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A Randomised Controlled Trial of Vocational Intervention for Young People with First Episode Psychosis: Method

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Abstract

Young people who are experiencing first episode psychosis (FEP) are at increased risk of being unemployed compared to either their same age peers in the general population, or those with other mental illnesses. Significant research has been conducted examining employment interventions for those with chronic psychotic illness. This has yielded strong results in favour of an intervention called Individual Placement and Support (IPS). However, significantly less work has examined the benefit of this approach to those in FEP when the potential for vocational rehabilitation is perhaps greater. This study adds to the knowledge of vocational intervention in first episode psychotic illness. Additionally it expands this work into the areas of cognition, social cognition, social inclusion and economics.

The study is a single-blind, randomized controlled trial comparing receiving high quality FEP treatment as usual plus IPS (IPS+TAU) to a FEP treatment as usual (TAU) intervention alone within a specialised FEP service.

The study recruited 146 people attending a first episode psychosis service over 2 years. They were assessed at baseline, 6 months (end of intervention) 12 and 18 months with a battery covering psychopathology, economic, demographic, social cognitive, cognitive and diagnostic variables.

This paper describes the methodology for the largest attempted study of IPS in FEP. This study has the capacity to answer questions about the benefits on illness and economic impacts of vocational recovery in FEP. Further it has the capacity to extend knowledge about the contribution of cognitive and social cognitive factors to recovery in this domain.

Introduction

Unemployment is the main psychosocial disability that people with psychotic illnesses such as schizophrenia experience (1). Being unemployed, even in the absence of mental illness, limits the degree to which one can participate in society or the economy, increases the risk of alcohol or other substance use, is a risk factor for the onset of mental illness, and can either place pressure on current relationships or make initiating new ones difficult. It also means the unemployed individual is unlikely to access the benefits of living in society, being able to pay for holidays, quality housing, and build a future through savings. Evidence suggests that for young people in particular, periods of unemployment can have 'scarring' effects on future employment opportunities increasing the risk of longer-term poverty and social exclusion (2). For those with mental illness, unemployment reinforces social and economic marginalisation, has the potential to exacerbate symptoms, increases risk of homelessness, and often persists after other symptoms of illness have resolved.

Despite wanting to work in the open labour market (3-6), there are high rates of unemployment among those with mental illness (7). Among the first-episode psychosis (FEP) group, there is a level of unemployment of 40%-50% (1, 8). This compares to 3.5%-4.5% of their same aged peers in the general community (9). For those whose illness persists beyond a first episode and develops into a chronic psychotic illness, unemployment rates rise to 70% – 92% (8, 10-12).

Over and above the individual consequences of unemployment in this group, there are economic costs to the community; these are significant. In Australia, costs associated with

people with schizophrenia being unemployed totalled $927 million, or approximately half of the total cost of illness of $1.85 billion in 2001 (11). This included forgone salary, lost tax income and the costs of benefits payments as well as costs associated with carers and their lost income. The costs associated with unemployment of people with schizophrenia have been found to be of similar magnitude in other countries and regions (13). For example, in the USA approximately half (US$32 billion) of the total costs of schizophrenia (US$63 billion) were associated with unemployment (14).

Compared to the general population, people with psychotic illness also have less education (1, 5, 12, 15-17). Australian studies show that between 25% and 50% have less than a Year 10 education, and only about a third had finished Year 12. This is in comparison to the general population in Australia where well over 80% (18) (19) of people have completed Year 12 by the age of 24. It is well established that higher levels of education are associated with less unemployment and higher wages in the general population (20, 21). This relationship is also found to be true for those with a diagnosis of schizophrenia irrespective of course of illness (22). Given this low educational attainment it comes as no surprise that unemployment is the main psychosocial disability of people with psychotic illnesses (1), because even in the absence of a mental illness, this low level of education would mitigate against successful vocational outcomes in life. Therefore, it is imperative that in addressing the vocational functioning of young people with psychosis, education is considered equally with employment.

