Refining Individual Placement and Support (IPS-LITE)

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/12/2009		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/04/2010	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
04/10/2017	Mental and Behavioural Disorders			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Protocol V.2 - 09/10/2009

Study information

Scientific Title

Is brief Individual Placement and Support (IPS-LITE) as effective as open-ended Individual Placement and Support (IPS) in obtaining employment for individuals with psychiatric disorders? A randomised controlled trial

Acronym

IPS-LITE Trial

Study objectives

Modified IPS model (IPS-LITE), with its clearer time-frame, will return an equal or greater proportion of patients to employment compared to standard IPS. The primary outcome is return to open employment for at least one day.

Ethics approval required

Old ethics approval format

Ethics approval(s)

IOW, Portsmouth & SE Hampshire Research Ethics Committee, 22/09/2009, ref: 09/H0501/53

Study design

Single-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

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

Clinically established diagnosis of mental illness

Interventions

Eligible participants will be identified from a newly established IPS service during the IPS service eligibility assessment. Patients will enter the study in the same time when they enter the service.

After obtaining of the written consent the baseline interview will be administered by research assistant. Recruitment period will last 15 months with follow-up of 18 months and assessments at baseline, 9 months and 18 months. The interviews will consist of appropriate validated and

standardised questionnaires. Data will be obtained from patients' medical records. After 18-months of trial the IPS service continues as usual.

After the baseline interview participants will be randomised to either IPS-LITE (intervention group) or IPS standard (control group).

Control group:

IPS workers are integrated into the secondary mental health team and have a maximum caseload of 25 clients. Clients usually remain in the care of the MH team and the approach is to ascertain job preferences from motivated clients and, through local knowledge of employers, help them identify and obtain open employment without prolonged preliminary assessment or training. IPS workers continue to support client and employer indefinitely according to need.

Intervention group:

IPS-LITE follows exactly the same principles as IPS, including integration with the MH team, maximum caseload and procedures for job search and support. However it restricts the period of engagement. Clients unplaced after 9 months will be discharged back to the MH team who can re-refer if clinical circumstances change (re-referral will be treated as an outcome, not as new study subjects). Engagement and support will be reduced when clients have been continuously employed for 13 weeks, handing back to the MH team at 16 weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Worked for at least one day.

All outcomes are measured at 9 months and 18 months after the baseline assessment.

Secondary outcome measures

- 1. Worked for at least 13 weeks
- 2. Number of days worked
- Number of hours worked
- 4. Job tenure (length of longest job)
- 5. Time to first job
- 6. Client disengagement from IPS
- 7. Hospitalisation (Y/N)
- 8. Number of days hospitalised

All outcomes are measured at 9 months and 18 months after the baseline assessment.

Overall study start date

01/09/2009

Completion date

31/05/2012

Eligibility

Key inclusion criteria

- 1. Aged 18 60 years, either sex
- 2. Clinically established diagnosis of mental illness
- 3. Enhanced care programme approach (CPA)
- 4. Unemployed for a minimum of six months
- 5. Declared wish to obtain open employment
- 6. Written and informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

160

Key exclusion criteria

- 1. Incapacity to give informed consent (e.g. advanced dementia or mental disorder too severe to give informed consent)
- 2. Incapacity to communicate in English

Date of first enrolment

01/09/2009

Date of final enrolment

31/05/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Oxford

Oxford United Kingdom OX3 7JX

Sponsor information

Organisation

Oxfordshire and Buckinghamshire Mental Health NHS Foundation Trust (UK)

Sponsor details

Littlemore Mental Health Centre Sandford Road Littlemore Oxford England United Kingdom OX4 4XN

Sponsor type

Hospital/treatment centre

Website

http://www.obmh.nhs.uk/

ROR

https://ror.org/04c8bjx39

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme funding pending as of 23/02/2010 (ref: PB-PG-0909-20029)

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?
Results article	results	01/10/2015		Yes	No