorder, Mental retardation, Alcohol or substance abuse or dependency, Suicidal or violent
(Stein MB et al., 2002)	Yes	No	3	NR/21/19	NR
(Hamner MB et al., 2003)	Yes	No	4	NR/40/40	Risperidone hypersensitivity,-Medically significant disorders, Alcohol or substance abuse or dependency, Schizophrenia, Bipolar disorder, Suicidal or violent
(Monnelly EP et al., 2003)	Yes	No	4	NR/16/16	Schizophrenia, Bipolar disorder with psychotic features, Organic mental disorder, Antipsychotic medications, Alcohol/substance dependency in remission
(Bogenschutz MP et al., 2004)	Yes	No	3	NR/40/40	Psychotropic medications, Pregnant, Bipolar disorder, Psychotic disorder, Major depressive disorder, Alcohol or substance abuse or dependency, Suicidal or violent, Neurological disorder

Author, Year	Intention-to-treat analysis	Post-randomization exclusions	Quality rating (Jadad score)	Number screened/ Eligible/ Enrolled	Exclusion criteria
(Zanarini MC et al., 2001)	Yes	No	5	30/28/28	Previous exposure to study drug, Medically significant disorders, Seizure disorder or epilepsy or risk, Psychotropic medications, Alcohol or substance abuse or dependency, Suicidal or violent, Pregnant, Lactating
(Koenigsberg HW et al., 2003)	Yes	No	4	NR/25/25	Alcohol or substance abuse or dependency, Use psychotropic medications within 2 wks
(Sallee FR et al., 2000)	Yes	No	3	29/28/28	Abnormal laboratory results, Neuroleptic malignant syndrome, Atypical antipsychotics sensitivity, Major depressive disorder, Pervasive developmental disorder, Autism, Mental retardation, Eating disorders
(Breder C et al., 2004)	Yes	No	1	NR/487/487	NR
(De Deyn P et al., 2005)	Yes	No	3	NR/208/208	Bipolar disorder, Schizophrenia, Delirium, Amnestic disorder, Schizoaffective disorder, Mood disorders with psychotic features, Psychotic features accounted better by disease other than the one studied or by effects of a substance, Refractory to neuroleptics
(Streim JE et al., 2004)	Yes	No	2	NR/256/256	NR
(McQuade R et al., 2004)	Yes	No	2	567/161/161	NR
(Kennedy J et al., 2005)	Yes	No	3	446/268/268	DSM-IV Axis I disorder, not including primary condition studied, Neurologic disorder, not including primary conditioned studied, NPI > 1 on delusions, hallucinations, agitation/aggression or dysphoria items, Score ≥ 1 on cholinesterase inhibitor use, antioxidant or herbal supplement items ≤ 4 week
(Soler J et al., 2005)	Yes	No	2	125/60/60	DSM-IV Axis I disorder, not including primary condition studied, Psychotherapy, Sexually active females of child bearing age not using an effective contraceptive method
(Scahill L et al., 2003)	Yes	No	3	49/34/34	Major depressive disorder, Psychosis/psychotic features, Anxiety disorder, Wechsler Intelligence Scale age approximate IQ < 70, Previous adequate trial of risperidone, Medically significant disorders, Y-BOCS or CY-BOCS > 15, Psychotropic medications

Author, Year	Run-in/ Randomization Method Washout/ Randomization Method	Class naïve patients only	Control group standard of care	Funding	Relevance
(McCracken JT et al., 2002)	2-4 week washout period for all psychotropics	NR	No - Placebo	Source: Government, Industry & Private Role: described	Yes
(Shea S et al., 2004)	NR NR	NR	No - Anticonvulsant, anti-EPS, anxiety, sleep medications only	Source: Industry Role: Described	Yes
(De Deyn PP et al., 2004)	Run-in period reported NR	NR	No - Antidepressants, benzodiazepines, acetylcholinesterase inhibitors	Source: Industry Role: NR	Yes
(Street JS et al., 2000)	Run-in period reported NR	NR	No - Benzodiazepines prn only	Source: Government, Industry & Private Role: described	Yes
(Ruths S et al., 2004)	Run-in period reported NR	No	No	Source: NR Role: NR	Yes
(Zhong X et al., 2004)	NR NR	NR	No - Placebo	Source: NR Role: NR	Yes
(Ballard CG et al., 2004)	NR NR	NR	No - Placebo	Source: Unclear Role: NR	Yes
(Brodaty H et al., 2003)	NR Washout period reported	No	No - Anti-EPS, oxazepam, sedatives prn only	Source: Industry Role: described	Yes
(Katz IR et al., 1999)	NR Washout period reported	NR	No - Anti-EPS, benzodiazepines, chloral hydrate prn only	Source: Industry Role: described	Yes
(Meguro K et al., 2004)	NR NR	NR	No	Source: Private Role: NR	Yes
(Mertens C, 1993)	Run-in period reported NR	No	No - Placebo	Source: Industry Role: NR	Yes
(Corya S et al., 2002)	NR NR	NR	No - Placebo	Source: Industry Role: NR	Yes
(Howanitz E et al., 2001)	NR NR	NR	No - Placebo	Source: NR Role: NR	Yes
(Kinrys G et al., 2002)	Run-in period reported NR	NR	Yes	Source: Industry Role: NR	Yes
(Rothschild AJ et al., 2004)	NR NR	NR	No - Benzodiazepines prn only	Source: Industry Role: NR	Yes
(Shi L et al., 2004)	NR Washout period reported	NR	No - Anti-EPS, benzodiazepines only	Source: Industry Role: NR	Yes
(Street JS et al., 2000)	NR NR	NR	NR	Source: Industry Role: NR	Yes
(Tohen M et al., 2003)	NR Washout period reported	NR	No - Anti-EPS, benzodiazepines only	Source: Industry Role: described	Yes
(Tohen M et al., 2000)	NR Washout period reported	No	No - Lorazepam, benztropine	Source: Industry Role: NR	Yes

Author, Year	Run-in/ Randomization Method Washout/ Randomization Method	Class naïve patients only	Control group standard of care	Funding	Relevance
(Tohen M et al., 1999)	NR Washout period reported	NR	No - Lorazepam, benztropine	Source: Industry Role: NR	Yes
(Tohen M et al., 2003)	NR NR	NR	No - Placebo	Source: Industry Role: NR	Yes
(Tollefson GD et al., 1999)	NR NR	No	No - Anti-EPS, benzodiazepines prn	Source: Industry Role: NR	Yes
(van Reekum R et al., 2002)	Run-in period reported NR	No	NR	Source: Private (Non-Industry) Role: NR	Yes
(Calabrese J et al., 2004)	NR NR	NR	No - Placebo	Source: Industry Role: NR	Yes
(Mintzer J et al., 2004)	NR Washout period reported	No	No - Placebo	Source: Industry Role: NR	Yes
(Gharabawi GM et al., 2004)	Run-in period reported NR	No	Yes	Source: Industry Role: NR	Yes
(Daniels DG et al., 1999)	NR Washout period reported	No	No - Lorazepam, benztropine, beta-blockers only	Source: Industry Role: NR	Yes
(Keck P Jr et al., 1998)	NR Washout period reported	NR	No - Lorazepam, benztropine, beta-blockers only	Source: Industry Role: NR	Yes
(Bartzokis G et al., 2004)	NR NR	NR	Yes	Source: Government, Industry & Private Role: NR	Yes
(Padala PR et al., 2005)	NR Washout period reported	NR	No - Placebo	Source: Industry Role: NR	Yes
(Reich DB et al., 2004)	NR NR	NR	Yes	Source: Industry Role: NR	Yes
(Bystritsky A et al., 2004)	NR NR	NR	Yes	Source: Industry Role: NR	Yes
(Buchsbaum MS, 2003)	NR NR	NR	NR	Source: NR Role: NR	Limited
(Erzegovesi S et al., 2005)	Run-in period reported NR	NR	Yes	Source: NR Role: NR	Yes
(Hollander E et al., 2003)	NR NR	NR	Yes	Source: Industry & Private Role: described	Yes
(Butterfield MI et al., 2001)	NR NR	NR	NR	Source: Industry Role: NR	Yes
(Stein MB et al., 2002)	Run-in period reported NR	NR	No - SRI	Source: Industry Role: NR	Yes
(Hamner MB et al., 2003)	Run-in period reported Washout period reported	No	Yes	Source: Industry Role: described	Yes

Author, Year	Run-in/ Randomization Method Washout/ Randomization Method	Class naïve patients only	Control group standard of care	Funding	Relevance
(Monnelly EP et al., 2003)	NR NR	Yes	Yes	Source: Government & Industry Role: NR	Yes
(Bogenschutz MP et al., 2004)	NR NR	No	Yes	Source: Industry Role: NR	Yes
(Zanarini MC et al., 2001)	NR NR	No	NR	Source: Industry Role: NR	Limited
(Koenigsberg HW et al., 2003)	Run-in period reported NR	NR	No - No other psychotropic medications allowed	Source: Government & Industry Role: described	Yes
(Sallee FR et al., 2000)	NR NR	NR	No - Placebo	Source: Industry Role: NR	Yes
(Breder C et al., 2004)	NR Washout period reported	NR	No - Placebo	Source: Industry Role: NR	Yes
(De Deyn P et al., 2005)	NR Washout period reported	No	No - Placebo	Source: Industry Role: NR	Yes
(Streim JE et al., 2004)	NR NR	NR	No - Placebo	Source: Industry Role: NR	Yes
(McQuade R et al., 2004)	Run-in period reported NR	No	No - Placebo	Source: Industry Role: NR	Yes
(Kennedy J et al., 2005)	NR Washout period reported	No	Yes	Source: Industry Role: NR	Yes
(Soler J et al., 2005)	NR NR	NR	Yes	Source: Government & Industry Role: NR	Yes
(Scahill L et al., 2003)	NR Washout period reported	No	No - Placebo	Source: Government, Industry & Private Role: NR	Yes

Acronyms in Evidence Table:

CCT	Clinical control trial
kg	kilograms
lbs	pounds
ND	Not described
NOS	Not otherwise specified
NR	Not reported
RCT	Randomized control trial
RR	Risk ratio
SMD	Standard mean difference
WMD	Weighted mean difference

Outcomes:

ABC	Aberrant Behavior Checklist
ACES	Agitation-Calmness Evaluation Scale
ADAS-cog	Alzheimer's Disease Assessment Scale
ADHDRS	DuPaul Attention Deficit Hyperactivity Scale
ADL	Activities of Daily Life
AIAQ	Anger, Irritability, and Assault Questionnaire
ASI	Addiction Severity Index
BABS	Brown Assessment of Beliefs Scale
BAI	Beck Anxiety Index
BDHI	Buss-Durkee Hostility Index
BDI	Beck Depression Index
BDS	Blessed Dementia Scale
BEHAVE-AD	Behavioral Pathology in Alzheimer's Disease Rating Scale
BPRS	Brief Psychiatric Rating Scale
BRMES	Bech-Rafaelsen Melancholia Scale
CAPS	Clinician Administered PTSD Scale
CDSS	Calgary Depression Scale for Schizophrenia
CES-D	Center for Epidemiologic Studies Depression Scale
CGI	Clinical Global Impression Scale
CMAI	Cohen-Mansfield Agitation Inventory
CM-PNB	Cohen-Mansfield Physically Non-Aggressive Behavior
CPRS	Children's Psychiatric Rating Scale
CSDD	Cornell Scale for Depression in Dementia
CY-BOCS	Children's Yale-Brown Obsessive-Compulsive Scale
DCM	Dementia Care Mapping
DES	Dissociative Experiences Scale
DTS	Davidson Trauma Scale
E-BEHAVE-AD	Empirical Behavioral Pathology in Alzheimer's Disease Rating Scale
FAST	Functional Assessment Staging Rating Scale
GAF	Global Assessment of Functioning Scale
HAM-A	Hamilton Rating Scale for Anxiety
HAM-D/HDRS	Hamilton Rating Scale for Depression
IGT	Iowa Gambling Task
MADRS	Montgomery-Asberg Depression Rating Scale
MDRS	Mattis Dementia Rating Scale
MMSE	Mini-Mental State Examination
M-NCAS	Modified Strain in Nursing Care Assessment