Given the scale of the vocational problem in FEP, the desire of consumers to work, and the societal economic burden of this problem, it is imperative that consumers and clinicians are provided with evidence-based interventions to improve their educational and occupational

prospects.

An intervention to address vocational functioning in mental illness

Supported Employment is acknowledged as being the superior form of vocational intervention for people with established mental illness in terms of achieving an outcome of employment in the open labour market (1). Supported employment is an intervention in which an individual is aided to find a job and then supported to remain in the job. Individual Placement and Support (IPS) (23) is the most defined and most studied form of supported employment. IPS has eight fundamental principles (24), which are as follows:

1. IPS is open to any person with mental illness who wants to look for work
2. IPS is integrated with the mental health treatment team
3. IPS is focussed on competitive employment as an outcome
4. Personalised benefits planning/counselling is provided in IPS
5. Job searching commences directly on entry into the IPS program and is not determined by measures of work-readiness or illness variables
6. The IPS worker develops relationships with employers based upon client interests
7. Potential jobs are chosen based on consumer preference
8. Support provided in the program is time-unlimited, continuing after employment is obtained, and is adapted to individual needs

Prior to the study currently being described there were 11 Randomised Controlled Trials (RCTs) of IPS (25). All had found that IPS was significantly better on all employment outcome measures compared to various control conditions. All but one of these trials (16)(described below) was conducted with people who had been unwell for significant periods of time. Given the vocational goals and difficulties of young people with FEP

frequently include completion of education, it is important to note that the IPS model is extended to integrate Supported Education (cite Nuechterlein et al., 2008; Rinaldi et al., 2010; Allott et al., in press).

An argument for early vocational intervention in mental illness

Psychotic illnesses have their peak onset between the ages of 15 and 25 years (26). This is also the stage of life in which people finish school and enter the workforce. The onset of mental illness at this time can be extremely disruptive. This disruption means that education is not completed, or completed to a lower standard than might otherwise have been achieved, and basic vocational skills are not learned. At the same time, people in this situation develop no history of work experience. These factors may explain why, even in the light of eventual symptomatic remission (27), people with these illnesses tend not to achieve good vocational outcomes (8).

There is a window of opportunity to minimise or prevent vocational disability in this group by applying evidence-based vocational interventions as part of their early recovery. Prior to starting the current study, there had been one RCT of supported employment in a first-episode psychosis sample (16). We conducted this as a pilot for the proposed study. In our pilot study, relative to a treatment as usual (TAU) group, the IPS group gained a greater number of jobs (23 vs. 4), earned significantly more money (median $2432 vs. $0), had jobs with a higher rate of pay ($18 p.h. vs. $15 p.h.) and worked significantly longer (median 5.0 vs. 0.0 weeks). The percentage of those dependent on benefits decreased significantly in the IPS group from 80% to 55%, while there was no change in the percentage of the TAU group dependent on benefits (57.1% at both time points). These results indicate that a 6-month intervention with high fidelity to the IPS model (23) can have a significant impact on

unemployment and benefit status and help return people to study among those with a first episode of psychosis. Importantly, there was a 0% refusal rate for participation in this project.

Rationale for current study

There are a number of reasons for wanting to conduct another, larger, RCT of this intervention in this population. While the previous findings were positive in regards to finding employment, the small sample size limited the conclusions that could be drawn about a number of other important factors. These included considerations of the effect that employment might have on symptoms in FEP. There is a paucity of literature examining the role of functional recovery in symptomatic recovery in FEP. A larger study would allow some insight into this relationship.

Another reason for a larger trial is that in order to usefully translate findings in this area into policy and practice a strong economic analysis is required. An unfortunate reality of psychosocial interventions is that they very often do not get implemented as routine practice (28). There is evidence that an intervention similar to IPS was in use in Boston between 1913 and 1918 (29) and yet did not persist. It is important to gather the economic evidence to aid the case for translation.

