A protocol for the First Episode Psychosis Outcome Study (FEPOS): ≥15 year follow-up after treatment at the Early Psychosis Prevention and Intervention Centre, Melbourne, Australia.

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Abstract

**Background:** Specialist early intervention (SEI) service models are designed to treat symptoms, promote social and vocational recovery, prevent relapse, and resource and up-skill patients and their families. The benefits of SEI over the first few years have been demonstrated. While early recovery can be expected to translate to better long-term outcomes by analogy with other illnesses, there is limited evidence to support this from follow-up studies. The current study involves the long-term follow-up of a sub-set of first episode psychosis (FEP) patients, with a range of diagnoses, who were first treated at Orygen’s Early Psychosis Prevention and Intervention Centre (EPPIC) between 1998 and 2000. The aim of this paper is to present the methodology for this follow-up study.

**Methods:** Between January 1998 and December 2000, 786 patients between the ages of 15-29 years were treated at EPPIC, located in Melbourne, Australia. Our cohort consists of 661 people (82 were transferred/discharged and 43 were not diagnosed with a psychotic disorder at time of discharge). The 18-month treatment characteristics of this cohort have been extensively examined in the First Episode Psychosis Outcome Study (FEPOS). The ≥15 year outcomes of this cohort are being examined in this study, known as FEPOS15.

**Results:** Participant follow-up is ongoing. In order to extend and assess broader outcomes of the cohort, data linkage with health-related databases will be conducted.

**Conclusion:** This study will provide a comprehensive evaluation of the long-term trajectory of psychotic disorders after treatment for FEP in a SEI service.

**Keywords:** psychotic disorders, follow-up studies, prognosis, delivery of health care, treatment, schizophrenia, early intervention, staging
1. INTRODUCTION

Psychotic disorders are among the most burdensome and costly illnesses worldwide (Rossler, Salize, van Os, & Riecher-Rossler, 2005). For many individuals, the onset of psychosis occurs at a crucial time in young adulthood (Berger, Fraser, Carbone, & McGorry, 2006; de Girolamo, Dagani, Purcell, Cocchi, & McGorry, 2012; Kessler et al., 2007); during the years that vocational and educational achievements, social relationships and identity formation are key developmental goals (A. K. Malla, Norman, & Joobber, 2005). Derailment of these goals adds to the risks of deleterious long-term effects, and the emotional and financial burdens experienced by affected individuals, their family members and the communities supporting them (Awad & Voruganti, 2008; Nuttall et al., 2019).

Early intervention approaches aim to treat symptoms of psychosis and minimise distress and disruption for individuals. Specialist early intervention (SEI) service models are designed to reduce duration of untreated psychosis, manage symptoms, promote social and vocational recovery, prevent relapse, and resource and up-skill patients and their families (Cotton et al., 2016; A. Malla & McGorry, 2019; Rossler et al., 2005).

There is a strong rationale for early intervention (Birchwood, Todd, & Jackson, 1998; P. D. McGorry, Killackey, & Yung, 2007; Santesteban-Echarri et al., 2017), and demonstrated benefits of SEI. Indeed, a recent meta-analytical study by Correll et al. (2018) of ten randomised trials of SEI, found that SEI was superior to treatment as usual with respect to outcomes such all-cause treatment discontinuation, they were less likely to have at least one hospitalisation, and they reduced positive and negative symptoms; with these effects observed up with up to 24-months of treatment. However, long-term outcomes of SEI for FEP are less well known (Chan et al., 2019; Morgan et al., 2021). Many of the studies reviewed by Correll et al. (2018) now involve long-term follow-up of their cohorts (e.g., the OPUS trial in Denmark; Austin et al., 2015). Other studies have used alternative designs. The Treatment and Intervention in Psychosis (TIPS) study employed a quasi-experimental design, looking at the benefits of early detection in Norway; they have followed their cohort over 10 years (Hegelstad et al., 2012). Findings from such studies indicate that early detection results in minimising deficits and better functioning (Hegelstad et al., 2012), there is much heterogeneity in illness trajectories (Austin et al., 2015; Morgan et al., 2021), and that approximately a third of those followed up have symptomatic remission and are no longer taking antipsychotic medication (Wils et al., 2017).