MOSES	Multidimentional Observational Scale for Elderly Subjects
MOVES	Motor Tic, Obsessions, and Compulsions, Vocal Tic Evaluation Survey
N-CBRF	Nisonger Child Behavior Rating Scale
NIMH-OC	National Institute of Mental Health Obsessive-Compulsive Scale
NPI	Neuropsychiatric Inventory
NPI/NH	Neuropsychiatric Inventory/Nursing Home
NPI-Q	Neuropsychiatric Inventory Questionnaire
OAS-M	Overt Aggression Scale-Modified
PANSS	Positive and Negative Symptom Scale
PCL-M	Patient Checklist for PTSD--Military Version
PDC	Depression cluster
PDS	Progressive Deterioration Scale
PGDRS	Psychogeriatric Dependency Rating Scale
PGI	Patient Global Impressions
QLDS	Quality of Life in Depression Scale
Q-LES-Q	Quality of Life Enjoyment and Satisfaction Questionnaire
QLS	Quality of Life Scales
QUALID	Quality of Life in Late-Stage Dementia Scale
ROAS	Retrospective Overt Aggression Scale
SANS	Scale for the Assessment of Negative Symptoms
SCL-90	Symptom Checklist-90
SDS	Sheehan Disability Scale
SF-36	Medical Outcomes Study 36-Item Short-Form Health Survey
SIB	Severe Impairment Battery
SIB-Q	Self-injurious Behavior Questionnaire
SIP	Structured Interview for PTSD
SPQ	Schizotypal Personality Questionnaire
SPRINT	Short PTSD Rating Interview
STAS-AX	State-Trait Anger Expression Inventory
STAT-S	Spielberger State-Trait Anger Scale, state version
STAT-T	Spielberger State-Trait Anger Scale, trait version
TOP-8	Treatment Outcome PTSD Scale
TSSS	Tourette's Syndrome Severity Scale
VAS	Visual Analog Scale
Y-BOCS	Yale-Brown Obsessive-Compulsive Scale
YGTSS	Yale Global Tic Severity Scale
YMRS	Young Mania Rating Scale

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C8: Quality Tables – Augmentation Trials

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?	Patient masked?
(Tohen M et al., 2002)	Method NR	Method NR	Yes	Yes	NR	Yes, but not described	Yes, but not described
(Yargic LI et al., 2004)	Method NR	Method NR	Yes	Yes	Yes	No	No
(Atmaca M et al., 2002)	Method NR	Method NR	Yes	Yes	NR	NR	NR
(Denys D et al., 2004)	Method NR	Method NR	Yes	Yes	Yes	Yes	Yes
(Cavedini P et al., 2004)	Yes	Method NR	Yes	Yes	Yes	No	Yes
(McDougle CJ et al., 2000)	Yes	Method NR	Yes	Yes	Yes	Yes, but not described	Yes, but not described
(Shapira NA et al., 2004)	Method NR	Method NR	Yes	Yes	NR	Yes, but not described	Yes, but not described
(Dunner D et al., 2003)	Method NR	Method NR	Yes	Yes	Yes	No	No
(Carey PD et al., 2005)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
(Fineberg NA et al., 2005)	Method NR	Method NR	Yes	Yes	Yes, but not described	Yes, but not described	Yes, but not described
(Li X et al., 2005)	Method NR	Method NR	NR	Yes	NR	Yes, but not described	Yes, but not described

Author, Year	Attrition, crossovers, adherence, contamination	Loss to follow-up: differential/high	Intention-to-treat analysis	Post-randomization exclusions	Quality rating (Jadad score)	Number screened/ Eligible/Enrolled
(Tohen M et al., 2002)	Yes/NR /NR /NR	No	Yes	No	3	501/344/344
(Yargic LI et al., 2004)	Yes/NR /NR /NR	NR	No	No	2	NR/120/NR
(Atmaca M et al., 2002)	Yes/NR /NR /NR	No	Yes	No	2	52/27/27
(Denys D et al., 2004)	Yes/NR /NR /NR	No	Yes	No	4	NR/40/40
(Cavedini P et al., 2004)	NR /NR /NR /NR	NR	No	No	4	NR/30/30
(McDougle CJ et al., 2000)	Yes/NR /NR /NR	No	Yes	No	4	70/36/36
(Shapira NA et al., 2004)	Yes/NR /NR /NR	No	Yes	No	3	74/44/44
(Dunner D et al., 2003)	NR /NR /Yes/NR	NR	Yes	No	1	90/64/64
(Carey PD et al., 2005)	Yes/NR /NR /NR	No	Yes	Yes, exclusions reported by group:0/1/.	5	NR/42/42
(Fineberg NA et al., 2005)	Yes/NR /NR /NR	No	Yes	No	3	NR/21/21
(Li X et al., 2005)	Yes/Yes/Yes/NR	NR	No	No	2	27/16/16

Author, Year	Exclusion criteria	Run-in/Randomization Method Washout/Randomization Method	Class naïve patients only	Control group standard of care	Funding	Relevance
(Tohen M et al., 2002)	NR	NR Washout period reported	NR	Yes	Source: Industry Role: NR	Yes
(Yargic LI et al., 2004)	HAM-D Item 3 > 2, Psychotic disorder, Use psychotropic medications within 4 wks, Medically significant disorders, Abnormal laboratory results, Bipolar disorder, Alcohol or substance abuse or dependency, Pregnant	NR NR	NR	Yes	Source: NR Role: NR	Yes
(Atmaca M et al., 2002)	NR	Run-in period reported NR	NR	Yes	Source: NR Role: NR	Yes
(Denys D et al., 2004)	Tic disorder, Tourettes disorder, Major depressive disorder, Pregnant, Organic mental disorder, Seizure disorder or epilepsy or risk, Neurological disorder, Bipolar disorder	NR NR	NR	Yes	Source: Industry Role: NR	Yes
(Cavedini P et al., 2004)	DSM-IV Axis I disorder, not including primary condition studied, Tic disorder, Medically significant disorders, Severe internal or neurological disease, Brain injury or head trauma, Alcohol or substance abuse or dependency	NR NR	Yes	Yes	Source: NR Role: NR	Yes
(McDougle CJ et al., 2000)	Non-healthy, Pregnant, Use psychotropic medications within 4 wks	Run-in period reported NR	NR	Yes	Source: Government & Private Role: described	Yes
(Shapira NA et al., 2004)	Major depressive disorder, Psychotic disorder, Bipolar disorder, Alcohol or substance abuse or dependency, Seizure disorder or epilepsy or risk, Encephalitis, Brain injury or head trauma, Medically significant disorders	Run-in period reported NR	NR	Yes	Source: Government & Industry Role: NR	Yes
(Dunner D et al., 2003)	NR	Run-in period reported NR	NR	Yes	Source: Industry Role: NR	Yes

Author, Year	Exclusion criteria	Run-in/Randomization Method Washout/Randomization Method	Class naïve patients only	Control group standard of care	Funding	Relevance
(Carey PD et al., 2005)	Lactating, Sexually active females of child bearing age not using an effective contraceptive method, Medically significant disorders, Brain injury or head trauma, Co-existing Axis -I disorder unless deemed to be secondary to OCD, Brain Surgery, Seizure disorder or epilepsy or risk, Medications that that interact with Quetiapine	Run-in period reported NR	No	Yes	Source: Industry Role: NR	Yes
(Fineberg NA et al., 2005)	DSM-IV Axis I disorder, not including primary condition studied, DSM-IV Axis I disorder, not including primary condition studied or depression with MADRS < 30, Tourettes disorder, Resistant to antipsychotic treatment	NR NR	No	Yes	Source: Industry Role: described	Yes
(Li X et al., 2005)	DSM-IV Axis I disorder, not including primary condition studied, SADS-L (Schedule for Affective Disorders and Schizophrenia - Lifetime version) Criteria, Major motor disorder, Vocal tics	Run-in period reported Washout period reported	NR	Yes	Source: Industry Role: NR	Yes

Acronyms in Evidence Table:

CCT	Clinical control trial
kg	kilograms
lbs	pounds
ND	Not described
NOS	Not otherwise specified
NR	Not reported
RCT	Randomized control trial
RR	Risk ratio
SMD	Standard mean difference
WMD	Weighted mean difference

Outcomes:

ABC	Aberrant Behavior Checklist
ACES	Agitation-Calmness Evaluation Scale
ADAS-cog	Alzheimer's Disease Assessment Scale
ADHDRS	DuPaul Attention Deficit Hyperactivity Scale
ADL	Activities of Daily Life
AIAQ	Anger, Irritability, and Assault Questionnaire
ASI	Addiction Severity Index
BABS	Brown Assessment of Beliefs Scale
BAI	Beck Anxiety Index
BDHI	Buss-Durkee Hostility Index
BDI	Beck Depression Index
BDS	Blessed Dementia Scale
BEHAVE-AD	Behavioral Pathology in Alzheimer's Disease Rating Scale
BPRS	Brief Psychiatric Rating Scale
BRMES	Bech-Rafaelsen Melancholia Scale
CAPS	Clinician Administered PTSD Scale
CDSS	Calgary Depression Scale for Schizophrenia
CES-D	Center for Epidemiologic Studies Depression Scale
CGI	Clinical Global Impression Scale
CMAI	Cohen-Mansfield Agitation Inventory
CM-PNB	Cohen-Mansfield Physically Non-Aggressive Behavior
CPRS	Children's Psychiatric Rating Scale
CSDD	Cornell Scale for Depression in Dementia
CY-BOCS	Children's Yale-Brown Obsessive-Compulsive Scale
DCM	Dementia Care Mapping
DES	Dissociative Experiences Scale
DTS	Davidson Trauma Scale
E-BEHAVE-AD	Empirical Behavioral Pathology in Alzheimer's Disease Rating Scale
FAST	Functional Assessment Staging Rating Scale
GAF	Global Assessment of Functioning Scale
HAM-A	Hamilton Rating Scale for Anxiety
HAM-D/HDRS	Hamilton Rating Scale for Depression
IGT	Iowa Gambling Task
MADRS	Montgomery-Asberg Depression Rating Scale
MDRS	Mattis Dementia Rating Scale
MMSE	Mini-Mental State Examination
M-NCAS	Modified Strain in Nursing Care Assessment
MOSES	Multidimentional Observational Scale for Elderly Subjects
MOVES	Motor Tic, Obsessions, and Compulsions, Vocal Tic Evaluation Survey
N-CBRF	Nisonger Child Behavior Rating Scale
NIMH-OC	National Institute of Mental Health Obsessive-Compulsive Scale

