



**Universiteit Utrecht**



# Representation of people with intellectual disabilities in randomised controlled trials on antipsychotic treatment for behavioural problems

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# Population in RCTs versus population in clinical practice

- demographics and socio-economic status
- disease severity
- co-morbidity
- time patterns
- compliance



H.G. Leufkens and J. Urquhart (1994)

## People with intellectual disability (ID)

- Prevalence of ID in the general population  $\approx 1\%$
- Specific healthcare needs
- Prevalence of problematic behaviour 16% - 50% (depending on definition)
- Treatment with antipsychotics is common although evidence is lacking





# Aim

- **Frequency of people with intellectual disability in RCTs on antipsychotic treatment for behavioural problems**
- **Characteristics of included people with ID**

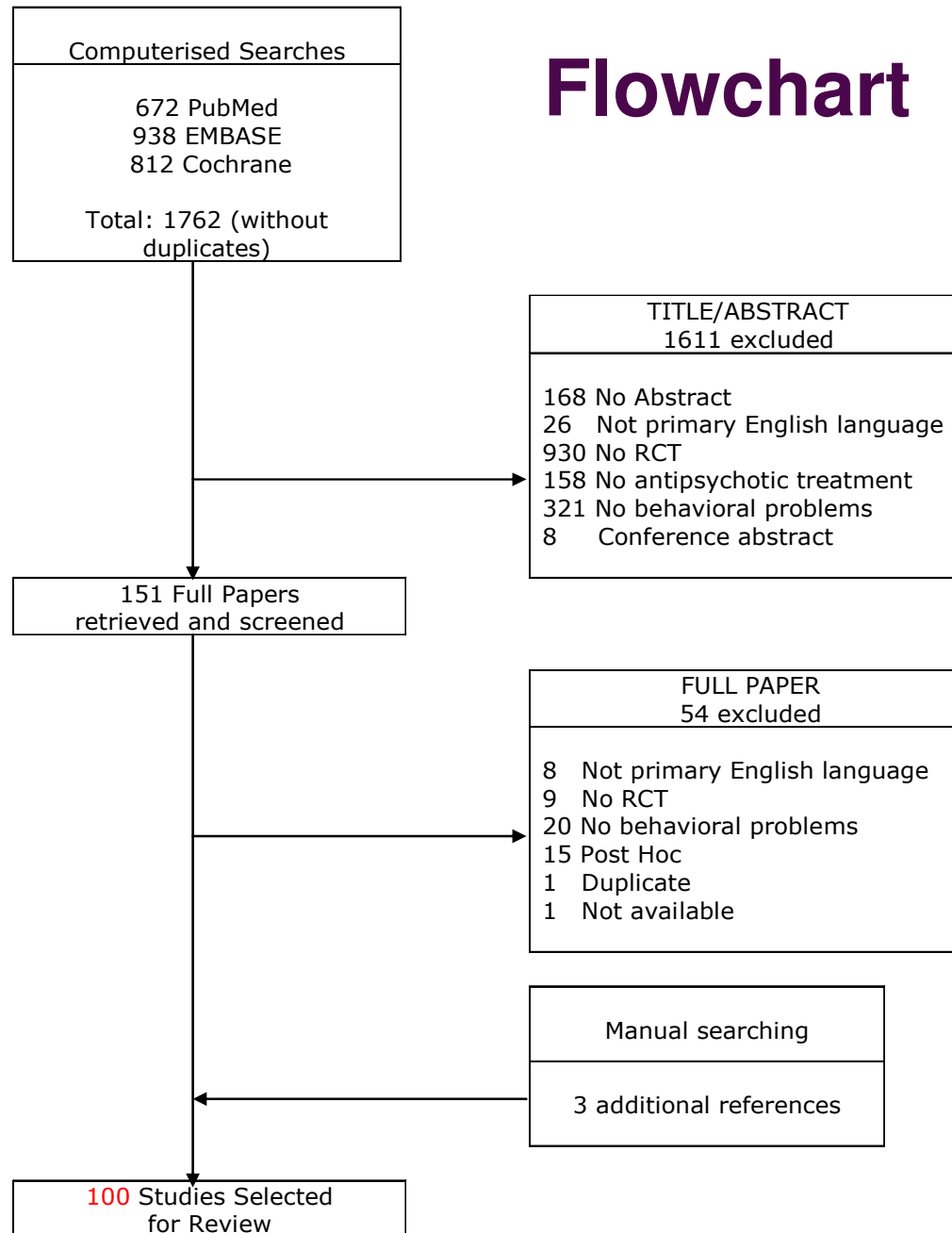


# Methods

- **Systematic literature search**
- **Embase, PubMed, Cochrane**
- **1966-2009**
- **Selection criteria:**
  - RCT in any population
  - Treatment with at least 1 antipsychotic
  - Outcome: effect on behavioural problems
- **Data extraction: size and nature of population, special focus on ID population**



# Flowchart





**Table 1: The characteristics of the included randomized controlled trials on antipsychotic treatment for behavioural problems**

Study characteristics		n (study)	n (patients)	n patients/ n study	range min-max
Study		100 (100%)	12,926 (100%)	129	11-1445
Year of publication	<1990	18 (18%)	1,325 (10%)	74	11-610
	1990-1999	24 (24%)	2,321 (18%)	97	20-625
	2000-2009	58 (58%)	9,280 (72%)	160	15-1445
Primary target population					
	Dementia/elderly	45 (45%)	5,580 (43%)	124	15-625
	Intellectual disability	21 (21%)	1,165 (9%)	55	11-160
	Schizophrenia	11 (11%)	4,111 (32%)	374	16-1445
	Personality disorder	6 (6%)	356 (3%)	59	24-108
	Bipolar disorder	3 (3%)	826 (6%)	275	20-773
	Post traumatic stress disorder	1 (1%)	15 (0%)	15	15-15
	Child behavior disorder**	13 (13%)	873 (7%)	67	19-335