Existing first episode long-term outcome studies (>10 years) have included participants at baseline across multiple developmental phases (i.e., adolescence, early adulthood, later adulthood) (Chan et al., 2019; Menezes, Arenovich, & Zipursky, 2006), typically accessing
standard adult mental health services. They have focused on predictors of symptom change, with limited investigation of predictors of other outcomes (e.g., QoL, social participation, functioning, neurocognition), and of inter-relationships between baseline and such outcome variables. Few studies have examined the outcomes in services from representative geographically defined catchment areas (Addington & Addington, 2008a, 2008b; Baldwin et al., 2005; Kirkbride et al., 2006; Singh et al., 2000).

Thus, there is a paucity of information regarding the long-term effectiveness of SEI for FEP, treatment received post-SEI treatment, which factors best predict long-term outcomes, and how the extent and quality of such treatment impacts on long-term outcome. There are numerous long-term follow-up studies focusing on outcomes of patients with first episode schizophrenia or non-affective psychosis; however, for many of these studies, did not received SEI (Menezes et al., 2006). A follow-up study of a cohort who had SEI treatment is needed. We were cognizant of the need to incorporate specific elements into the study including: a cohort of individuals treated according to evidence-based guidelines at an SEI service, recruited at the same phase of illness, and free from the confounding effects of previous treatment (Menezes et al., 2006), with comprehensive historical information on each patient ascertained at the time of their first-episode.

A study such as this was possible due to a unique opportunity at the Early Psychosis and Prevention Centre (EPPIC). Previously we had conducted a medical file audit study (the First Episode Psychosis Outcome Study, FEPOS) of 661 consecutive patients registered at EPPIC between 1998 and 2000 (Conus, Cotton, Schimmelmann, McGorry, & Lambert, 2007). Inclusion criteria were based on the EPPIC clinical entry criteria and included: (i) age between 15-29 years; (ii) the first episode of psychosis; and (iii) resident in the EPPIC catchment area (north-western suburbs of Melbourne, Australia). Exclusion criteria included: (i) residing outside the catchment; (ii) a diagnosis of psychotic disorder related to a general medical condition; or (iii) a non-psychotic disorder. Premorbid, service entry, treatment and 18-month discharge characteristics were collected. Most importantly, the cohort comprised patients who had their ‘first contact with treatment’ rather than being a ‘first inpatient admission’ sample, avoiding a biased cohort of patients with severe psychopathology and advanced illness (Conus et al., 2007).

Characteristics of early illness and treatment course to the point of discharge from EPPIC were captured including variables such as duration of prodrome, duration of untreated psychosis (DUP) and age of illness onset; past history of psychiatric disorder (Diagnostic and Statistical Manual for Mental Disorders (4th ed.; text rev. DSM-IV-TR; American Psychiatric Association., 2000); baseline and discharge DSM-IV-TR diagnoses, symptom severity,
insight, functioning; suicide attempts during treatment; treatment duration, number of inpatient admissions, treatment non-adherence, and substance use.

The current study is a ≥15-year follow-up study of the FEPOS cohort treated at EPPIC; is one of the longest, largest and most comprehensive studies of the multidimensional outcomes of a SEI service for psychosis. The study has three main aims: (i) to describe and model clinical, functional, neurocognitive, physical health and QoL outcomes of a treated representative sample ≥15-years after presentation to an SEI service; (ii) to document treatment received after discharge from a SEI service and determine how this treatment might impact on long-term outcome; and (iii) to determine and delineate best predictors of good and poor ≥15-year outcomes overall and within different outcome domains. Here, we present the protocol for FEPOS-15.
2. METHODS

2.1 Study Design

This is a closed cohort study, a follow-up of a sample ≥15 years after initial contact with EPPIC. A cross-sectional design is employed, with a comprehensive suite of outcomes investigated (see Figure 1). These include symptoms, functioning, QoL, substance use, cognition, physical health and mortality.