NPI	Neuropsychiatric Inventory
NPI/NH	Neuropsychiatric Inventory/Nursing Home
NPI-Q	Neuropsychiatric Inventory Questionnaire
OAS-M	Overt Aggression Scale-Modified
PANSS	Positive and Negative Symptom Scale
PCL-M	Patient Checklist for PTSD--Military Version
PDC	Depression cluster
PDS	Progressive Deterioration Scale
PGDRS	Psychogeriatric Dependency Rating Scale
PGI	Patient Global Impressions
QLDS	Quality of Life in Depression Scale
Q-LES-Q	Quality of Life Enjoyment and Satisfaction Questionnaire
QLS	Quality of Life Scales
QUALID	Quality of Life in Late-Stage Dementia Scale
ROAS	Retrospective Overt Aggression Scale
SANS	Scale for the Assessment of Negative Symptoms
SCL-90	Symptom Checklist-90
SDS	Sheehan Disability Scale
SF-36	Medical Outcomes Study 36-Item Short-Form Health Survey
SIB	Severe Impairment Battery
SIB-Q	Self-injurious Behavior Questionnaire
SIP	Structured Interview for PTSD
SPQ	Schizotypal Personality Questionnaire
SPRINT	Short PTSD Rating Interview
STAS-AX	State-Trait Anger Expression Inventory
STAT-S	Spielberger State-Trait Anger Scale, state version
STAT-T	Spielberger State-Trait Anger Scale, trait version
TOP-8	Treatment Outcome PTSD Scale
TSSS	Tourette's Syndrome Severity Scale
VAS	Visual Analog Scale
Y-BOCS	Yale-Brown Obsessive-Compulsive Scale
YGTSS	Yale Global Tic Severity Scale
YMRS	Young Mania Rating Scale

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REJECTED: Foreign Language Article

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Table A. Dementia studies – Atypical Antipsychotics Compared to Placebo

Adverse Events	Drug	# of studies	Placebo		Intervention Groups		Pooled OR	95% CI	NNH[1]	95% CI NNH
			# adverse events	sample size	# adverse events	sample size				
Anticholinergic Events	Olanzapine	1	12	90	60	178	3.29	(1.62, 7.17)	5.00	(3.00, 10.00)
Appetite or Weight/Decrease	Aripiprazol	1	13	121	23	122	1.93	(0.88, 4.38)	NC	NC
Appetite or Weight/Decrease	Olanzapine	2	15	141	32	363	0.75	(0.38, 1.56)	NC	NC
Appetite or Weight/Decrease	Risperidone	1	8	94	11	196	0.64	(0.23, 1.90)	NC	NC
Appetite or Weight/Increase	Aripiprazol	1	3	102	5	106	1.63	(0.31, 10.78)	NC	NC
Appetite or Weight/Increase	Olanzapine	2	2	184	24	382	6.12	(1.49, 54.04)	19.00	(12.00, 43.00)
Appetite or Weight/Increase	Risperidone	1	1	94	6	196	2.93	(0.35, 136.52)	NC	NC
Cardiovascular	Aripiprazol	1	10	121	32	122	4.22	(1.84, 10.63)	6.00	(4.00, 11.00)
Cardiovascular	Olanzapine	4	5	298	38	678	3.31	(1.27, 10.91)	25.00	(16.00, 60.00)
Cardiovascular	Risperidone	4	27	665	110	1060	2.33	(1.48, 3.78)	16.00	(12.00, 25.00)
Cardiovascular/BP/Decrease	Aripiprazol	1	6	125	4	131	0.63	(0.13, 2.71)	NC	NC
Cardiovascular/BP/Increase	Aripiprazol	1	5	102	4	106	0.76	(0.15, 3.65)	NC	NC
Cardiovascular/BP/Increase	Olanzapine	1	1	67	2	137	0.98	(0.05, 58.55)	NC	NC
Cardiovascular/Rhythm	Aripiprazol	1	1	102	2	106	1.94	(0.10, 115.71)	NC	NC
Cardiovascular/Rhythm	Olanzapine	1	2	67	3	137	0.73	(0.08, 8.92)	NC	NC
Cardiovascular/Rhythm	Risperidone	1	6	19	7	20	1.16	(0.25, 5.49)	NC	NC
Constitutional/Fever or Infection	Olanzapine	3	5	231	38	541	3.23	(1.23, 10.71)	21.00	(13.00, 50.00)
Constitutional/Fever or Infection	Risperidone	3	19	427	59	825	1.41	(0.80, 2.57)	NC	NC
Dermatologic	Aripiprazol	2	52	246	96	253	2.35	(1.54, 3.62)	6.00	(4.00, 11.00)
Dermatologic	Olanzapine	1	7	47	19	159	0.78	(0.29, 2.35)	NC	NC
Dermatologic	Risperidone	2	82	333	133	629	1.24	(0.87, 1.79)	NC	NC
Endocrine/Diabetes	Risperidone	1	5	238	4	235	0.81	(0.16, 3.80)	NC	NC
Endocrine/Prolactin	Risperidone	1	0	238	0	235	NC	NC	NC	NC
Gastrointestinal	Aripiprazol	2	18	246	45	253	2.72	(1.48, 5.18)	10.00	(6.00, 21.00)
Gastrointestinal	Olanzapine	1	6	90	24	178	2.18	(0.82, 6.77)	NC	NC
Gastrointestinal	Risperidone	1	61	170	38	167	0.53	(0.32, 0.87)	-8.00	(-28.00, -4.00)
HEENT	Olanzapine	1	3	47	16	159	1.64	(0.44, 9.17)	NC	NC
HEENT	Risperidone	2	27	333	80	629	1.27	(0.78, 2.12)	NC	NC
HEENT/Eye	Risperidone	1	18	170	20	167	1.15	(0.55, 2.40)	NC	NC
Heme	Risperidone	1	12	238	8	235	0.66	(0.23, 1.81)	NC	NC

NC = Not Calculated

Table A. Dementia studies – Atypical Antipsychotics Compared to Placebo - continued

Adverse Events	Drug	# of studies	Placebo		Intervention Groups		Pooled OR	95% CI	NNH[1]	95% CI NNH
			# adverse events	sample size	# adverse events	sample size				
Infections	Olanzapine	1	5	90	10	178	1.01	(0.30, 3.90)	NC	NC
Infections	Risperidone	2	33	333	54	629	1.05	(0.64, 1.75)	NC	NC
Liver Function Test Abnormality	Aripiprazol	1	1	102	0	106	0.00	(0.00, 37.53)	NC	NC
Musculoskeletal	Olanzapine	1	3	90	0	178	0.00	(0.00, 1.21)	NC	NC
Neuro	Olanzapine	3	35	326	95	482	2.23	(1.43, 3.55)	11.00	(7.00, 24.00)
Neuro	Quetiapine	1	16	142	13	94	1.26	(0.53, 2.97)	NC	NC
Neuro	Risperidone	2	26	236	44	281	1.50	(0.85, 2.70)	NC	NC
Neuro/CVA	Aripiprazol	1	1	102	1	106	0.96	(0.01, 76.25)	NC	NC
Neuro/CVA	Olanzapine	2	2	232	5	278	2.09	(0.32, 23.27)	NC	NC
Neuro/CVA	Quetiapine	1	1	142	1	94	1.51	(0.02, 119.85)	NC	NC
Neuro/CVA	Risperidone	3	6	550	21	487	3.88	(1.49, 11.91)	31.00	(19.00, 82.00)
Neuro/Fatigue	Aripiprazol	2	14	246	41	253	3.67	(1.83, 7.90)	10.00	(6.00, 19.00)
Neuro/Fatigue	Olanzapine	3	9	326	36	482	2.37	(1.08, 5.75)	21.00	(13.00, 57.00)
Neuro/Fatigue	Quetiapine	1	2	142	4	94	3.10	(0.43, 34.89)	NC	NC
Neuro/Fatigue	Risperidone	2	4	236	20	281	3.56	(1.13, 14.96)	18.00	(11.00, 50.00)
Neuro/Headache	Olanzapine	2	2	209	9	237	4.86	(0.95, 48.01)	NC	NC
Neuro/Headache	Quetiapine	1	2	142	1	94	0.75	(0.01, 14.67)	NC	NC
Neuro/Headache	Risperidone	2	13	312	13	252	1.17	(0.49, 2.81)	NC	NC
Neuro/Movement Disorder/EPS	Aripiprazol	3	16	348	39	359	2.53	(1.34, 5.01)	16.00	(10.00, 42.00)
Neuro/Movement Disorder/EPS	Olanzapine	1	1	142	12	100	19.04	(2.73, 827.61)	9.00	(6.00, 21.00)
Neuro/Movement Disorder/EPS	Quetiapine	1	1	142	2	94	3.05	(0.16, 182.09)	NC	NC
Neuro/Movement Disorder/EPS	Risperidone	4	29	713	114	949	2.82	(1.81, 4.51)	13.00	(10.00, 18.00)
Neuro/Movement Disorder/Gait	Olanzapine	4	15	373	79	641	2.75	(1.52, 5.29)	12.00	(9.00, 20.00)
Neuro/Movement Disorder/Gait	Quetiapine	1	3	142	3	94	1.52	(0.20, 11.63)	NC	NC
Neuro/Movement Disorder/Gait	Risperidone	3	8	406	32	448	3.04	(1.32, 7.84)	19.00	(13.00, 41.00)
Neuro/Movement Disorder/Tardive Dyskinesia	Olanzapine	1	4	142	3	100	1.07	(0.15, 6.46)	NC	NC
Neuro/Movement Disorder/Tardive Dyskinesia	Quetiapine	1	4	142	2	94	0.75	(0.07, 5.36)	NC	NC
Neuro/Movement Disorder/Tardive Dyskinesia	Risperidone	3	14	475	4	714	0.31	(0.07, 1.03)	NC	NC
Neuro/Pain	Aripiprazol	1	7	121	32	122	5.52	(2.25, 15.57)	5.00	(3.00, 9.00)
Neuro/Pain	Olanzapine	2	10	137	36	337	1.31	(0.60, 3.10)	NC	NC

NC = Not Calculated

Table A. Dementia studies – Atypical Antipsychotics Compared to Placebo - continued

