

# Comparison between extension of specialised early intervention for first episode psychosis and regular care: a randomised controlled trial

**Submission date**

20/03/2009

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☒ Protocol

**Registration date**

10/06/2009

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

06/07/2020

**Condition category**

Mental and Behavioural Disorders

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MCT-94189

# Study information

## Scientific Title

A randomised controlled evaluation of 'extended specialised early intervention service' versus 'regular care' for management of early psychosis over the five year critical period

## Acronym

PEPP RCT

## Study objectives

Primary hypothesis:

Individuals in the experimental group will show higher rates of symptomatic remission and experience longer periods of remission than the control group throughout the extension period of three years.

Secondary hypotheses:

1. The difference in remission rates will be mediated by the level of medication adherence in the two groups
2. As the experimental group is expected to have higher levels of working alliance with their treatment providers than the control group, we hypothesise that the difference in the level of medication adherence between the two groups and retention in treatment will be predicted by working alliance
3. The experimental group will have better clinical outcomes (lower relapse rates and levels of symptoms), functional outcomes (social/occupational functioning), and quality of life than the control group

Finally, we will assess the cost-effectiveness of extended specialised early intervention (SEI) versus the control intervention. A hypothesis for this is not easily justified as the determination of whether the greater benefits are worth the extra cost, if incurred, is a matter of judgement. Cost-effectiveness analysis serves to clarify just what additional resources are required to achieve a given degree of additional benefit.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Douglas Institute Research Ethics Board (REB) approved in June 2007; last modification approved in November 2008.

## Study design

Open-label randomised controlled design

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

First episode psychosis

**Interventions**

Experimental intervention: extended specialised early intervention service (SEI) - Patients randomised to the experimental condition will receive an extension of the SEI service beyond the current two years. It is important to recognise that it is the effectiveness of the total package of an extended SEI service, with its multiple components and not any single component of that model that is being tested. Individual treatment components included in the SEI extension are described below briefly with each component having its efficacy already well established in numerous controlled studies. The entire 'package' meets standards of optimum SEI service as outlined in the International Early Psychosis Association guidelines and has been proven to be effective after two years of delivery in several randomised controlled trials (RCTs) (e.g., the OPUS trial). In the proposed study, the SEI service will be extended for an additional three years for the experimental condition to cover the entire 'critical period'. Specifically, patients in the extended SEI service will receive the following:

1. Modified assertive case management
2. Continued emphasis on appropriate treatment goals
3. Continued family support and intervention
4. Cognitive Behaviour Therapy (CBT)
5. Treatment of problems associated with substance abuse

Control intervention: SEI for two years followed by regular care -

Patients randomised to the control condition will receive treatment as usual in general medical or regular psychiatric services that are normally available to all patients in the absence of an SEI service. Under usual circumstances, patients are provided treatment in a variety of settings and there is often great variability in the level and quality of care received by patients. Regular care can include any of the following:

1. Hospital out-patient services where most of the care is provided by psychiatrists with or without nursing or other professional involvement
2. Care by psychiatrists in community office practice
3. Care by family physicians with variable support from psychiatric services. Such care is usually provided in settings that treat other psychiatric patients with a variety of diagnoses and different levels of chronicity.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Defined by remission status, measured as the proportion of patients in complete remission (to make it comparable to the OPUS follow-up study in order to increase generalisability) achieved

by patients for the entire period of three years of the additional intervention (following randomisation). Using sustained remission as the primary outcome measure is justified because of high association of length of remission and functional outcome (work and social functioning). Remission status will be measured upon entry and every three months (at evaluation) until completion at 3 years.

### **Secondary outcome measures**

1. Clinical outcome, measured upon entry and every three months until completion
2. Functional outcome, measured every six months until completion
3. Quality of life, measured every six months until completion

### **Overall study start date**

01/04/2009

### **Completion date**

01/04/2014

## **Eligibility**

### **Key inclusion criteria**

The aim of our study is to demonstrate effectiveness of a model of care applicable to the largest number of persons with first episode psychosis (FEP) as they appear in clinical settings and not to show efficacy of a single treatment intervention for patients with pure unencumbered diagnoses. Therefore, the inclusion criteria are designed to recruit patients truly representative of FEP patients likely to be seen in any treatment facility:

1. Aged 18 - 35 years, either sex
  2. Able to provide informed consent
  3. Meeting Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria for a psychotic disorder (schizophrenia spectrum psychoses and affective psychosis) confirmed by the Structured Clinical Interview for DSM-IV Axis I disorders Patient Edition
  4. Have completed 24 months of treatment and follow-up in one of the two SEI services.
- Patients with co-morbid diagnosis of substance abuse and dependence will be included.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

240

### **Total final enrolment**

217

**Key exclusion criteria**

1. Lack of ability to provide informed consent as assessed by requesting patient to provide brief summary of treatment protocol following presentation of the consent form
2. Lack of ability to speak either English or French fluently as assessed by the patient indicating English or French as the preferred language for communication
3. Intelligence quotient (I.Q.) below 70 as assessed using the Wechsler Adult Intelligence Scale (WAIS) short form

**Date of first enrolment**

01/04/2009

**Date of final enrolment**

01/04/2014

**Locations****Countries of recruitment**

Canada

**Study participating centre**

**Douglas Hospital Research Centre**

Montreal

Canada

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**Sponsor information****Organisation**

Douglas Hospital Research Centre (Canada)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.douglasrecherche.qc.ca>

**ROR**

## Funder(s)

### Funder type

Research organisation

### Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-94189)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	14/02/2015		Yes	No
<a href="#">Results article</a>	results	01/07/2019	06/07/2020	Yes	No