(Inset Figure 1 about here)

Institutional ethics approval was obtained from Melbourne Health Human Research Ethics Committee (HREC; FEPOS-Mortality 2013.001, FEPOS-15 2013.146), the Australian Institute of Health and Welfare (EC 2013/1/3) and the Department of Justice and Regulation (FEPOS-Mortality CF/13/1240, FEPOS-15 CF/16/19611) HRECs.

2.2 Participants

There are 661 eligible individuals from the original FEPOS cohort (n=786) (Conus et al., 2007). Of this 786, 82 were transferred/discharged to other services and 43 excluded due to a non-psychotic diagnosis at service discharge.

2.3 Outcome measures

The assessment battery comprises questions sourced from other epidemiological or population-based studies to ensure comparability of data to relevant datasets, alongside widely-used standardised measures in psychosis research.

Demographics. Demographic information was obtained using items selected from the Australian Bureau of Statistics (ABS) 2011 Census, the Study of High Impact Psychosis (SHIP; V.A. Morgan et al., 2011), the Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK; Baker IDI Heart and Diabetes Institute, 2010) and the Australian Diabetes Obesity and Lifestyle Study (AusDiab; Barr et al., 2006). Items regarding housing were sourced from the Multidimensional Scale of Independent Functioning (Jagaer, Berns, & Czobor, 2003) and the Australian Housing and Urban Research Institute (AHURI).

Diagnoses. Lifetime psychiatric Axis I diagnoses are established using the Structured Clinical Interview for DSM-IV Axis I Disorders – Patient Edition Interview (SCID-I/P). The Standardised Assessment of Personality – Abbreviated Scale (SAPAS) (Moran, Leese, Lee, Thornicroft, & Mann, 2003) is used as a screening measure of personality disorder.
Symptom outcomes. Current symptomatology is assessed using the Positive and Negative Syndrome Scale (PANSS; Kay, Fiszbein, & Opler, 1987), the Montgomery-Asberg Depression Rating Scale (MADRS; Montgomery, 1979), the Young Mania Rating Scale (YMRS; Young, Biggs, Ziegler, & Meyer, 1978), the CGI-Severity (CGI-SGuy, 1976), CGI-Bipolar scale (CGI-BP; Spearing, Post, Leverich, Brandt, & Nolen, 1997), CGI-Schizophrenia scale (CGI-Sch; Haro et al., 2003), and the Generalised Anxiety Disorder Assessment (GAD-7; Spitzer, Kroenke, Williams, & Lowe, 2006).

Substance use. Information on drug use within the past month is gathered using Section II of the Opiate Treatment Index (OTI; Darke, Ward, Hall, Heather, & Wodak, 1991). Current alcohol use disorder is assessed using the Alcohol Use Disorders Identification Test (AUDIT; Saunders, Aasland, Barbor, De La Fuente, & Grant, 1993).

Functioning. The Global Assessment of Functioning, Modified Vocation Status Index (MVSI; Tohen et al., 2000), and Modified Location Code Index (MLCI; Tohen et al., 2000) were all completed during the original FEPOS, and repeated here. For a more comprehensive assessment of functioning we added the Personal and Social Performance Scale (PSP; Morosini, Magliano, Brambilla, Ugolini, & Pioli, 2000) and the Friendship Scale (Hawthorne, 2006, 2007; Hawthorne & Griffith, 2000).

Neurocognition. A brief and concise neuropsychological battery was designed to assess common domains impacted by psychotic disorders (Mesholam-Gately, Giuliano, Faraone, Goff, & Seidman, 2009) (see Table 1 for details).