			Placebo		Intervention Groups					
Adverse Events	Drug	# of studies	# adverse events	sample size	# adverse events	sample size	Pooled OR	95% CI	NNH[1]	95% CI NNH
Neuro/Pain	Risperidone	1	13	163	33	462	0.89	(0.44, 1.89)	NC	NC
Neuro/Sedation	Aripiprazol	3	10	348	54	359	6.68	(3.19, 15.72)	8.00	(6.00, 12.00)
Neuro/Sedation	Olanzapine	5	24	440	152	778	4.26	(2.66, 7.08)	7.00	(6.00, 9.00)
Neuro/Sedation	Quetiapine	1	7	142	21	94	5.51	(2.13, 16.08)	6.00	(4.00, 12.00)
Neuro/Sedation	Risperidone	6	87	922	249	1260	2.50	(1.89, 3.34)	10.00	(8.00, 13.00)
Psychiatric/Aggression	Olanzapine	1	1	94	14	204	6.82	(1.01, 292.81)	17.00	(10.00, 57.00)
Psychiatric/Aggression	Risperidone	2	19	264	22	363	0.91	(0.45, 1.85)	NC	NC
Psychiatric/Agitation	Aripiprazol	1	19	121	37	122	2.24	(1.16, 4.47)	7.00	(4.00, 24.00)
Psychiatric/Agitation	Olanzapine	4	36	373	76	641	1.19	(0.76, 1.90)	NC	NC
Psychiatric/Agitation	Quetiapine	1	14	142	11	94	1.21	(0.47, 3.03)	NC	NC
Psychiatric/Agitation	Risperidone	5	102	807	120	1145	0.84	(0.62, 1.14)	NC	NC
Psychiatric/Anxiety	Olanzapine	4	19	373	40	641	1.04	(0.57, 1.95)	NC	NC
Psychiatric/Anxiety	Quetiapine	1	3	142	0	94	0.00	(0.00, 3.65)	NC	NC
Psychiatric/Anxiety	Risperidone	2	12	236	20	281	0.89	(0.39, 2.12)	NC	NC
Psychiatric/Cognitive	Olanzapine	2	3	232	15	278	4.00	(1.08, 22.38)	24.00	(14.00, 93.00)
Psychiatric/Cognitive	Quetiapine	1	1	142	0	94	0.00	(0.00, 58.92)	NC	NC
Psychiatric/Cognitive	Risperidone	1	1	142	1	85	1.67	(0.02, 132.68)	NC	NC
Psychiatric/Depression	Olanzapine	2	4	232	16	278	3.05	(0.94, 13.04)	NC	NC
Psychiatric/Depression	Quetiapine	1	2	142	2	94	1.52	(0.11, 21.30)	NC	NC
Psychiatric/Depression	Risperidone	1	2	142	0	85	0.00	(0.00, 8.90)	NC	NC
Psychiatric/Psychotic	Olanzapine	3	14	326	62	482	2.81	(1.49, 5.64)	12.00	(8.00, 21.00)
Psychiatric/Psychotic	Quetiapine	1	3	142	0	94	0.00	(0.00, 3.65)	NC	NC
Psychiatric/Psychotic	Risperidone	2	13	236	32	281	1.35	(0.65, 2.96)	NC	NC
Psychiatric/Sleep	Olanzapine	3	13	326	30	482	1.50	(0.73, 3.26)	NC	NC
Psychiatric/Sleep	Quetiapine	1	5	142	5	94	1.54	(0.34, 6.88)	NC	NC
Psychiatric/Sleep	Risperidone	3	24	474	28	516	1.03	(0.56, 1.92)	NC	NC
Pulmonary	Aripiprazol	1	3	102	6	106	1.97	(0.41, 12.54)	NC	NC
Pulmonary	Olanzapine	1	3	94	0	204	0.00	(0.00, 1.10)	NC	NC
Pulmonary	Risperidone	1	3	94	6	196	0.96	(0.20, 6.05)	NC	NC
Severe	Risperidone	2	36	333	97	629	1.49	(0.96, 2.33)	NC	NC

NC = Not Calculated

Table A. Dementia studies – Atypical Antipsychotics Compared to Placebo - continued

Adverse Events	Drug	# of studies	Placebo		Intervention Groups		Pooled OR	95% CI	NNH[1]	95% CI NNH
			# adverse events	sample size	# adverse events	sample size				
Trauma	Aripiprazol	3	61	348	126	359	3.12	(2.09, 4.72)	6.00	(4.00, 9.00)
Trauma	Olanzapine	5	50	440	114	778	1.31	(0.89, 1.96)	NC	NC
Trauma	Quetiapine	1	21	142	7	94	0.46	(0.16, 1.20)	NC	NC
Trauma	Risperidone	5	289	807	403	1145	0.79	(0.63, 0.99)	-163.0	(27.00, -20.00)
Urinary	Aripiprazol	3	45	348	115	359	4.07	(2.61, 6.44)	5.00	(4.00, 8.00)
Urinary	Olanzapine	1	1	94	19	204	9.51	(1.47, 401.07)	12.00	(8.00, 27.00)
Urinary	Risperidone	4	71	665	164	1060	1.55	(1.13, 2.13)	21.00	(13.00, 63.00)

NC = Not Calculated

Table B. Dementia studies – Atypical Antipsychotics Compared to Acetylcholinesterase inhibitors

Adverse Events	Drug	# of studies	Acetylcholinesterase inhibitors		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
Appetite or Weight/Decrease	Risperidone	1	0	14	0	13	NC	NC
Gastrointestinal	Risperidone	1	10	14	2	13	0.10	(0.01, 0.78)
Neuro/Fatigue	Risperidone	1	2	14	1	13	1.09	(0.01, 92.68)
Neuro/Movement Disorder/EPS	Risperidone	1	0	14	2	13	+Inf	(0.03, Inf+)
Neuro/Sedation	Risperidone	1	0	14	4	13	+Inf	(0.88, Inf+)
Psychiatric/Agitation	Risperidone	1	1	14	1	13	+Inf	(0.03, Inf+)

NC = Not Calculated

Table C. Dementia studies – Atypical Antipsychotics Compared to Benzodiazepines

Adverse Events	Drug	# of studies	Benzodiazepines		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
Cardiovascular	Olanzapine	1	0	68	2	137	+Inf	(0.09, Inf+)
Cardiovascular/BP/Increase	Olanzapine	1	2	68	2	137	0.49	(0.03, 6.91)
Cardiovascular/Rhythm	Olanzapine	1	0	68	3	137	+Inf	(0.20, Inf+)
Neuro/Headache	Olanzapine	1	1	68	4	137	2.01	(0.19, 100.69)
Neuro/Sedation	Olanzapine	1	7	68	5	137	0.33	(0.08, 1.27)
Trauma	Olanzapine	1	3	68	3	137	0.49	(0.06, 3.74)

NC = Not Calculated

Table D. Dementia studies – Atypical Antipsychotics Compared to Conventional Antipsychotics

Adverse Events	Drug	# of studies	Conventionals		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
Appetite or Weight/Increase	Olanzapine	1	0	20	6	20	+Inf	(1.48, Inf+)
Appetite or Weight/Increase	Risperidone	1	0	20	0	20	NC	NC
Cardiovascular/BP/Decrease	Olanzapine	1	7	20	2	20	0.11	(0.00, 1.01)
Cardiovascular/BP/Decrease	Risperidone	1	7	20	4	20	0.47	(0.08, 2.36)
Cardiovascular/Rhythm	Olanzapine	1	5	20	0	20	0.00	(0.00, 0.98)
Cardiovascular/Rhythm	Risperidone	1	5	20	2	20	0.17	(0.00, 1.80)
Endocrine/Diabetes	Olanzapine	1	0	20	1	20	+Inf	(0.03, Inf+)
Endocrine/Diabetes	Risperidone	1	0	20	0	20	NC	NC
Gastrointestinal	Olanzapine	1	8	20	3	20	0.29	(0.04, 1.55)
Gastrointestinal	Risperidone	2	10	49	6	49	0.43	(0.10, 1.65)
HEENT/Decreased Salivation	Olanzapine	1	6	20	0	20	0.00	(0.00, 0.72)
HEENT/Decreased Salivation	Risperidone	1	6	20	0	20	0.00	(0.00, 0.72)
Neuro	Olanzapine	1	3	20	3	20	1.06	(0.12, 9.13)
Neuro	Risperidone	1	3	20	0	20	0.00	(0.00, 2.34)
Neuro/CVA	Olanzapine	2	116	5478	97	5347	1.11	(0.83, 1.49)
Neuro/CVA	Quetiapine	2	116	5478	44	2057	1.11	(0.76, 1.59)
Neuro/CVA	Risperidone	2	116	5478	229	9676	1.35	(1.07, 1.71)
Neuro/Fatigue	Olanzapine	1	0	20	0	20	NC	NC
Neuro/Fatigue	Risperidone	1	0	20	2	20	+Inf	(0.03, Inf+)
Neuro/Movement Disorder/Akathisia	Olanzapine	1	0	20	1	20	NC	NC
Neuro/Movement Disorder/Akathisia	Risperidone	1	0	20	0	20	NC	NC
Neuro/Movement Disorder/EPS	Olanzapine	1	4	20	0	20	0.00	(0.00, 1.42)
Neuro/Movement Disorder/EPS	Risperidone	1	4	20	2	20	0.23	(0.00, 2.65)
Neuro/Sedation	Olanzapine	1	2	20	6	20	4.01	(0.59, 46.77)
Neuro/Sedation	Risperidone	3	25	163	18	164	0.68	(0.33, 1.36)
Psychiatric/Sexual	Olanzapine	1	0	20	0	20	NC	NC
Psychiatric/Sexual	Risperidone	1	0	20	1	20	NC	NC
Psychiatric/Sleep	Olanzapine	1	0	20	0	20	NC	NC
Psychiatric/Sleep	Risperidone	1	0	20	1	20	NC	NC
Urinary	Risperidone	1	0	29	1	29	+Inf	(0.03, Inf+)

NC = Not Calculated

Table E. Dementia studies – Atypical Antipsychotic Compared to Another Atypical Antipsychotic

Adverse Events	Atypical antipsychotic 1	Atypical antipsychotic 2	# of studies	Atypical antipsychotic 1		Atypical antipsychotic 2		Pooled OR	95% CI
				# adverse events	sample size	# adverse events	sample size		
Cardiovascular/Rhythm	Risperidone	Olanzapine	1	0	19	1	20	+Inf	(0.02, Inf+)
Gastrointestinal	Risperidone	Olanzapine	1	1	20	0	20	NC	NC
Neuro	Quetiapine	Olanzapine	1	13	94	27	100	2.30	(1.34, 4.04)
Neuro	Risperidone	Olanzapine	1	13	85	27	100	2.04	(0.93, 4.67)
Neuro	Risperidone	Quetiapine	1	13	85	13	94	0.89	(0.35, 2.23)
Neuro/CVA	Quetiapine	Olanzapine	4	55	3877	105	14273	0.84	(0.66, 1.08)
Neuro/CVA	Risperidone	Olanzapine	3	60	11906	36	11854	0.71	(0.46, 1.10)
Neuro/CVA	Risperidone	Quetiapine	4	253	17445	55	3877	0.92	(0.67, 1.25)
Neuro/Fatigue	Quetiapine	Olanzapine	1	4	94	3	100	0.70	(0.20, 2.34)
Neuro/Fatigue	Risperidone	Olanzapine	1	3	85	3	100	0.85	(0.11, 6.49)
Neuro/Fatigue	Risperidone	Quetiapine	1	3	85	4	94	1.21	(0.20, 8.53)
Neuro/Headache	Quetiapine	Olanzapine	1	1	94	5	100	4.88	(1.02, 46.38)
Neuro/Headache	Risperidone	Olanzapine	1	5	85	5	100	0.84	(0.19, 3.80)
Neuro/Headache	Risperidone	Quetiapine	1	5	85	1	94	0.17	(0.00, 1.60)
Neuro/Movement Disorder/EPS	Quetiapine	Olanzapine	1	2	94	12	100	6.25	(2.09, 25.27)
Neuro/Movement Disorder/EPS	Risperidone	Olanzapine	1	10	85	12	100	1.02	(0.38, 2.81)
Neuro/Movement Disorder/EPS	Risperidone	Quetiapine	1	10	85	2	94	0.16	(0.02, 0.81)
Neuro/Movement Disorder/Gait	Quetiapine	Olanzapine	1	3	94	4	100	1.26	(0.38, 4.51)
Neuro/Movement Disorder/Gait	Risperidone	Olanzapine	1	1	85	4	100	3.48	(0.34, 174.38)
Neuro/Movement Disorder/Gait	Risperidone	Quetiapine	1	1	85	3	94	2.75	(0.22, 147.08)
Neuro/Movement Disorder/Tardive Dyskinesia	Quetiapine	Olanzapine	1	2	94	3	100	1.42	(0.33, 6.96)
Neuro/Movement Disorder/Tardive Dyskinesia	Risperidone	Olanzapine	1	3	85	3	100	0.85	(0.11, 6.49)
Neuro/Movement Disorder/Tardive Dyskinesia	Risperidone	Quetiapine	1	3	85	2	94	0.60	(0.05, 5.34)
Neuro/Sedation	Quetiapine	Olanzapine	1	21	94	24	100	1.10	(0.67, 1.81)
Neuro/Sedation	Risperidone	Olanzapine	3	52	352	77	388	1.47	(0.98, 2.22)
Neuro/Sedation	Risperidone	Quetiapine	1	13	85	21	94	1.59	(0.70, 3.74)
Psychiatric/Agitation	Quetiapine	Olanzapine	1	11	94	7	100	0.57	(0.26, 1.21)
Psychiatric/Agitation	Risperidone	Olanzapine	1	5	85	7	100	1.20	(0.31, 5.00)
Psychiatric/Agitation	Risperidone	Quetiapine	1	5	85	11	94	2.11	(0.64, 8.11)
Psychiatric/Anxiety	Quetiapine	Olanzapine	1	0	94	3	100	+Inf	(1.12, Inf+)

