ISRCTN13549282 https://doi.org/10.1186/ISRCTN13549282

Education and Employment focused Individual Placement and Support (IPS) for young people with an 'at risk mental state' for psychosis: a feasibility study

Submission date
30/11/2019

Recruitment status
No longer recruiting

Registration date
05/12/2019

Overall study status
Completed

Last Edited
17/10/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Psychosis is a mental health problem that causes people to perceive or interpret things differently from those around them. This might involve hallucinations or delusions. The first symptoms of psychosis typically emerge around late adolescence and early adulthood, when a young person is devoting full-time to complete compulsory education or is trying to secure her /his first paid employment. Experiencing symptoms at this stage of life often result in early interruption of studies, fewer qualifications and consequent difficulties in securing a job. Individual Placement and Support (IPS) which follows a “place and train” model is the most successful evidence-based intervention to support people with severe mental illness to find a competitive employment. The IPS model and its recent adaptation which includes a specific education focus has, however, never been evaluated with young clinical high risk (CHR) individuals. This project aims (i) to implement IPS in Early Detection for psychosis services, (ii) to measure the effects of IPS on social and occupational functioning and overall mental health; (ii) to evaluate CHR clients’ and staff experience with IPS.

Who can participate?
People aged 16 – 40 who meet criteria of being CHR of psychosis.

What does the study involve?
The study involves entering the Individual Placement and Support programme, tracking clients’ progresses with education and/or employment goals and evaluate if they have found this intervention helpful. Clients educational/employment goals will be assessed at the start of the study by an Occupational Therapist who is also a researcher. The IPS intervention is an individualised approach which involves intensive, individual support to re-engage or staying in education or employment. Depending on the clients’ needs and preference, this can include face-to-face meetings with the IPS-trained Occupational Therapist; support in preparing job or school applications; preparing CV; practicing for interviews; and joining the clinents in appointments when they request support (e.g. work place, educational institution, job centre). Because this is

an individualised intervention, the number of sessions that the clients will receive can range between 12 and 24 in 6 months, according to their needs. Clients will be asked to provide socio-demographic information (e.g. gender/age, employment and education history etc.), a brief medical history and answer some questions about their mental wellbeing, all these data will be kept confidential and will be coded.

Clients will be asked to complete some additional questionnaires regarding their current level of functioning, how they perceive themselves and how they use their time daily. These questionnaires will be completed at the start of the study, after three months and after six months. The questionnaires can be completed at OASIS or at the IoPPN. It will take approximately 1 hour and 30 minutes to complete the baseline questionnaires and interview while it will take approximately 50 minutes to complete the follow-up questionnaires and interview.

At the end of the intervention, clients will be asked to complete an evaluation form. It will take approximately 10 minutes to complete the evaluation form. Clients will be also asked some additional questions which will help to understand what they found useful and what could be improved in the intervention. This will take approximately 30 minutes, and, with permission, this will be audio recorded with an encrypted smartphone.

What are the possible benefits and risks of participating?
The intervention aims to provide individualised and intensive support with employment or/and educational goals to people who have experienced mental health difficulties. By participating, clients may contribute to the development of medical knowledge of which they and other young individuals could benefit.

There are no known risks associated with this intervention. It is possible that anxiety and emotional distress might be experienced as a result of clinical assessment, interviews and questionnaires. If clients experience distress or anxiety they are invited to let the research and /or the clinical team know. The clinical team will offer appropriate support (e.g. face-to-face appointment) as soon as possible.

