

Individual and placement support for alcohol and drug dependence

Submission date 05/01/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 01/02/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 09/02/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Many people with drug and alcohol dependence want to work, but struggle to access the open job market and achieve stable employment. Employment has been a key recovery strand of successive governments' drug strategies but despite this, employment rates for people in both drug and alcohol treatment remain low. There is a well-established international evidence base for Individual Placement and Support (IPS) in severe mental health settings. Findings from IPS studies in the addiction sector are promising although limited in scale, with strong results compared to generic support or programmes for similarly disadvantaged patients. The aim of this study is to build the evidence base around the provision of IPS as an effective employment support model for the drug and alcohol dependent treatment population.

Who can participate?

Working-age adults (18-65) with drug or alcohol dependence who are unemployed or inactive, receiving state benefits and are enrolled in community treatment for alcohol or drug dependence

What does the study involve?

Participants are randomly allocated to receive either time-limited employment support (IPS for 9 months plus 4 months in-work support) or the standard employment support individuals currently receive from mainstream employment support providers Jobcentre Plus and the forthcoming Work and Health Programme. Participants receiving IPS are seen once a week for the first month, then at least bi-weekly for the remainder of the 9-month employment support period up to the point of securing a job. This may be flexible, dependent on the level of support that is needed and it would be expected that there would be additional phone and email contact during this time. During this period, the employment specialist works with the participant to identify the type of work they would like to do, their skills, experience and aspirations and the types of jobs that match these. The employment specialist works with the client to help them update their CV and supports them in applying for jobs, contacting employers or agencies on their behalf, or jointly with them. The objective is to help clients look for jobs quickly after joining the IPS programme, rather than requiring them to go through pre-employment activities such as volunteering, training courses or intermediate work experiences, as often featured in the traditional approach from mainstream 'train and place' employment support services. The

employment support phase also includes personalised benefits planning. The employment specialist supports the participant in receiving benefits advice via a 'Better Off Calculation' and, where relevant, clarifies rules around 'permitted work'. This helps participants to understand how their financial situation will be affected by moving into paid work. Once participants obtain employment, the employment specialist is expected to provide support, including one-to-one contact, on a weekly basis for the first month of employment. Examples of support may include meeting with the client to talk about how the job is going, meeting with the employer to obtain feedback, reminder phone calls and support to help the client get to work on time. After the first month, it is expected that the support would reduce to two 'check-ins' per month for the remainder of the 4 month in-work support period but again, this may vary dependent on the participant's needs.

What are the possible benefits and risks of participating?

Participants benefit from gaining access to intensive and specialist employment support, but receive no other direct benefit. Eligibility to access community substance misuse treatment and other services is unchanged for participants in both groups, and is not affected if participants withdraw or drop out. As a form of labour market support, there are no side effects associated with engagement in IPS.

Where is the study run from?

The study is being run by Public Health England at seven sites around England - Birmingham, Blackpool, Brighton and Hove, Derbyshire, Haringey, Sheffield, and Staffordshire.

When is the study starting and how long is it expected to run for?

July 2017 to March 2021

Who is funding the study?

The Work and Health Unit, which brings together the Department for Work and Pensions and the Department of Health (UK)

Who is the main contact?

Paul Anders

Contact information

Type(s)

Public

Contact name

Mr Paul Anders

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Nil known

Study information

Scientific Title

Effectiveness and cost-effectiveness of employment support during treatment for drug and alcohol dependence: the Individual Placement and Support for Alcohol and Drug dependence (IPS-AD) trial

Acronym

IPS-AD

Study objectives

To determine the effectiveness and cost-effectiveness of employment specialist support (IPS practice model) versus standard employment support in community drug and alcohol dependence treatment services. The study will be a multi-centre, randomised controlled trial (RCT) with data-linkage capture of the primary outcome measure to estimate the effectiveness of IPS. The study aim will be to determine whether the IPS approach is effective for the target population and whether the level of exposure to IPS is associated with the outcomes achieved.