NC = Not Calculated

Table E. Dementia studies – Atypical Antipsychotic Compared to Another Atypical Antipsychotic - continued

Adverse Events	Atypical antipsychotic 1	Atypical antipsychotic 2	# of studies	Atypical antipsychotic 1		Atypical antipsychotic 2		Pooled OR	95% CI
				# adverse events	sample size	# adverse events	sample size		
Psychiatric/Anxiety	Risperidone	Olanzapine	1	0	85	3	100	+Inf	(0.35, Inf+)
Psychiatric/Anxiety	Risperidone	Quetiapine	1	0	85	0	94	NC	NC
Psychiatric/Cognitive	Quetiapine	Olanzapine	1	0	94	5	100	+Inf	(2.17, Inf+)
Psychiatric/Cognitive	Risperidone	Olanzapine	1	1	85	5	100	4.39	(0.48, 211.54)
Psychiatric/Cognitive	Risperidone	Quetiapine	1	1	85	0	94	0.00	(0.00, 35.27)
Psychiatric/Depression	Quetiapine	Olanzapine	1	2	94	4	100	1.91	(0.50, 8.83)
Psychiatric/Depression	Risperidone	Olanzapine	1	0	85	4	100	+Inf	(0.57, Inf+)
Psychiatric/Depression	Risperidone	Quetiapine	1	0	85	2	94	+Inf	(0.17, Inf+)
Psychiatric/Psychotic	Quetiapine	Olanzapine	1	0	94	7	100	+Inf	(3.28, Inf+)
Psychiatric/Psychotic	Risperidone	Olanzapine	1	0	85	7	100	+Inf	(1.27, Inf+)
Psychiatric/Psychotic	Risperidone	Quetiapine	1	0	85	0	94	NC	NC
Psychiatric/Sleep	Quetiapine	Olanzapine	1	5	94	5	100	0.94	(0.34, 2.57)
Psychiatric/Sleep	Risperidone	Olanzapine	1	4	85	5	100	1.07	(0.22, 5.56)
Psychiatric/Sleep	Risperidone	Quetiapine	1	4	85	5	94	1.14	(0.24, 5.93)
Trauma	Quetiapine	Olanzapine	1	7	94	17	100	2.54	(1.27, 5.32)
Trauma	Risperidone	Olanzapine	1	10	85	17	100	1.53	(0.62, 3.99)
Trauma	Risperidone	Quetiapine	1	10	85	7	94	0.61	(0.19, 1.86)

NC = Not Calculated

Table F. Dementia studies – Risperidone with Rivastigamine Compared to Rivastigamine

		Rivastigamine		Risperidone + Rivastigamine			
Adverse Events	# of studies	# adverse events	sample size	# adverse events	sample size	Pooled OR	95% CI
Appetite or Weight/Decrease	1	0	14	14	63	+Inf	(0.75, +Inf)
Gastrointestinal	1	10	14	30	63	0.40	(0.08, 1.60)
Neuro/Fatigue	1	2	14	17	63	4.12	(0.53, 189.40)
Neuro/Movement Disorder/EPS	1	0	14	3	63	+Inf	(0.04, +Inf)
Neuro/Sedation	1	0	14	17	63	+Inf	(1.09, +Inf)
Psychiatric/Agitation	1	1	14	7	63	+Inf	(0.30, +Inf)

NC = Not Calculated

Table G. Autism/Tourette's studies – Atypical Antipsychotics Compared to Placebo

Adverse Events	Drug	# of studies	Placebo		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
Accidental Overdose	Risperidone	1	1	39	1	40	0.97	(0.01, 78.47)
Appetite or Weight/Decrease	Risperidone	3	7	109	8	105	1.20	(0.37, 4.03)
Appetite or Weight/Increase	Risperidone	3	20	149	56	144	5.94	(2.94, 12.62)
Cardiovascular/BP/Decrease	Risperidone	2	1	91	11	89	12.47	(1.75, 547.58)
Cardiovascular/Rhythm	Risperidone	1	1	52	0	49	0.00	(0.00, 41.39)
Constitutional/Fever or Infection	Risperidone	2	19	131	20	128	1.10	(0.52, 2.30)
Dermatologic	Risperidone	1	7	52	11	49	1.85	(0.59, 6.22)
Endocrine	Ziprasidone	1	0	12	1	16	+Inf	(0.02, Inf+)
Endocrine/Prolactin	Ziprasidone	1	0	12	5	16	+Inf	(0.78, Inf+)
Gastrointestinal	Risperidone	3	54	109	68	105	3.24	(1.41, 7.92)
HEENT	Risperidone	2	33	91	49	89	2.31	(1.19, 4.54)
HEENT/Decreased Salivation	Risperidone	1	5	52	9	49	2.10	(0.58, 8.66)
HEENT/Eye	Risperidone	1	0	18	2	16	+Inf	(0.21, Inf+)
HEENT/Increased Salivation	Risperidone	2	4	91	17	89	5.35	(1.63, 23.08)
Infections	Risperidone	2	8	91	20	89	3.12	(1.18, 9.02)
Liver Function Test Abnormality	Risperidone	1	2	52	1	49	0.52	(0.01, 10.37)
Neuro	Risperidone	2	5	70	8	65	1.81	(0.49, 7.40)
Neuro/Fatigue	Risperidone	3	16	109	39	105	4.40	(2.04, 9.94)
Neuro/Headache	Risperidone	2	8	91	14	89	1.96	(0.72, 5.72)
Neuro/Movement Disorder	Risperidone	1	0	79	3	79	+Inf	(0.42, Inf+)
Neuro/Movement Disorder/Akathisia	Ziprasidone	1	0	12	1	16	+Inf	(0.02, Inf+)
Neuro/Movement Disorder/EPS	Risperidone	2	9	131	34	128	4.85	(2.15, 12.08)
Neuro/Movement Disorder/Gait	Risperidone	1	2	39	0	40	0.00	(0.00, 5.17)
Neuro/Movement Disorder/Tardive Dyskinesia	Risperidone	2	5	91	6	89	1.27	(0.31, 5.55)
Neuro/Sedation	Risperidone	3	10	109	56	105	12.09	(5.40, 29.61)
Neuro/Sedation	Ziprasidone	1	5	12	12	16	3.97	(0.66, 28.56)
Psychiatric	Risperidone	1	0	18	2	16	+Inf	(0.21, Inf+)
Psychiatric/Aggression	Risperidone	1	0	39	1	40	+Inf	(0.02, Inf+)
Psychiatric/Agitation	Risperidone	1	3	52	3	49	1.06	(0.14, 8.36)

NC = Not Calculated

Table G. Autism/Tourette's studies – Atypical Antipsychotics Compared to Placebo (continued)

Adverse Events	Drug	# of studies	Placebo		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
Psychiatric/Anxiety	Risperidone	1	10	52	12	49	1.36	(0.47, 3.96)
Psychiatric/Apathy	Risperidone	1	0	39	5	40	+Inf	(0.94, Inf+)
Psychiatric/Cognitive	Risperidone	1	0	18	2	16	+Inf	(0.21, Inf+)
Psychiatric/Sexual/Decreased Function	Risperidone	1	0	18	2	16	+Inf	(0.21, Inf+)
Psychiatric/Sleep	Risperidone	3	31	110	25	104	0.78	(0.39, 1.57)
Thirst	Risperidone	1	5	52	6	49	1.31	(0.31, 5.84)
Urinary	Risperidone	1	15	52	15	49	1.09	(0.42, 2.79)

NC = Not Calculated

Table H. Autism/Tourette's studies – Atypical Antipsychotics Compared to Clondine

Adverse Events	Drug	# of studies	Clonidine		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
HEENT/Decreased Salivation	Risperidone	1	1	12	0	9	0.00	(0.00, 52.00)
Neuro	Risperidone	1	2	12	1	9	0.64	(0.01, 14.44)
Neuro/Movement Disorder/EPS	Risperidone	1	1	12	2	9	2.97	(0.13, 201.94)
Neuro/Sedation	Risperidone	1	5	12	1	9	0.19	(0.00, 2.32)

NC = Not Calculated

Table I. Autism/Tourette's studies – Atypical Antipsychotics Compared to Conventional Antipsychotics

Adverse Events	Drug	# of studies	Conventionals		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
Appetite or Weight/Decrease	Olanzapine	1	1	6	0	6	0.00	(0.00, 39.00)
Appetite or Weight/Increase	Olanzapine	1	5	6	6	6	+Inf	(0.03, Inf+)
Appetite or Weight/Increase	Risperidone	1	20	24	22	26	1.10	(0.18, 6.75)
Cardiovascular/BP/Decrease	Olanzapine	1	1	6	0	6	0.00	(0.00, 39.00)
Dermatologic	Olanzapine	1	1	6	0	6	0.00	(0.00, 39.00)
Gastrointestinal	Olanzapine	1	0	6	2	6	+Inf	(0.19, Inf+)
HEENT/Decreased Salivation	Olanzapine	1	1	6	1	6	1.00	(0.01, 94.01)
Neuro/Fatigue	Risperidone	1	9	24	10	26	1.04	(0.29, 3.81)
Neuro/Headache	Risperidone	1	2	24	5	26	2.57	(0.37, 29.80)
Neuro/Movement Disorder	Risperidone	1	5	24	2	26	0.32	(0.03, 2.25)
Neuro/Movement Disorder/EPS	Olanzapine	1	2	6	0	6	0.00	(0.00, 5.16)
Neuro/Movement Disorder/EPS	Risperidone	1	8	24	4	26	0.37	(0.07, 1.68)
Neuro/Movement Disorder/Gait	Olanzapine	1	1	6	0	6	0.00	(0.00, 39.00)
Neuro/Movement Disorder/Tardive Dyskinesia	Olanzapine	1	0	6	0	6	NC	NC
Neuro/Sedation	Olanzapine	1	2	6	5	6	7.96	(0.43, 588.32)
Neuro/Sedation	Risperidone	1	10	24	12	26	1.20	(0.34, 4.25)
Psychiatric/Depression	Risperidone	1	6	24	8	26	1.33	(0.33, 5.68)
Psychiatric/Sleep	Olanzapine	1	0	6	1	6	+Inf	(0.03, Inf+)
Psychiatric/Sleep	Risperidone	1	7	24	1	26	0.10	(0.00, 0.90)
Trauma	Risperidone	1	6	24	1	26	0.12	(0.00, 1.16)
Urinary	Olanzapine	1	1	6	1	6	1.00	(0.01, 94.01)