Physical health. The physical health assessment includes questions about: risk for type 2 diabetes and cardiovascular disease; other common health problems; lifestyle factors (including smoking, dietary patterns and physical activity); functioning associated with physical health; and sexual health. Questions were sourced from epidemiological surveys including the Australian Bureau of Statistics 2011 Census, Danish Centre for Strategic Research in Type 2 Diabetes (Nielsen, Thomsen, Steffensen, & Christiansen, 2012), AUSDRISK (Baker IDI Heart and Diabetes Institute, 2010), AusDiab (Barr et al., 2006), National Nutrition Survey (1995) (McLennan & Podger, 1998), National Health Survey in 2001 and 2012; and SHIP (V. A. Morgan et al., 2011). Other assessments included the International Physical Activity Questionnaire (IPAQ) – short form (Craig et al., 2003), the SF-12v2™ Health Survey by QualityMetric Incorporated (Ware Jr, Kosinski, & Keller, 1996) and the Sexual Health and Behaviour questionnaire (E. Y. Chen, Brown, Lo, & Linehan, 2007). The Diabetes Knowledge Questionnaire from AusDiab (Barr et al., 2006) was included for people with a pre-existing diagnosis of diabetes only. A brief screening instrument was included to ascertain rates of epilepsy in the cohort (Ottman et al., 2010).
Physical health measures including weight, hip, waist and height measurements, and blood pressure are taken. A fasting blood sample is collected to assess plasma glucose levels, total cholesterol, high- and low-density lipoprotein cholesterol, triglycerides, and Apolipoprotein B100 and A1. These measures have been associated with cardiovascular disease (L. Chen, Magliano, & Zimmet, 2011; Yusuf et al., 2004). Fasting blood glucose results and current treatment with hypoglycaemic drugs will be used to assess current diabetes status.

**Life chart.** Patterns of change over the entire course of illness are assessed using the Life Chart Schedule (LCS; World Health Organization, 1992). The LCS allows for a retrospective assessment across four domains: (i) symptomatology (number of psychotic episodes); (ii) treatment (medication, hospitalizations, case management, psychotherapy); (iii) residence; and (iv) work (Susser et al., 2000). Importantly, the LCS provides an opportunity to map illness course (episodic, continuous, no further evidence of psychosis) and the quantity and type of treatments (including uptake of prescribed medication) received. Only the second part of the LCS will be administered, as the first part relates to the past two years, while the second covers the entire period of illness.

**Quality of life.** The Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q-18; Endicott, Nee, Harrison, & Blumenthal, 1993) and the Assessment of Quality of Life – 4 dimensions (AQoL; Hawthorne, 2009; Hawthorne & Osborne, 2005) are used to assess subjective QoL and utility objective, respectively. The first item from the Australian version of the World Health Organization Quality of Life Scale (WHOQoL-Bref; Murphy, Herrman, Hawthorne, Pinzone, & Evert, 2000) is also included as a global index of QoL.

**Service utilisation, treatment, medication.** A range of questions are included regarding service utilisation for psychiatric conditions, substance use disorders and physical ailments. These questions were sourced from SHIP (V.A. Morgan et al., 2011). Consent was requested from participants to access information from the Client Management Interface/Operational Data Store (CMI/ODS; Victorian state-based database of mental health service contacts including registered and unregistered contact, community and case contacts), Medicare Benefits Scheme (MBS) and Pharmaceutical Benefits Scheme (PBS) related to service contacts and medication usage since their time at EPPIC.

**Mortality.** FEPOS-Mortality involves further data linkage to identify additional deaths and associated causes and contributors. We conducted data linkage with the National Coronial Information System (NCIS), the National Death Index (NDI), local state coroners, and the registry of Births, Deaths and Marriages. Not only was cause of death determined, but
Coroner’s reports will be scrutinized for circumstances surrounding death including social and interpersonal outcomes.