Ethics approval required

Old ethics approval format

Ethics approval(s)

East of England - Cambridge East Research Ethics Committee, 21/12/2017, ref: 17/EE/0454

Study design

Multi-centre pragmatic two-arm parallel-group mixed-methods superiority 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 to request a patient information sheet

Health condition(s) or problem(s) studied

Adult, unemployed, in treatment for drug and/or alcohol dependence

Interventions

Randomisation is individual, allocation ratio 1:1. This is accessed via a secure website and created and independently managed by the King's College London Clinical Trials Unit.

1. Intervention: Employment specialist support following the 'Individual Placement and Support' model (IPS)
2. Treatment-as-usual (TAU) control: Standard support (Jobcentre Plus/Work & Health Programme)

The intervention is Individual Placement and Support (IPS), an evidence-based intervention that operates according to the following fidelity principles:

1. Eligibility is based on individual choice
2. Supported employment is integrated with treatment
3. Competitive employment is the goal, (not sheltered placements or volunteering)
4. Rapid job search (within four weeks), minimal prevocational training
5. Job finding, and all assistance, is individualised
6. Employers are approached with the needs of individuals in mind
7. Follow-along supports are continuous
8. Financial planning is provided

Clients will be seen once a week for the first month, then at least bi-weekly for the remainder of the 9-month employment support period up to the point of securing a job. This may be flexible, dependent on the level of support that is needed and it would be expected that there would be additional phone and email contact during this time.

Employment specialists will work with any individual in drug and alcohol treatment who expresses a desire to work and who meets the inclusion criteria. All eligible people interested in working will be able to receive IPS services regardless of job readiness factors, work history, qualifications, their substance misuse and related factors (such as physical and mental health, history of offending behaviour or homelessness).

During this period, the employment specialist will work with the individual to identify the type of work they would like to do, their skills, experience and aspirations and the types of jobs that match these. The employment specialist will work with the client to help them update their CV and will support them in applying for jobs, contacting employers or agencies on their behalf, or jointly with them.

The objective will be to help clients look for jobs quickly after joining the IPS programme, rather than requiring them to go through pre-employment activities such as volunteering, training courses or intermediate work experiences, as often featured in the traditional approach from mainstream 'train and place' employment support services.

The employment support phase will also include personalised benefits planning. The employment specialist will support the individual in receiving benefits advice via a 'Better Off

Calculation' and, where relevant, clarify rules around 'permitted work'. This will help clients to understand how their financial situation will be affected by moving into paid work.

Once people obtain employment, the employment specialist will be expected to provide support, including one-to-one contact, on a weekly basis for the first month of employment. Examples of support may include meeting with the client to talk about how the job is going, meeting with the employer to obtain feedback, reminder phone calls and support to help the client get to work on time.

After the first month, it is expected that the support would reduce to two 'check-ins' per month for the remainder of the 4 month in-work support period but again, this may vary dependent on individuals' needs.

Intervention Type

Behavioural

Primary outcome measure

At least 1 day of employment in the open market during an 18-months follow-up from the time of enrolment in the trial. This will be measured via matching administrative datasets at 18 months after enrolment.

Secondary outcome measures

1. Employment:

1.1. Total time worked (days/hours), measured via matching administrative datasets at 18 months after enrolment

1.2. Time to first employment during follow-up, measured via matching administrative datasets at 18 months after enrolment

1.3. Number of appointments (individual jobs attained), measured via matching administrative datasets at 18 months after enrolment

1.4. Duration of longest employment (tenure), measured via matching administrative datasets at 18 months after enrolment

1.5. Continuous employment for at least 13 weeks during follow-up (used by the UK Office of National Statistics for employment statistics and captures sustained employment), measured via matching administrative datasets at 18 months after enrolment

The secondary employment outcome measures will also be monitored via data linkage with the LMS and HMRC data held by DWP.