NC = Not Calculated

Table J. Depression/OCD/PD/PTSD studies – Atypical Antipsychotics Compared to Placebo

Adverse Events	Drug	# of studies	Placebo		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
Appetite or Weight/Increase	Olanzapine	5	33	575	213	580	11.16	(7.40, 17.24)
Appetite or Weight/Increase	Quetiapine	1	2	21	2	21	1.00	(0.07, 15.13)
Appetite or Weight/Increase	Risperidone	1	0	19	3	20	+Inf	(0.40, Inf+)
Appetite or Weight/Increase	Ziprasidone	1	0	92	2	210	+Inf	(0.08, Inf+)
Cardiovascular	Olanzapine	1	0	100	7	101	+Inf	(1.21, Inf+)
Cardiovascular	Ziprasidone	1	0	48	2	91	+Inf	(0.10, Inf+)
Cardiovascular/BP/Decrease	Olanzapine	1	5	377	5	370	1.02	(0.23, 4.47)
Cardiovascular/BP/Decrease	Ziprasidone	1	0	92	3	210	+Inf	(0.18, Inf+)
Cardiovascular/BP/Increase	Olanzapine	1	6	377	2	370	0.34	(0.03, 1.90)
Cardiovascular/Rhythm	Olanzapine	1	1	377	1	370	1.02	(0.01, 80.20)
Dermatologic	Ziprasidone	1	0	48	7	91	+Inf	(0.78, Inf+)
Endocrine/Diabetes	Olanzapine	2	86	10673	20	3073	0.80	(0.46, 1.32)
Endocrine/Diabetes	Quetiapine	1	85	10296	3	922	0.39	(0.08, 1.19)
Endocrine/Diabetes	Risperidone	1	85	10296	5	2860	0.21	(0.07, 0.51)
Endocrine/Prolactin	Risperidone	1	0	10	1	15	+Inf	(0.02, Inf+)
Gastrointestinal	Olanzapine	5	78	615	70	615	0.86	(0.60, 1.24)
Gastrointestinal	Quetiapine	2	10	202	43	382	2.45	(1.18, 5.61)
Gastrointestinal	Risperidone	1	0	18	1	19	+Inf	(0.02, Inf+)
Gastrointestinal	Ziprasidone	2	61	140	131	301	0.97	(0.63, 1.50)
HEENT	Ziprasidone	1	1	48	4	91	2.15	(0.21, 108.65)
HEENT/Decreased Salivation	Olanzapine	4	40	606	93	596	2.71	(1.80, 4.13)
HEENT/Decreased Salivation	Quetiapine	2	14	202	161	393	8.90	(4.93, 17.27)
HEENT/Decreased Salivation	Risperidone	1	1	6	2	10	1.23	(0.05, 88.30)
HEENT/Decreased Salivation	Ziprasidone	1	4	92	17	210	1.93	(0.61, 8.13)
HEENT/Eye	Olanzapine	1	5	100	1	101	0.19	(0.00, 1.77)
Liver Function Test Abnormality	Olanzapine	2	0	169	12	171	+Inf	(3.16, Inf+)
Liver Function Test Abnormality	Ziprasidone	1	0	48	1	91	+Inf	(0.01, Inf+)
Musculoskeletal	Quetiapine	1	0	21	1	21	+Inf	(0.03, Inf+)

NC = Not Calculated

Table J. Depression/OCD/PD/PTSD studies – Atypical Antipsychotics Compared to Placebo (continued)

Adverse Events	Drug	# of studies	Placebo		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
Neuro	Aripiprazol	1	14	83	6	78	0.41	(0.12, 1.22)
Neuro	Olanzapine	2	8	129	23	125	3.36	(1.38, 9.08)
Neuro	Quetiapine	2	26	202	81	393	1.81	(1.08, 3.10)
Neuro	Risperidone	1	0	6	1	10	+Inf	(0.02, Inf+)
Neuro	Ziprasidone	2	9	140	31	301	1.61	(0.72, 3.99)
Neuro/Fatigue	Olanzapine	3	20	506	55	495	2.98	(1.72, 5.35)
Neuro/Fatigue	Quetiapine	1	4	21	4	32	0.71	(0.09, 4.92)
Neuro/Fatigue	Risperidone	1	0	10	1	15	+Inf	(0.02, Inf+)
Neuro/Fatigue	Ziprasidone	1	0	48	3	91	+Inf	(0.22, Inf+)
Neuro/Headache	Olanzapine	3	94	506	68	495	0.69	(0.48, 0.98)
Neuro/Headache	Ziprasidone	2	40	140	68	301	0.72	(0.44, 1.17)
Neuro/Movement Disorder	Olanzapine	1	0	9	0	19	NC	NC
Neuro/Movement Disorder/Akathisia	Aripiprazol	1	1	83	5	78	+Inf	(1.00, Inf+)
Neuro/Movement Disorder/Akathisia	Risperidone	1	0	18	1	19	+Inf	(0.02, Inf+)
Neuro/Movement Disorder/Akathisia	Ziprasidone	2	9	140	32	301	1.69	(0.76, 4.15)
Neuro/Movement Disorder/EPS	Aripiprazol	1	1	83	0	78	NC	NC
Neuro/Movement Disorder/EPS	Olanzapine	1	0	9	1	19	+Inf	(0.01, Inf+)
Neuro/Movement Disorder/EPS	Risperidone	1	1	10	0	15	0.00	(0.00, 26.00)
Neuro/Movement Disorder/EPS	Ziprasidone	2	5	140	26	301	3.32	(1.12, 13.41)
Neuro/Movement Disorder/Tardive Dyskinesia	Olanzapine	1	0	9	0	19	NC	NC
Neuro/Pain	Olanzapine	1	3	69	8	70	2.82	(0.64, 17.24)
Neuro/Pain	Ziprasidone	2	12	140	26	301	1.02	(0.48, 2.29)
Neuro/Sedation	Aripiprazol	1	6	83	4	78	0.84	(0.16, 4.09)
Neuro/Sedation	Olanzapine	7	72	644	179	645	3.02	(2.21, 4.14)
Neuro/Sedation	Quetiapine	2	33	202	227	393	7.33	(4.69, 11.73)
Neuro/Sedation	Risperidone	3	0	35	11	45	+Inf	(2.55, Inf+)
Neuro/Sedation	Ziprasidone	2	9	140	47	301	2.64	(1.23, 6.33)

NC = Not Calculated

Table J. Depression/OCD/PD/PTSD studies – Atypical Antipsychotics Compared to Placebo (continued)

Adverse Events	Drug	# of studies	Placebo		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
Neuro/Speech Disorder	Quetiapine	1	0	21	1	21	+Inf	(0.03, Inf+)
Psychiatric	Olanzapine	2	15	129	6	125	0.38	(0.12, 1.09)
Psychiatric	Quetiapine	1	1	21	1	21	1.00	(0.01, 82.37)
Psychiatric/Aggression	Olanzapine	2	14	129	7	125	0.48	(0.16, 1.33)
Psychiatric/Agitation	Aripiprazol	1	9	83	5	78	0.57	(0.14, 1.99)
Psychiatric/Agitation	Olanzapine	2	31	129	18	125	0.53	(0.26, 1.05)
Psychiatric/Agitation	Ziprasidone	2	16	140	22	301	0.60	(0.29, 1.27)
Psychiatric/Anxiety	Aripiprazol	1	17	83	22	78	1.43	(0.65, 3.20)
Psychiatric/Anxiety	Olanzapine	3	67	506	62	495	0.92	(0.62, 1.37)
Psychiatric/Cognitive	Quetiapine	1	0	21	3	21	+Inf	(0.43, Inf+)
Psychiatric/Depression	Aripiprazol	1	12	83	9	78	0.75	(0.25, 2.19)
Psychiatric/Depression	Olanzapine	1	8	69	9	70	1.12	(0.36, 3.59)
Psychiatric/Irritability	Quetiapine	1	1	21	2	21	2.07	(0.10, 130.31)
Psychiatric/Mania	Aripiprazol	1	11	83	5	78	0.40	(0.09, 1.45)
Psychiatric/Mania	Quetiapine	1	7	181	9	361	0.63	(0.21, 2.04)
Psychiatric/Psychotic	Olanzapine	1	10	45	4	50	0.23	(0.04, 0.96)
Psychiatric/Self-injurious behavior	Olanzapine	1	0	9	0	19	NC	NC
Psychiatric/Sexual/Decreased Function	Quetiapine	1	0	21	1	21	+Inf	(0.03, Inf+)
Psychiatric/Sexual/Decreased Function	Risperidone	2	1	16	1	25	0.63	(0.01, 49.71)
Psychiatric/Sexual/Decreased Function	Ziprasidone	1	0	92	2	210	+Inf	(0.08, Inf+)
Psychiatric/Sleep	Aripiprazol	1	17	83	12	78	0.76	(0.30, 1.87)
Psychiatric/Sleep	Olanzapine	2	77	477	39	471	0.46	(0.30, 0.71)
Psychiatric/Sleep	Ziprasidone	2	15	140	26	301	0.74	(0.36, 1.58)
Psychiatric/Suicidal Ideation	Aripiprazol	1	0	26	0	26	NC	NC
Psychiatric/Suicidal Ideation	Olanzapine	1	0	9	0	19	NC	NC
Psychiatric/Suicidal Ideation	Risperidone	1	0	10	1	15	+Inf	(0.02, Inf+)
Pulmonary	Ziprasidone	1	2	48	8	91	2.21	(0.42, 22.18)
Urinary	Risperidone	1	0	8	1	8	+Inf	(0.03, Inf+)

NC = Not Calculated

Table K. Depression/OCD/PD/PTSD studies – Atypical Antipsychotics Compared to Conventional Antipsychotics

