

Defining and Selecting Participants

The Inclusion - Exclusion Criteria
Form

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Who to Include

- Participants drawn from the population to which you wish to generalize
 - Patients with depression
 - Overweight patients with Type II diabetes
 - Schizophrenia patients with persistent psychotic symptoms
 - Families whose child has died in a disaster

Restrictive Criteria: Study of Family and Medication Treatment in Schizophrenia

- Population of interest:
 - Schizophrenia diagnosis
 - Significant engagement with family of origin
- Hypothesis:
 - Family and patient will master skills that will reduce stress and relapse and enhance coping

Study of Family and Antipsychotic Medication in Schizophrenia

- Inclusion Criteria

- Age 18 - 55
- Acutely symptomatic
- Diagnosis by DSM
- Consent from patient *and* family
- Willing to have home visits at family home
- four or more hours of family contact/week
- Male or female

- Exclusion Criteria

- Medical co-morbidity
 - epilepsy, organic brain syndrome, liver damage, pregnancy
- Current substance dependence
- Not transient
- Only medication will be study medication

Complex Inclusion Criteria: Comparison of Two Medications in Ambulatory Refractory Schizophrenia

- Population of interest:
 - Schizophrenia diagnosis
 - Symptomatic despite treatment with medication at adequate dose and duration
- Primary Hypothesis:
 - Clozapine, a medication restricted to refractory schizophrenia, will be more efficacious than risperidone, a novel medication in general use
- Secondary Hypothesis
 - Differences will be seen in narrowly and broadly defined inclusion groups

Case Example: Comparison of Two Medications in Ambulatory, Refractory Schizophrenia

- Inclusion criteria - all patients
 - Consent to randomization
 - Age 18 - 60
 - Schizophrenia diagnosis
 - Outpatient
 - Receiving anti-psychotic medication
 - Meet symptom severity criteria
 - History of failure to respond to both high and low dose

Case Example: Comparison of Two Medications in Ambulatory, Refractory Schizophrenia

- Exclusion Criteria - all patients
 - Neuroleptic malignant syndrome
 - Patient receives an agent with potential to suppress bone marrow function
 - CNS disease, bone marrow depression, blood dyscrasia, glaucoma, *significant* cardiovascular, renal or hepatic disease
 - Pregnant or unwilling to avoid pregnancy

Case Example: Comparison of Two Medications in Ambulatory, Refractory Schizophrenia

- Restrictive group
Exclusion Criteria
 - **No prior exposure to either medication**
 - **No current substance dependence**
 - **No concurrent other psychotropic medications**
- Broad group Inclusion Criteria
 - **No prior exposure to either medication**
 - **No current substance dependence**
 - **No concurrent other psychotropic medications**

Patients with depression

- Inclusion criteria
- Exclusion criteria

Overweight patients with Type II diabetes

- Inclusion criteria
- Exclusion criteria

Schizophrenia patients with persistent psychotic symptoms

- Inclusion criteria
- Exclusion criteria

Families whose child has died in a disaster

- Inclusion criteria
- Exclusion criteria