There is also a need to identify predictors of poor and good outcome to assist in both the allocation of scarce resources, and to identify any need for augmenting interventions. There are a number of candidates in this regard, but the most promising based on current evidence are neurocognition and social cognition (30). Most domains of neurocognition and social cognition are impaired in people with FEP relative to healthy controls (31), but it is unclear which specific components of these are most strongly related to vocational functioning (32).

This study will address this gap in knowledge. There is emerging evidence that vocational rehabilitation might lead to improved neurocognitive functioning in chronic schizophrenia (33). However, there is little evidence concerning the potential positive impact that employment or education might have on neurocognitive and social cognitive functioning in people with FEP. This study will be able to address this question.

At the time of design of the study, there was little evidence on the health and health service usage impacts of IPS. For example, do people with psychosis who are working have fewer symptoms than those who are not? Do they manage their symptoms better? Do they have fewer inpatient admissions? It is known from more recent research that people with FEP who make a more general functional recovery, tend to use services less (34). This study will allow us to determine if a more specific functional recovery – in the domain of vocational functioning – leads to less use of services, and better health outcomes. Answering these questions in a FEP population was an important component of the rationale for the current study.

Further, just as it is important to know about the effect of employment and education on symptoms, it is equally important to examine the effect of vocational recovery on social inclusion. Employment is often mentioned as a key to social inclusion (17) and it is important to discover if being in a job or doing a course increases social inclusion for young people with psychosis.

Finally, the longitudinal nature of the study will allow for a more complex and complete view of the changes in all of these areas both during the period of intervention, and in the 12 months following.

Aims and Hypotheses

General Aim

This study aimed to determine through a RCT whether or not IPS+TAU produces superior vocational, health, economic, social and cognitive outcomes compared to TAU alone (case management, medical review, group programs and referral to external government-funded employment agencies).

To achieve the general aim the study had a specific primary aim and a number of secondary aims. Each aim was linked to a testable hypothesis. The primary aim and hypothesis of the study is below, along with a list of the specific secondary aims.

Primary Aim

To examine whether or not people with FEP who receive IPS engage in more educational courses, obtain more jobs or both, compared to those who receive high quality TAU alone at the end of intervention (6 months post-baseline) and at 12 and 18 months post-baseline.

Primary Hypothesis

That being in the IPS group will lead to higher levels of employment, greater time spent employed and enrolment in more educational courses than treatment-as-usual. This was measured by whether or not an individual had obtained a job or enrolled in a course over the period of interest, and if they had obtained a job, how many hours had they been employed.

Secondary Aims

1. To examine the impact of vocational recovery on symptoms and hospitalisation over an 18-month period.

2. To determine neurocognitive and social cognitive predictors of vocational recovery
3. To examine the impact of vocational recovery on social participation
4. To examine the economic cost and impact of the intervention
5. To examine the impact of vocational recovery on self-reported health service usage
6. To determine the impact of vocational recovery on neurocognitive and social cognitive functioning

Method

Setting and Sample

The study was carried out at the Early Psychosis Prevention and Intervention Centre (EPPIC), which is a sub-program of Orygen Youth Health. Orygen Youth Health is a public mental health service for young people aged 15-25 years living in the north and north-west of metropolitan Melbourne, Australia. The catchment area covers a population of approximately 1 million people of whom approximately 250,000 are in the appropriate age-range.

The population from which our sample was recruited consisted of young people with a first episode of psychosis living in the defined geographical catchment area of EPPIC. All people aged between 15 and 25 years, living in the catchment area, experiencing a first episode of psychosis become clients of EPPIC. Clients of EPPIC receive up to 24 months of clinical care. The EPPIC program includes medical review, inpatient facilities where indicated, outpatient case management, a group program that has a number of vocationally-oriented groups, access to a school with programs for clients of EPPIC, and in terms of employment services, referral to local employment agencies contracted by the Federal Government to provide employment support to job seekers.

Any client who expressed an interest in employment or education, whether that was to find a

job or course or to receive support to stay in a current job or course was eligible to be referred by their case manager to the study. Referral could occur at any time during their engagement with EPPIC, so long as they had at least 6 months left in the program.