			Conventionals		Intervention Groups			
Adverse Events	Drug	# of studies	# adverse events	sample size	# adverse events	sample size	Pooled OR	95% CI
Appetite or Weight/Decrease	Olanzapine	1	115	636	149	1306	0.58	(0.44, 0.77)
Appetite or Weight/Increase	Aripiprazol	1	14	431	44	859	1.61	(0.85, 3.21)
Appetite or Weight/Increase	Olanzapine	2	112	768	392	1437	2.59	(2.02, 3.34)
Cardiovascular/Rhythm	Olanzapine	1	63	636	86	1306	0.64	(0.45, 0.92)
Constitutional	Olanzapine	1	36	636	45	1306	0.59	(0.37, 0.96)
Constitutional/Fever or Infection	Olanzapine	1	48	636	56	1306	0.55	(0.36, 0.84)
Endocrine/Diabetes	Olanzapine	1	7	2756	15	2703	2.19	(0.84, 6.36)
Endocrine/Diabetes	Quetiapine	1	7	2756	3	922	1.28	(0.21, 5.63)
Endocrine/Diabetes	Risperidone	1	7	2756	5	2860	0.69	(0.17, 2.52)
Gastrointestinal	Olanzapine	2	161	768	209	1437	0.60	(0.48, 0.77)
HEENT/Decreased Salivation	Olanzapine	1	103	636	290	1306	1.48	(1.15, 1.91)
HEENT/Eye	Olanzapine	1	96	636	139	1306	0.67	(0.50, 0.90)
HEENT/Increased Salivation	Olanzapine	1	124	636	113	1306	0.39	(0.29, 0.52)
Heme	Olanzapine	1	0	132	6	131	+Inf	(1.22, Inf+)
Musculoskeletal	Olanzapine	1	16	132	4	131	0.25	(0.06, 0.80)
Neuro	Aripiprazol	1	38	431	65	859	0.85	(0.55, 1.32)
Neuro/Fatigue	Olanzapine	1	104	636	150	1306	0.66	(0.50, 0.88)
Neuro/Movement Disorder	Olanzapine	1	115	636	102	1306	0.38	(0.29, 0.52)
Neuro/Movement Disorder/Akathisia	Aripiprazol	1	108	431	111	859	0.44	(0.33, 0.60)
Neuro/Movement Disorder/Akathisia	Olanzapine	2	266	768	203	1437	0.31	(0.25, 0.38)
Neuro/Movement Disorder/EPS	Aripiprazol	1	171	431	118	859	0.24	(0.18, 0.32)
Neuro/Movement Disorder/EPS	Olanzapine	2	389	768	369	1437	0.29	(0.24, 0.36)
Neuro/Movement Disorder/Gait	Olanzapine	1	20	636	22	1306	0.53	(0.27, 1.03)
Neuro/Sedation	Aripiprazol	1	32	431	43	859	0.66	(0.40, 1.09)
Neuro/Sedation	Olanzapine	1	199	636	339	1306	0.77	(0.62, 0.95)
Psychiatric	Olanzapine	1	15	636	13	1306	0.42	(0.18, 0.94)
Psychiatric/Agitation	Aripiprazol	1	30	431	53	859	0.88	(0.54, 1.45)

NC = Not Calculated

Table K. Depression/OCD/PD/PTSD studies – Atypical Antipsychotics Compared to Conventional Antipsychotics (continued)

Adverse Events	Drug	# of studies	Conventionals		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
Psychiatric/Anxiety	Aripiprazol	1	50	431	108	859	1.10	(0.76, 1.60)
Psychiatric/Anxiety	Olanzapine	1	51	132	27	131	0.41	(0.22, 0.73)
Psychiatric/Lability	Olanzapine	1	7	132	10	131	1.55	(0.48, 5.45)
Psychiatric/Psychotic	Aripiprazol	1	70	431	156	859	1.14	(0.83, 1.58)
Psychiatric/Sleep	Aripiprazol	1	88	431	185	859	1.07	(0.80, 1.44)
Psychiatric/Sleep	Olanzapine	1	632	636	1122	1306	0.03	(0.01, 0.09)
Sweating	Olanzapine	1	84	636	89	1306	0.48	(0.35, 0.67)
Urinary	Olanzapine	1	39	636	47	1306	0.57	(0.36, 0.91)

NC = Not Calculated

Table L. Depression/OCD/PD/PTSD studies – Atypical Antipsychotics Compared to Mood Stabilizers

			Mood Stabilizers		Intervention Groups			
Adverse Events	Drug	# of studies	# adverse events	sample size	# adverse events	sample size	Pooled OR	95% CI
Gastrointestinal	Quetiapine	1	0	14	2	14	+Inf	(0.19, Inf+)
HEENT	Olanzapine	1	0	126	6	125	+Inf	(1.21, Inf+)
HEENT/Decreased Salivation	Olanzapine	1	8	126	42	125	7.41	(3.22, 19.23)
Heme/Low platelets	Olanzapine	1	10	126	0	125	0.00	(0.00, 0.42)
Liver Function Test Abnormality	Olanzapine	1	0	126	6	125	+Inf	(1.22, Inf+)
Neuro	Olanzapine	1	15	126	20	125	1.41	(0.65, 3.12)
Neuro/Fatigue	Olanzapine	1	17	126	20	125	1.22	(0.57, 2.63)
Neuro/Headache	Olanzapine	2	40	340	37	342	0.91	(0.54, 1.54)
Neuro/Movement Disorder/EPS	Olanzapine	1	6	126	21	125	4.02	(1.50, 12.64)
Neuro/Pain	Olanzapine	1	18	126	17	125	0.94	(0.43, 2.06)
Neuro/Sedation	Olanzapine	2	26	340	55	342	2.81	(1.59, 5.07)
Neuro/Sedation	Quetiapine	1	0	14	2	14	+Inf	(0.19, Inf+)
Neuro/Speech Disorder	Olanzapine	1	1	126	10	125	10.79	(1.49, 475.41)
Psychiatric/Agitation	Olanzapine	1	14	126	14	125	1.01	(0.42, 2.40)
Psychiatric/Anxiety	Olanzapine	2	31	340	25	342	0.79	(0.43, 1.42)
Psychiatric/Depression	Olanzapine	1	25	214	45	217	1.97	(1.13, 3.51)
Psychiatric/Mania	Olanzapine	1	44	214	17	217	0.33	(0.17, 0.61)
Psychiatric/Sleep	Olanzapine	2	49	340	24	342	0.43	(0.25, 0.75)

NC = Not Calculated

Table M. Depression/OCD/PD/PTSD studies – Atypical Antipsychotics Compared to SRIs

Adverse Events	Drug	# of studies	SRI		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
Cardiovascular	Risperidone	1	0	10	1	10	+Inf	(0.03, Inf+)
Dermatologic	Risperidone	1	1	10	1	10	1.00	(0.01, 87.11)
Gastrointestinal	Risperidone	1	7	10	5	10	0.45	(0.05, 3.67)
Gastrointestinal	Ziprasidone	1	0	21	9	43	+Inf	(1.07, Inf+)
HEENT	Ziprasidone	1	0	21	3	43	+Inf	(0.20, Inf+)
HEENT/Decreased Salivation	Olanzapine	1	4	60	10	62	2.36	(0.61, 11.16)
HEENT/Decreased Salivation	Risperidone	1	3	10	1	10	0.28	(0.00, 4.35)
HEENT/Decreased Salivation	Ziprasidone	1	0	21	6	43	+Inf	(0.60, Inf+)
HEENT/Eye	Risperidone	1	0	10	0	10	NC	NC
HEENT/Eye	Ziprasidone	1	0	21	5	43	+Inf	(0.46, Inf+)
HEENT/Increased Salivation	Risperidone	1	0	10	0	10	NC	NC
Infections	Ziprasidone	1	0	21	5	43	+Inf	(0.46, Inf+)
Musculoskeletal	Risperidone	1	0	10	1	10	+Inf	(0.03, Inf+)
Neuro	Olanzapine	2	16	74	12	78	0.66	(0.25, 1.68)
Neuro	Risperidone	1	1	10	0	10	0.00	(0.00, 39.00)
Neuro	Ziprasidone	1	1	21	15	43	10.42	(1.38, 473.14)
Neuro/Fatigue	Olanzapine	1	5	60	11	62	3.00	(0.82, 13.75)
Neuro/Fatigue	Risperidone	1	2	10	2	10	1.00	(0.06, 17.08)
Neuro/Fatigue	Ziprasidone	1	0	21	9	43	+Inf	(1.07, Inf+)
Neuro/Headache	Risperidone	1	1	10	1	10	1.00	(0.01, 87.11)
Neuro/Movement Disorder	Olanzapine	1	0	14	0	16	NC	NC
Neuro/Movement Disorder	Risperidone	1	0	10	1	10	+Inf	(0.03, Inf+)
Neuro/Movement Disorder/Akathisia	Olanzapine	1	5	14	4	16	0.61	(0.09, 3.78)
Neuro/Movement Disorder/EPS	Risperidone	1	1	10	1	10	1.00	(0.01, 87.11)
Neuro/Movement Disorder/EPS	Ziprasidone	1	1	21	7	43	3.82	(0.44, 183.88)
Neuro/Movement Disorder/Tardive Dyskinesia	Olanzapine	1	0	14	0	16	NC	NC
Neuro/Pain	Ziprasidone	1	0	21	4	43	+Inf	(0.32, Inf+)

NC = Not Calculated

Table M. Depression/OCD/PD/PTSD studies – Atypical Antipsychotics Compared to SRIs (continued)

Adverse Events	Drug	# of studies	SRI		Intervention Groups		Pooled OR	95% CI
			# adverse events	sample size	# adverse events	sample size		
Neuro/Sedation	Olanzapine	2	6	74	23	78	6.04	(1.95, 22.41)
Neuro/Sedation	Risperidone	1	2	10	5	10	3.72	(0.40, 53.84)
Neuro/Sedation	Ziprasidone	1	2	21	8	43	2.15	(0.37, 22.77)
Neuro/Sensory	Risperidone	1	0	10	0	10	NC	NC
Psychiatric/Agitation	Risperidone	1	0	10	0	10	NC	NC
Psychiatric/Agitation	Ziprasidone	1	0	21	9	43	+Inf	(1.07, Inf+)
Psychiatric/Anxiety	Risperidone	1	0	10	1	10	+Inf	(0.03, Inf+)
Psychiatric/Anxiety	Ziprasidone	1	2	21	0	43	0.00	(0.00, 2.55)
Psychiatric/Cognitive	Risperidone	1	1	10	0	10	0.00	(0.00, 39.00)
Psychiatric/Cognitive	Ziprasidone	1	0	21	4	43	+Inf	(0.32, Inf+)
Psychiatric/Depression	Risperidone	1	0	10	0	10	NC	NC
Psychiatric/Sexual/Decreased Function	Risperidone	1	2	10	0	10	0.00	(0.00, 5.23)
Psychiatric/Sexual/Decreased Function	Ziprasidone	1	1	21	0	43	0.00	(0.00, 19.05)
Psychiatric/Sleep	Risperidone	1	2	10	1	10	0.46	(0.01, 10.51)
Psychiatric/Sleep	Ziprasidone	1	1	21	13	43	8.45	(1.10, 386.39)
Psychiatric/Suicide Attempt	Olanzapine	1	1	14	0	16	0.00	(0.00, 34.12)
Sweating	Risperidone	1	1	10	1	10	1.00	(0.01, 87.11)
Urinary	Risperidone	1	1	10	0	10	0.00	(0.00, 39.00)

NC = Not Calculated

Table N. Depression/OCD/PD/PTSD studies – Atypical Antipsychotics Compared to Tricyclic Antidepressants

			Tricyclic Antidepressants		Intervention Groups			
Adverse Events	Drug	# of studies	# adverse events	sample size	# adverse events	sample size	Pooled OR	95% CI
Cardiovascular/BP/Decrease	Olanzapine	1	10	20	4	20	0.26	(0.05, 1.21)
Endocrine/Prolactin	Olanzapine	1	1	20	6	20	7.76	(0.80, 393.79)

NC = Not Calculated

Table O. Depression/OCD/PD/PTSD studies – Atypical Antipsychotics Compared to SNRIs

			SNRI		Intervention Groups			
Adverse Events	Drug	# of studies	# adverse events	sample size	# adverse events	sample size	Pooled OR	95% CI
Neuro/Fatigue	Olanzapine	1	5	59	11	62	2.94	(0.81, 13.51)
Neuro/Sedation	Olanzapine	1	5	59	11	62	2.94	(0.81, 13.51)

NC = Not Calculated

Table P. Depression/OCD/PD/PTSD studies – Atypical Antipsychotic Compared to Another Atypical Antipsychotic