2. Personal, vocational, social functioning and support:

2.1. Job search self-efficacy, measured using the Job Search Self-Efficacy-Behaviour (JSSE-B) scale at enrolment, 6, 12 and 18 months

2.2. Clinical, health and social functioning (i.e. use of illicit substances; consumption of alcohol; non-medical drug injecting behaviour; psychological and physical health and well-being via TOP; DSM-5 remission status), measured using SCID-CV at enrolment, 6, 12 and 18 months

2.3. Drug and alcohol treatment: total time in treatment, number of treatment journeys, treatment status at end of follow-up (in treatment, left: successfully; left: unsuccessfully), measured via analysis of the National Drug Treatment Monitoring System (NDTMS) at 18 months after enrolment

The clinical, health and social functioning outcomes will be collected and monitored using the National Drug Treatment Monitoring System (NDTMS), using data that is already routinely collected by PHE on all individuals in substance misuse treatment.

3. QALY/healthcare/societal cost-related:

3.1. Health-related quality of life (EQ5D-5L), measured via analysis of the National Drug Treatment Monitoring System (NDTMS) at 18 months after enrolment

3.2. Net change in the number of convictions and time spent in prison (before and after the study) by offence type (Police National Computer), measured via matching administrative datasets at 18 months after enrolment

3.3. Contact with inpatient and outpatient hospital services (HES), measured via matching administrative datasets at 18 months after enrolment

Overall study start date

01/07/2017

Completion date

31/03/2021

Eligibility

Key inclusion criteria

1. Aged 18-65 years
2. Enrolled in treatment for drug or alcohol use disorder for at least 14 days with current diagnosis of a specified drug and/or alcohol use disorder
3. Unemployed or inactive at study screening visit for at least 6 months with declared wish to obtain open job market employment
4. Able to attend the community addiction clinic as required in the protocol
5. Able to communicate (verbal and written English) at a level required to engage with a psychosocial intervention
6. Able to provide personal National Insurance number to facilitate data linkage

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

2,400

Total final enrolment

1720

Key exclusion criteria

1. Currently receiving detoxification treatment for drug or alcohol withdrawal
2. Clinically significant (or otherwise uncontrolled) severe mental health, intellectual disability, organic brain disease or dementia, or physical disability that is judged by the local clinical lead to prevent the person accepting IPS
3. Suicide planning (past month) or suicide attempt (past 6 months)
4. Current legal proceedings which are likely to result in imprisonment
5. Current enrolment in an IPS trial, or within the past 6 months
6. Previously enrolled in, and dropped out of, the IPS-AD trial

Date of first enrolment

08/05/2018

Date of final enrolment

30/09/2019

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Change, Grow, Live

Brighton

United Kingdom

BN1 1YR

Study participating centre

Blackpool Council

Blackpool

United Kingdom

FY1 1NF

Study participating centre

Cranstoun

Esher

United Kingdom

KT10 9AD

Study participating centre
Intuitive Thinking Skills - Derbyshire
Derby
United Kingdom
DE22 3LZ

Study participating centre
St Mungo's
London
United Kingdom
E1W 1YW

Study participating centre
Sheffield Health & Social Care NHS Foundation Trust
Sheffield
United Kingdom
S10 3TG

Study participating centre
ADS - Staffordshire
Stafford
United Kingdom
ST16 2DH

Sponsor information

Organisation
Public Health England

Sponsor details
Skipton House
80 London Road
London
United Kingdom
SE1 6LH

Sponsor type
Government

Website

Funder(s)

Funder type

Government

Funder Name

Work and Health Unit (UK Department for Work and Pensions & Department of Health)

Results and Publications

Publication and dissemination plan

Front-facing publication of the Statistical Analysis Plan and the study protocol will address matters of transparency for the analysis. Accordingly, the study will be pre-registered with the Centre for Open Science (<https://www.osf.io>) and protocol published in a trials journal.

The statistical analysis of outcomes, including effectiveness, cost effectiveness and cost-benefit will be published alongside an independently produced integrated process and realist evaluation. This will be published on the .gov.uk website; publication in an appropriate journal may also be sought.

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

National data protection and cross governmental data sharing protocols prohibit individual level availability of the dataset to anyone outside of the study. The study data will be held by Public Health England.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/02/2020	13/02/2020	Yes	No
HRA research summary			28/06/2023	No	No
Results article		18/01/2024	09/02/2024	Yes	No