Where is the study run from?
1. South London and Maudsley NHS Foundation Trust, UK
2. King's College London, UK

When is the study starting and how long is it expected to run for?
May 2019 to April 2021

Who is funding the study?
Maudsley Charity, UK

Who is the main contact?
Dr Stefania Tognin
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Study website
https://www.kcl.ac.uk/ioppn/research/office/research/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
243427

Study information

Scientific Title
Individual placement and support in early psychosis

Acronym
IPS-ED

Study objectives
1. Are the IPS protocol and research procedures appropriate, feasible and acceptable?
2. Can the study recruit and retain people in treatment according to target?
3. What is the sample size for the definitive trial?
4. What are the research and intervention resources needed, including training and supervision, for the final trial and future implementation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/01/2019, London-Dulwich Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; +44 (0)207 104 8052; NRESCommittee.London-Dulwich@nhs.net), ref:

Study design
Feasibility study with a quasi-experimental historical control design

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
The IPS intervention is an individualised approach which involves intensive, individual support to re-engage or stay in education or employment. Depending on the client's needs and preference, this can include face-to-face meetings with the IPS trained Occupational Therapist; support in preparing job or school applications; preparing CV; practicing for interviews; and joining the client in appointments when they request support (e.g. work place, educational institution, job centre). None of the information collected as part of this research study will be shared during these appointments with third parties (e.g. work place, educational institution, job centre).

Clients enrolment in the IPS programme will terminate at 6 months (+/- 2 months)from the end of the intervention phase.

This is feasibility study. The resrachers will collect pre-post intervention measures which will include: clients' level of functioning, rates of employment and rates of education enrolment, self-efficacy, and time used.

The researchers will also compare clients' level of functioning, rates of employment and rates of education enrolment with data collected as part of an existing approved audit (historical control group receiving treatment as usual).

Intervention Type
Behavioural

Primary outcome measure
Feasibility of the intervention assessed using:
1. Evidence of the acceptability assessed by interviews
2. Feasibility of delivering the intervention and conducting the research assessment assessed using data integrity
3. Willingness to be recruited, take part in the intervention and drop-out rate measured using consent forms and records
4. Number of eligible participants
5. Willingness to be re-assessed after the intervention (at every follow-up participants will be asked if they wish to be reassessed)
6. Standard deviation of the secondary outcome measures to estimate the sample size for the definitive trial
7. Research and intervention resources, including training and supervision, necessary for delivering the IPS intervention
8. Rates of employment/enrolment on educational course at 3 and 6 months follow up

Secondary outcome measures
At baseline, 3 months and 6 months:
1. Symptoms of psychosis or attenuated symptoms of psychosis measured using the CAARMS
2. Self-efficacy measured using the General Self-Efficacy Scale
3. Functioning assessed using the Global Assessment of Functioning and Social and Occupational Functioning Scale
4. How participants use their time measured using the Time Use Survey (TUS)
5. Health and social aspects measured using the Health of the Nation Outcome Scale (HoNOS)

Overall study start date
01/04/2019

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Met criteria for being at clinical high risk of psychosis at some point within the previous 12 months of the commencement of the study and would have been under the care of the OASIS teams
2. Aged 16-40 years
3. Provide informed consent
4. Express interest in vocational/educational support
5. At least 12 months of treatment remaining with the OASIS team

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Unable to fully comprehend the purpose of the study or make a rational decision whether or not to participate (i.e. not 'Gillick competent')
2. Antipsychotic medication for > 30 days (cumulative number of days) in the 3 months before the baseline assessments (including self-ratings and screening assessments), at doses that would be adequate for treating a first episode of psychosis (i.e. excludes very low doses)
3. Any past episode of frank psychosis lasting > 7 days

Date of first enrolment
01/06/2019

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South London and Maudsley NHS Foundation Trust
London
United Kingdom
CR0 2PR

Study participating centre
King's College London
Department of Psychosis Studies
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Sponsor information

Organisation

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Sponsor type
University/education

Website
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ROR
https://ror.org/0220mzb33

Organisation
South London & Maudsley NHS Fundation Trust

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Charity

Funder Name
Maudsley Charity

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The project outcomes will be disseminated using SLaM newsletters, KCL press office, and through presentations at international conferences. The project will also receive national and international visibility through scientific publications and summaries for a non-expert audience.

Intention to publish date
30/04/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Not expected to be made available