Procedure

The study protocol was approved by the Melbourne Health Human Research Ethics Committee (HREC 2007.648).

As mentioned, potential participants were referred to the study by their case manager after expressing an interest in addressing their vocational recovery. Following referral, potential participants would meet with a member of the study team who would explain the study in detail using the participant information and consent form (also referred to as a plain language statement – in plain language) as a guide. The study team member would answer any questions the potential participant had about the study. The participant would then provide written consent to participate.

In keeping with the inclusive philosophy of IPS, inclusion criteria were only that the participant was a current client of EPPIC and had expressed a desire to pursue a vocational objective. A further inclusion criterion was that the participant had at least 6 months remaining as a client of EPPIC. This was an ethical requirement to ensure that during the intervention phase of the trial all participants would have ready access to clinical care if necessary.

Exclusion criteria were having severe intellectual disability or having florid psychosis that prevented the determination of ability to provide informed consent. Further, because of

limitations of resources, it was also necessary to have an exclusion criteria concerning lack of fluency in English; however this did not affect any participants.

Between April 2009 and April 2011, 171 young people were approached after referral by their case manager to participate. Of these, 25 refused to participate or were too unwell to consent to participation. The remaining 146 completed baseline assessments and were then randomised to the IPS or TAU condition.

Randomisation

The participants were allocated to the two groups using a computer program for blocked randomisation in random permutated blocks of 4 and 8. This was done to prevent prediction of group membership before it was assigned. Randomisation was conducted by the study statistician (SMC) who was not associated with assessments and treatments. She was the only person aware of the allocation sequence. She then provided the group allocation to the study lead who informed the employment consultant and the participant's case manager of the group to which the participant had been allocated. All effort was taken to keep research assistants blinded to study condition. RAs had no contact with the employment consultant, and participants were reminded at the start of each assessment that they were not to let the RA know whether they had been working with the employment consultant or not. In analyses, accuracy in group prediction non-significantly different from chance will be taken to indicate that the blind was successful. This was checked by keeping a record of the RA's belief of group membership at each assessment point

Assessments

Assessments were conducted at four time points: Baseline (T0), 6 months (T1), which for

those in the IPS group was also the end of the intervention, 12 months (T2), and the final one at 18 months (T3).

The assessments were conducted by trained research assistants (RAs) with a minimum 4-year graduate psychology degree. The assessments covered demographics, economics, psychopathology and symptom severity as well as neurocognition and social cognition. The assessments took between 1.5 and 4 hours to complete. Participants were given $20 for each assessment to reimburse them for transport and other costs associated with attending the assessment.

Measures

The assessment battery was designed so as to cause as small a burden as possible to the participants while still resulting in the gathering of information necessary to examine the questions of interest. In all cases the assessments conducted were largely the same with two exceptions. Firstly, at T1-T3 participants were asked about their employment history in the previous 6/12 months. Secondly, neurocognitive and social cognitive assessments were only conducted at T0 and T3. Details of the measures used are below.

Demographics

The demographic section of the assessment covered eight areas: Basic demographics (including educational achievement and history); current employment/job seeking; employment history; non-earnings related income; use of health services; contact with justice system; important dates (birth, onset of symptoms, registration with service etc.), and; treatment information (medication, compliance, family history of mental illness etc.).

At 6, 12 and 18 months significantly more detail was collected about educational and employment activity since the previous assessment. Similarly more in-depth information was collected about income and activities pertinent to social inclusion. Some of the data collected in the demographic section will form the basis for the economic analyses. Separately, the IPS employment consultant kept records about all appointments and contacts with people allocated to her.