Adverse Events	Atypical antipsychotic 1	Atypical antipsychotic 2	# of studies	Atypical antipsychotic 1		Atypical antipsychotic 2		Pooled OR	95% CI
				# adverse events	sample size	# adverse events	sample size		
Appetite or Weight/Decrease	Risperidone	Quetiapine	1	0	175	4	553	+Inf	(0.21, Inf+)
Appetite or Weight/Decrease	Ziprasidone	Olanzapine	1	10	192	2	202	0.18	(0.02, 0.87)
Appetite or Weight/Increase	Risperidone	Quetiapine	1	6	175	14	553	0.73	(0.26, 2.36)
Appetite or Weight/Increase	Ziprasidone	Olanzapine	1	19	192	62	202	4.02	(2.25, 7.48)
Cardiovascular	Ziprasidone	Olanzapine	2	7	328	16	335	2.39	(0.91, 7.01)
Constitutional	Ziprasidone	Olanzapine	1	52	136	39	133	0.67	(0.39, 1.15)
Constitutional/Fever or Infection	Ziprasidone	Olanzapine	1	5	192	0	202	0.00	(0.00, 1.42)
Dermatologic	Ziprasidone	Olanzapine	1	14	136	10	133	0.71	(0.27, 1.79)
Endocrine	Ziprasidone	Olanzapine	1	6	136	14	133	2.54	(0.88, 8.34)
Endocrine/Diabetes	Quetiapine	Olanzapine	1	3	922	15	2703	1.71	(0.70, 5.03)
Endocrine/Diabetes	Risperidone	Olanzapine	1	5	2860	15	2703	3.19	(1.10, 11.22)
Endocrine/Diabetes	Risperidone	Quetiapine	1	5	2860	3	922	1.86	(0.29, 9.60)
Gastrointestinal	Ziprasidone	Olanzapine	2	76	328	57	335	0.66	(0.43, 1.00)
HEENT/Bruxism	Ziprasidone	Olanzapine	1	4	192	0	202	0.00	(0.00, 1.42)
HEENT/Decreased Salivation	Risperidone	Quetiapine	1	12	175	80	553	2.30	(1.20, 4.75)
HEENT/Decreased Salivation	Ziprasidone	Olanzapine	1	20	192	32	202	1.56	(0.82, 3.01)
Heme	Ziprasidone	Olanzapine	1	3	136	5	133	1.73	(0.33, 11.36)
Musculoskeletal	Ziprasidone	Olanzapine	1	8	136	8	133	1.02	(0.32, 3.24)
Neuro	Risperidone	Quetiapine	1	12	175	70	553	1.97	(1.02, 4.09)
Neuro/Headache	Risperidone	Quetiapine	1	11	175	52	553	1.55	(0.77, 3.37)
Neuro/Headache	Ziprasidone	Olanzapine	1	25	192	32	202	1.21	(0.66, 2.24)
Neuro/Movement Disorder	Ziprasidone	Olanzapine	1	0	192	5	202	+Inf	(0.88, Inf+)
Neuro/Movement Disorder/EPS	Risperidone	Quetiapine	1	75	175	227	553	0.92	(0.64, 1.31)
Neuro/Sedation	Risperidone	Quetiapine	1	27	175	173	553	2.49	(1.57, 4.06)
Neuro/Sensory	Ziprasidone	Olanzapine	1	8	136	6	133	0.76	(0.21, 2.57)
Psychiatric/Agitation	Risperidone	Quetiapine	1	3	175	34	553	3.75	(1.16, 19.33)
Psychiatric/Anxiety	Ziprasidone	Olanzapine	1	82	136	64	133	0.61	(0.37, 1.02)
Psychiatric/Irritability	Ziprasidone	Olanzapine	1	7	192	2	202	0.26	(0.03, 1.42)
Psychiatric/Psychotic	Ziprasidone	Olanzapine	1	15	192	5	202	0.30	(0.08, 0.89)

NC = Not Calculated

Table P. Depression/OCD/PD/PTSD studies – Atypical Antipsychotic Compared to Another Atypical Antipsychotic (continued)

Adverse Events	Atypical antipsychotic 1	Atypical antipsychotic 2	# of studies	Atypical antipsychotic 1		Atypical antipsychotic 2		Pooled OR	95% CI
				# adverse events	sample size	# adverse events	sample size		
Psychiatric/Sleep	Risperidone	Quetiapine	1	17	175	65	553	1.24	(0.69, 2.32)
Psychiatric/Sleep	Ziprasidone	Olanzapine	1	35	192	25	202	0.66	(0.36, 1.19)
Pulmonary	Ziprasidone	Olanzapine	1	24	136	16	133	0.64	(0.30, 1.33)
Urinary	Ziprasidone	Olanzapine	1	9	136	5	133	0.55	(0.14, 1.90)

NC = Not Calculated

Table Q. Depression/OCD/PD/PTSD studies – Olanzapine with Fluoxetine Comapred to Fluoxetine

		Fluoxetine		Olanzapine + Fluoxetine			
Adverse Events	# of studies	# adverse events	sample size	# adverse events	sample size	Pooled OR	95% CI
Neuro	1	0	14	1	15	+Inf	(0.02, +Inf)
Neuro/Movement Disorder	1	0	14	0	15	NC	NC
Neuro/Movement Disorder/Akathisia	1	5	14	5	15	0.90	(0.15, 5.44)
Neuro/Movement Disorder/Tardive Dyskinesia	1	0	14	0	15	NC	NC
Neuro/Sedation	1	3	14	7	15	3.08	(0.50, 24.41)
Psychiatric/Suicide Attempt	1	1	14	0	15	0.00	(0.00, 36.40)

NC = Not Calculated

Table R. Depression/OCD/PD/PTSD studies – Quetiapine with Paraxetine Compared to Paraxetine

		Paroxetine		Quetiapine + Paraxetine			
Adverse Events	# of studies	# adverse events	sample size	# adverse events	sample size	Pooled OR	95% CI
Appetite or Weight/Increase	1	1	54	12	58	12.22	(1.66, 545.28)
Psychiatric/Anxiety	1	7	54	1	58	0.12	(0.00, 0.98)
Psychiatric/Sleep	1	17	54	0	58	0.00	(0.00, 0.18)

NC = Not Calculated

Table S. Depression/OCD/PD/PTSD studies – Risperidone with Paraxetine Compared to Paraxetine

		Paroxetine		Risperidone + Paroxetine			
Adverse Events	# of studies	# adverse events	sample size	# adverse events	sample size	Pooled OR	95% CI
Appetite or Weight/Decrease	1	1	10	0	10	0.00	(0.00, 39.00)
Appetite or Weight/Increase	1	3	10	6	10	3.27	(0.41, 33.28)
Cardiovascular	1	0	10	0	10	NC	NC
Dermatologic	1	1	10	0	10	0.00	(0.00, 39.00)
Gastrointestinal	1	7	10	3	10	0.20	(0.02, 1.68)
HEENT/Decreased Salivation	1	3	10	1	10	0.28	(0.00, 4.35)
HEENT/Eye	1	0	10	1	10	+Inf	(0.03, +Inf)
HEENT/Increased Salivation	1	0	10	1	10	+Inf	(0.03, +Inf)
Musculoskeletal	1	0	10	0	10	NC	NC
Neuro	1	1	10	1	10	1.00	(0.01, 87.11)
Neuro/Fatigue	1	2	10	1	10	0.46	(0.01, 10.51)
Neuro/Headache	1	1	10	0	10	0.00	(0.00, 39.00)
Neuro/Movement Disorder	1	0	10	0	10	NC	NC
Neuro/Movement Disorder/EPS	1	1	10	1	10	1.00	(0.01, 87.11)
Neuro/Sedation	1	2	10	2	10	1.00	(0.06, 17.08)
Neuro/Sensory	1	0	10	1	10	+Inf	(0.03, +Inf)
Psychiatric/Agitation	1	0	10	1	10	+Inf	(0.03, +Inf)
Psychiatric/Anxiety	1	0	10	0	10	NC	NC
Psychiatric/Cognitive	1	1	10	1	10	1.00	(0.01, 87.11)
Psychiatric/Depression	1	0	10	1	10	+Inf	(0.03, +Inf)
Psychiatric/Sexual/Decreased Function	1	2	10	3	10	1.67	(0.14, 25.60)
Psychiatric/Sleep	1	2	10	1	10	0.46	(0.01, 10.51)
Sweating	1	1	10	0	10	0.00	(0.00, 39.00)
Urinary	1	1	10	0	10	0.00	(0.00, 39.00)

NC = Not Calculated

Table T. Depression/OCD/PD/PTSD studies – Risperidone with SRI Compared to SRI

		SRI		Risperidone vs SRI			
Adverse Events	# of studies	# adverse events	sample size	# adverse events	sample size	Pooled OR	95% CI
Appetite or Weight/Increase	1	3	16	6	20	1.83	(0.31, 13.66)
Cardiovascular/Rhythm	1	1	16	0	20	0.00	(0.00, 31.20)
Gastrointestinal	1	1	16	1	20	0.79	(0.01, 66.06)
HEENT/Decreased Salivation	1	5	16	5	20	0.74	(0.13, 4.10)
HEENT/Eye	1	2	16	0	20	0.00	(0.00, 4.19)
Neuro	1	5	16	3	20	0.40	(0.05, 2.54)
Neuro/Headache	1	5	16	0	20	0.00	(0.00, 0.75)
Neuro/Movement Disorder/EPS	1	1	16	0	20	0.00	(0.00, 31.20)
Neuro/Sedation	1	8	16	17	20	5.37	(0.96, 40.18)
Psychiatric/Agitation	1	6	16	6	20	0.72	(0.14, 3.60)
Psychiatric/Sleep	1	1	16	1	20	0.79	(0.01, 66.06)
Sweating	1	4	16	1	20	0.17	(0.00, 1.94)
Urinary	1	0	16	1	20	+Inf	(0.02, +Inf)

NC = Not Calculated

Table U. Depression/OCD/PD/PTSD studies – Quetiapine with SRI Compared to SRI

		SRI		Quetiapine + SRI			
Adverse Events	# of studies	# adverse events	sample size	# adverse events	sample size	Pooled OR	95% CI
Appetite or Weight/Increase	1	0	20	10	20	+Inf	(3.43, +Inf)
Cardiovascular/Rhythm	1	2	20	0	20	0.00	(0.00, 5.28)
Gastrointestinal	2	2	33	6	34	3.36	(0.52, 38.17)
HEENT/Decreased Salivation	1	8	20	11	20	1.81	(0.44, 7.73)
Neuro	2	0	33	7	34	+Inf	(1.66, +Inf)
Neuro/Fatigue	1	0	20	2	20	+Inf	(0.19, +Inf)
Neuro/Headache	1	1	13	0	14	0.00	(0.00, 36.21)
Neuro/Pain	1	0	20	2	20	+Inf	(0.19, +Inf)
Neuro/Sedation	2	9	33	22	34	9.32	(2.16, 58.89)
Psychiatric	1	3	20	2	20	0.64	(0.05, 6.29)
Psychiatric/Anxiety	1	1	13	0	14	0.00	(0.00, 36.21)
Psychiatric/Cognitive	1	0	20	3	20	+Inf	(0.43, +Inf)
Psychiatric/Sleep	1	0	20	2	20	+Inf	(0.19, +Inf)
Sweating	1	6	20	2	20	0.27	(0.02, 1.80)

NC = Not Calculated