2.4 Procedures

**Phase I: FEPOS-Mortality.** In 2006, we ascertained that 19 people from the original FEPOS cohort were deceased (Robinson et al., 2010). At the commencement of this study, and randomly throughout, additional searches of mortality databases were and continue to be conducted. This ensures that family members or friends of those deceased are not inadvertently contacted regarding potential participation in the follow-up study.

**Phase II – Locating Potential Participants.** The original FEPOS was a medical file audit; consent was not obtained from participants (HREC approval was obtained for this waiver of consent). There had been no contact with the FEPOS cohort since their discharge from EPPIC and contact details at the time of discharge were not previously obtained. We adopted and adapted a tracking algorithm to obtain current contact details, having been used to good effect in previous outcome studies at Orygen (see Table 1, Henry et al., 2010; Nelson et al., 2013).

Following receipt of approval from each organisation’s governing bodies, details including name, date of birth, mental health UR and/or Medicare number (if available) of the cohort were matched with those of various organisations (with details obtained regarding the strength of match, that is, whether one, two or more details were matched on each individual). One of two outcomes followed matching: (i) most recent contact details were provided to the study team, allowing us to directly contact potential participants; or (ii) study information was sent from organisations on our behalf, advising identified individuals of the study and inviting them to participate. Australian electoral roll and on-line searches (e.g. Google, LinkedIn) were conducted to further assist in locating individuals. Advertisements and study information were distributed to mental health services, private clinicians and community support services to assist in reaching potential participants.

**Phase III: Contacting Potential Participants.** Opt-in or opt-out approaches have been employed to engage the cohort initially, depending on availability of current contact details. The opt-in approach requires interested individuals to contact the research team to learn more about the project and participate. It is used where written information only can be provided to the individual. The opt-out approach is offered when both addresses and phone numbers are available. Following an initial letter to individuals, telephone contact is made to
ascertain interest in the study. The option to decline further communication is offered, with a pre-filled form and a reply-paid envelope provided.

**Phase IV: Assessment.** After obtaining informed consent, the FEPOS-15 assessment battery is administered. With a wide breadth of outcomes, and large assessment battery, a range of options are provided to participants.

The full FEPOS-15 assessment involves a clinical interview covering the entire battery including self-report measures and a physical health assessment (including a fasting blood sample). A reduced assessment package or a brief telephone interview are offered to participants unwilling or unable to complete the full assessment (due to geographical or time constraints). These assessments are designed to be built upon, so that participants can complete further assessments should they wish, still utilising the existing information. The reduced assessment focuses on core measures of symptoms, diagnosis, functioning and QoL outcomes at time of follow-up. This can be completed in person, over the phone or using online video technology.

The brief telephone assessment comprises nine questions related to mental health contacts, physical and mental health, functioning and overall QoL.

*Staff Training and Inter-Rater Reliability.* All research assistants have received comprehensive training on the administration and scoring of measures and interview techniques. With participants’ consent, interviews are recorded and used to complete inter-rater reliability checks at regular intervals.

### 2.7 Statistical Analyses

Findings from the study will be reported in accordance with the Strengthening the Reporting Observational Studies in Epidemiology (STROBE) guidelines (von Elm et al., 2007). Patterns (and duration) of remission and recovery and the types of physical health problems will be estimated for the cohort overall and for subgroups (e.g., diagnostic groups). To examine inter-relationships between various domains of outcome at 15-years we will use structural equation modelling. We are also interested in elucidating patterns of symptoms and functioning, from the point of first contact at EPPIC to the 15-year follow-up; we will use techniques such as latent class and factor analysis (to consider both dimensional and categorical aspects of outcome) and longitudinal mixture analysis to examine patterns of outcome. Importantly, these techniques will allow us to map both within- and between-subject
variation in illness trajectories. Both unifactor (unadjusted single predictor) and multiple predictor statistical analyses will be conducted to determine what relates to 'good' outcome.