Symptom and Psychopathology measures

The symptom and psychopathology section of the assessment included a number of standard assessments and self-report questionnaires. This section of the assessment was administered at all time points. The Structured Clinical Interview for DSM-IV-TR (35), was used to determine Axis I diagnoses. Negative symptoms were assessed with the Scale for the Assessment of Negative Symptoms (36). Positive symptoms were assessed with the positive symptoms subscale of the Brief Psychiatric Rating Scale (37). Level of depression was measured using the Center for Epidemiological Studies – Depression (38) scale, while substance use was assessed using the Opiate Treatment Index (39).

Functioning, Quality of life and Social Inclusion Measures

Functioning was assessed using the single item Social and Occupational Functioning Assessment Scale (40). Self-reported quality of life and social inclusion were measured using the World Health Organisation Quality of Life Scale –BREF (41) and the Social Inclusion Measure (42), respectively. These three scales were administered at all time-points.

Neurocognition and Social Cognition

A large neurocognition and social cognition battery was administered at baseline and 18

months. The battery was designed to cover the domains known to be affected in psychotic illness. The battery was not administered at the 6 and 12 month timepoints. This was to avoid practice effects and reduce participant burden. Additionally, one test – the Wide Range Achievement Test (WRAT) – Reading subtest was only administered at baseline in order to establish an estimate of pre-morbid IQ.

Neurocognition

In order to estimate pre-morbid IQ we used the word reading subtest of the Wide Range Achievement Test – Fourth Edition (WRAT-4) – Reading subtest (43).

A variety of subtests of the Wechsler Adult Intelligence Scale – III (WAIS-III) (44, 45) were used to measure various neurocognitive domains. An estimate of current IQ was obtained using the 'Information' and 'Picture Completion' subtests. Digit Span was used to assess auditory-verbal attention span and working memory. Letter-Number Sequencing was used to measure auditory-verbal working memory and mental sequencing ability. Finally, Similarities was used to test verbal reasoning and concept formation ability.

Attention, processing speed and mental flexibility were assessed using a letter cancellation task and the Trail Making Test A & B (TMT) (46, 47). Visual attention and processing speed were measured using the written version of the Symbol Digit Modalities Test (SDMT) (48). The Rey Auditory Verbal Memory Test (RAVLT) (49, 50) was used to test verbal learning and memory, while the Rey-Osterrieth Complex Figure Test (RCFT) (51, 52) was used to assess visuo-spatial constructional ability and visual memory. Finally, the Controlled Oral Word Association (COWA) and Animal Fluency (53) were used to assess phonemic verbal fluency and semantic verbal fluency respectively.

Social Cognition

Theory of mind was assessed both verbally using the False Belief and Deception Stories Task (54) and nonverbally using the Picture Sequencing Task (55). The Hinting Task (56) assessed pragmatic comprehension of speech (i.e., the ability to infer real intentions based on indirect speech content). Recognition of vocal and facial affect was assessed using the Diagnostic Analysis of Nonverbal Accuracy DANVA (faces and voices) - Adult Version (57)

The assessments and their time of administration are shown in Table 1.

TABLE 1 ABOUT HERE

Intervention

Those in the TAU group received all the services that they were eligible for as clients of EPPIC. This included medical review, clinical case management, group programs (some of which are vocationally oriented), and referral by case managers (at their discretion) to offsite agencies (e.g., housing, welfare or employment agencies). In addition, a local Department of Employment and Workplace Relations (DEWR) contracted employment service has an employment consultant on site at Orygen for one half day per week to which all clients were able to be referred by case managers if this was deemed appropriate. The project did not in any way try to influence the clinical decisions of case managers.