Study drugs	antipsychotic + placebo	52 (52%)	7,685 (59%)	148	15-1187
	antipsychotic + antipsychotic	24 (24%)	3,341 (26%)	139	11-1445
	antipsychotic + other	24 (24%)	1,900 (15%)	79	20-610



**Table 2: Inclusion and exclusion of persons with intellectual disabilities in randomized controlled trials on antipsychotic treatment for behavioural problems.**

	Jadad < 3			Jadad ≥ 3		
	100 (n = 12,926)			80 (n = 10,877)		
	n study	n population	n ID	n study	n population	n ID
<b>ID as inclusion criterion</b>						
Studies with ID as sole target population	21 (21%)	1,165 (9%)	1,165 (9%)	18 (23%)	1,050 (10%)	1,050 (10%)
Studies with and without people with ID	6 (6%)	590 (5%)	302 (2%)	6 (8%)	590 (5%)	302 (3%)
<b>ID as exclusion criterion</b>						
	10 (10%)	2,364 (18%)		7 (9%)	1,796 (17%)	
<b>ID not mentioned as inclusion or exclusion criterion</b>						
	63 (63%)	8,807 (68%)	unknown	49 (61%)	7,441 (68%)	unknown



## 27 RCTs included people with ID

### Heterogenic group of patients

- Age
- Psychiatric diagnosis
- Range level of intellectual ability

### Heterogeneity in methodology

- Measurement scales tot asses the efficacy on behavioural problems
- Defining level of intellectual ability
- Follow-up time

### Heterogeneity in effect of medication



# Limitations

- **Definition of behavioural problems**
- **Exclusion of articles without abstracts**
- **Focus only on antipsychotics**



# Conclusion

- **ID in 1 out of 4 of the RCTs on antipsychotic treatment for behavioural problems**
- **ID trials small samples**
- **Meta-analysis impossible because of heterogeneity**
- **Insufficient evidence**



## Recommendations for future research

- **Assessing intellectual ability in a standardised way**
- **Study inclusion/exclusion criteria and nature of target populations in trials related to the actual population in clinical practice**
- **Perform good observational research with high quality**
- **Heterogeneity of problematic behaviour (aetiology) Use standardised scales**
- **Other psychotropic drugs antidepressants**



# Questions?

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