2.8 Data management

An electronic case report form (eCRF) was developed for the study. Data is entered from paper records and transmitted via a secure website. Collection and collation of data is conducted according to Good Clinical Practice guidelines (Therapeutics Good Administration, 2018).

3. RESULTS

The study has commenced recruitment, with data collection ongoing. As of July 2021, we have identified 68 people in the cohort as deceased. We have encountered difficulties in locating and contacting a proportion of the cohort due to changes in privacy legislations pertaining to some administrative datasets. We have made contact with 358 individuals thus far, 234 have completed participation (of those, full assessment 133, part or reduced assessment 56, and brief assessment 45), 12 have requested follow-up contact, 111 have refused participation and one withdrew consent. As such, we are continuing to explore other avenues to maximise follow-up.

4. DISCUSSION

Given the worldwide proliferation of the EPPIC model of care since the late 1990s, it is imperative to formally evaluate the long-term outcomes of FEP patients treated at such SEI services. EPPIC was the first comprehensive SEI service in Australia incorporating assertive case management, low dose atypical antipsychotics, and stage specific psychotherapy. Since its inception hundreds of early intervention programs have been developed worldwide, many based on the EPPIC model (P. McGorry et al., 2008). It is crucial that early interventions are tailored and targeted to secure the best possible outcomes for the young people treated, not just during the course of EPPIC treatment, but into early adulthood and beyond.

With the current study, we are capitalizing on an opportunity to follow-up a cohort from a geographically defined area who received SEI. The integration of long-term outcome information with short-term results will enable us to understand the benefits and shortcomings of SEI treatment over the longer-term. Indeed, information is sparse on the long-term
outcomes of early detection and intervention, especially surrounding what should be the focus, timing and length of interventions (Austin et al., 2015; Hegelstad et al., 2012). Our study, will provide insight into which services and other supports might be most beneficial after initial SEI treatment, and those factors contributing to longer-term functional recovery, or lack thereof, with the aim of translating these findings into direct clinical practice. The results of this project have the potential to inform policy and maximize the quality and accessibility of mental health services for young people and their caregivers.

**Data Availability:** Data are still being collected for the study and are yet to be analysed. They are currently not available for sharing.

**Funding:** The original FEPOS medical file audit was funded by Eli Lilly Company Australia for special analysis of the comparison of Olanzapine and Risperidone in FEP (salary for 1 year for Dr Martin Lambert). FEPOS15 was supported by funding received from: National Health and Medical Research Council (APP1045997) and the Faculty of Medicine, Dentistry and Health Sciences, The University of Melbourne.

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The First Episode Psychosis Outcome Study – long-term outcomes


The First Episode Psychosis Outcome Study – long-term outcomes


Figure 1. Outcomes to be assessed in the FEPOS15 project.
Table 1

The tracking algorithm used to obtain current contact details of the FEPOS patients

<table>
<thead>
<tr>
<th>Tracking Algorithm</th>
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<tbody>
<tr>
<td>1. Mortality search through National Death Index (NDI) and National Coronal Information System (NCIS)</td>
</tr>
<tr>
<td>2. Client Management Interface (CMI) and Operational Data Store (ODS) of RAPID-this contains records of contacts with the Victorian public mental health system (note statewide access is required through DHS)</td>
</tr>
<tr>
<td>3. White Pages</td>
</tr>
<tr>
<td>4. National Electoral Roll</td>
</tr>
<tr>
<td>5. Medicare Australia-Medicare is able to match provided dates of birth and names to addresses on their records and send out letters on our behalf.</td>
</tr>
<tr>
<td>6. Victorian Registry of Births, Deaths and Marriages <em>(refer to step 2)</em></td>
</tr>
<tr>
<td>7. Social networking websites</td>
</tr>
<tr>
<td>8. VicRoads</td>
</tr>
<tr>
<td>9. Corrections Victoria</td>
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</tbody>
</table>
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