In addition to receiving TAU, those in the IPS group received service from an employment consultant (EC) working according to the IPS model located on site at EPPIC. The EC had over a decade of experience working in government-funded employment and disability employment services. She had also been the EC in our previously published trial (16). The EC's job was to meet with clients as soon as possible after randomisation and provide them

with an employment service based on the eight principles of the IPS model described above. The detail of her role varied depending on the individual needs of clients. However, it generally entailed an assessment of vocational goals, engagement in job search, writing resumes, interview training, sourcing appropriate clothes for interviews, employment skills training, among many other tasks. Fidelity to this model was assessed as described below. As well as rapid job search and supporting the job seeking process, she provided support to those who found work for the duration of the intervention. The nature of this support varied and was largely dependent on participant preferences, needs and also the degree of disclosure about illness to workplaces that participants were comfortable with (58). The EC also worked with participants to achieve an educational outcome such as enrolment in a course where that was the preferred or most appropriate outcome for the individual. Those in the IPS group had access to all normal EPPIC services. In all of the interventions the EC liaised with the participant's case manager, and clinical care was continued throughout. A manual for conducting IPS in FEP is now available from Orygen Youth Health (http://oyh.org.au/online-store).

Intervention Fidelity

Fidelity to the intervention was assessed using the Supported Employment Fidelity Scale (59) which is a measure of how well the program we implemented measured up to the ideals of supported employment. This scale examines issues such as the description of the vocational specialist's role, their case-load, and the process by which work is sought. It is conducted on the program of intervention; it is not a scale that is applied to individuals. The scale was administered by consensus achieved by two of the study authors (KA and EK) facilitated by a senior researcher at the Centre for Youth Mental Health who was otherwise unassociated with the study. Although less than optimal, it can be administered by the program being

assessed. We used it in this manner.

Economic analyses

With specific regard to the economic analyses, a number of variables were recorded. These included: The type and rate of benefit payments received; the cost of any courses undertaken and who paid these costs; and, income earned. Having recorded these variables the amount of tax paid can be calculated through standard formulae. Economic analyses are also planned which will examine data relating to health service usage and the cost of these services. As a consequence, the economic evaluation of the study will quantify the full costs and benefits to society of the programme. The economic evaluation will allow separate analysis of the private benefits to trial participants, and an overall analysis of social costs and benefits. Including a well considered economic analyses as an a priori aspect of the study design is a unique element of this study in comparison to other studies of vocational recovery in FEP.

Discussion

This paper describes a longitudinal randomised controlled trial testing IPS + TAU to TAU alone in a high quality specialist first episode psychosis service. Despite people in various stages of psychotic illness expressing a greater desire to achieve vocational recovery than symptomatic recovery, vocational outcomes for people with psychotic illness have been characterised more by failure than success. The effect of this has been to add to the social exclusion of those with psychotic illness and to further enforce their marginalisation. In the long run the consequences of vocational failure can be assumed to contribute to a range of other poor functional outcomes including homelessness, poor physical health, loneliness and

premature mortality. It is therefore necessary that trials of sufficient size adequately investigate both the efficacy and the economics of an intervention. This will allow for the translation of the intervention through policy into practice.

This study will address several of the gaps that we have identified in the existing research on this topic. In addition to a further examination of the effectiveness of IPS in FEP, it will provide the first prospective economic analysis of IPS in this population. Beyond vocational and economic outcomes, this trial will produce important data concerning the clinical outcomes and health service usage of young people with FEP who engage in employment and education. The trial will also conduct a significant investigation of the role of neurocognitive and social cognitive factors in gaining and maintaining employment or enrolling and succeeding in education. Further, and uniquely, this study has the capacity to discover any impact of employment on neurocognitive and social cognitive functioning. Finally, the follow-up points beyond the intervention phase will provide for the examination of the durability of any beneficial effect of IPS for people with FEP.

The psychiatric literature is littered with excellent psychosocial interventions that have not been routinely implemented. This study aims to address this downfall by not only testing IPS, but also gathering other evidence necessary to support translation and implementation. Further, evidence produced from this trial will allow for an understanding of what further interventions may be needed to augment IPS in order to optimise vocational outcomes for young people making a recovery from FEP.

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Table 1: Time of administration of components of the assessment battery

Measure	T1	T2	T3	T4
Demographics	x	x	x	x
Symptom and Psychopathology Measures	x	x	x	x
Functioning, Quality of Life and Social Inclusion Measures	x	x	x	x
Neurocognition	x			x
WRAT-4	x			
Social Cognition	x			x