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

Submission date	Recruitment status
20/03/2009	No longer recruiting
Registration date	**Overall study status**
10/06/2009	Completed
Last Edited	**Condition category**
06/07/2020	Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ashok Malla

Contact details
Douglas Hospital Research Centre
6875 LaSalle BLVD
Montreal
Canada
H4H 1R3

Additional identifiers

Protocol serial number
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.

Primary study design
Interventional

Study design
Open-label randomised controlled design

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
H4H 1R3

Sponsor information

Organisation
Douglas Hospital Research Centre (Canada)

ROR
https://ror.org/05dk2r620

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

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?
Results article	results	01/07/2019	06/07/2020	Yes	No
Protocol article	protocol	14/02/2015		Yes	No