

# Sheffield City Region Health-led Trial

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<b>Registration date</b> 28/10/2019	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/05/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This study looks at a voluntary employment service co-located within primary care and co-ordinated with the patient's health support. The service provides employment support to individuals with mild to moderate mental health and/or physical health conditions and who are (i) either unemployed and seeking work or (ii) who are in work but struggling at work as a result of their health or who are off-sick. Individuals will be voluntary participants of the service. The SCR service is a modified form of Individual Placement and Support (IPS) service and fidelity scale and has been developed through an ongoing process of intensive co-design and engagement with local health partners and service users. Service users will be given the support of trained IPS Employment Specialists – a personal caseworker for their core employment support needs and who co-ordinates wider health and support needs. These case workers will be responsible for supporting both in and out of work participants within a single service model, drawing on a range of activities/approaches to support their clients as required.

### Who can participate?

Patients aged 18 or older with mild to moderate mental health and/or physical health conditions and who are either (i) unemployed and seeking work or (ii) who are in work but struggling at work as a result of their health or who are off-sick, and registered with a GP practice in one of the following areas: Barnsley, Bassetlaw, Doncaster, Rotherham, or Sheffield.

### What does the study involve?

Participants are randomly allocated to either an intervention group (SCR service) or a control group (business-as-usual employment and health support services). Participants provide data before random allocation and agree to administrative data being drawn down for their case at this point. Following this they are invited to take part in follow-up surveys and some will be invited to take part in in-depth interviews and focus groups.

### What are the possible benefits and risks of participating?

The trial will establish whether Individual Placement and Support (a well evidenced intervention for people with severe mental health conditions) is effective and cost-effective for people with physical conditions and mild-to-moderate mental health conditions. It will also test this support for people who are employed have been on sick leave for 4+ weeks

Where is the study run from?

The evaluation is being conducted by independent researchers appointed and funded by the Department of Work and Pensions. The employment service will be implemented in Barnsley, Bassetlaw, Doncaster, Rotherham and Sheffield.

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

October 2016 to March 2022

Who is funding the study?

The programme is funded by the Work and Health Unit (a joint Department of Work & Pensions (DWP) and Department of Health (DH) unit) and NHS England.

Who is the main contact?

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## Contact information

### Type(s)

Scientific

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helen.gray@employment-studies.co.uk

## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
CPMS: 35171

## **Study information**

**Scientific Title**

## Sheffield City Region Health-led Trial

### **Study objectives**

This proposed research looks at a voluntary employment service co-located within primary care and co-ordinated with the patient's health support. The employment service will be implemented in Barnsley, Bassetlaw, Doncaster, Rotherham and Sheffield later this year. The service provides employment support to individuals with mild to moderate mental health and/or physical health conditions and who are (i) either unemployed and seeking work or (ii) who are in work but struggling at work as a result of their health or who are off-sick. Individuals will be voluntary participants of the service.

The SCR service is a modified form of Individual Placement and Support (IPS) service and fidelity scale and has been developed through an ongoing process of intensive co-design and engagement with local health partners and service users.

Service users will be given the support of trained IPS Employment Specialists – a personal caseworker for their core employment support needs and who co-ordinates wider health and support needs. These case workers will be responsible for supporting both in and out of work participants within a single service model, drawing on a range of activities/approaches to support their clients as required.

The programme will be evaluated using a randomised control trial (RCT) which means that following agreement to participate and the provision of written informed consent individuals will be randomly allocated to either an intervention group or a control group (business-as-usual employment and health support services). The evaluation is being conducted by independent researchers appointed and funded by the Department of Work and Pensions. The programme is funded by the Work and Health Unit (a joint Department of Work & Pensions (DWP) and Department of Health (DH) unit) and NHS England. The evaluation will start in October 2017 and should report in 2021.

### **RESEARCH QUESTIONS/HYPOTHESIS**

1. What impact, if any, does the provision of IPS type services to the selected client groups have upon attaining and sustaining employment?
2. What impact, if any, does the provision of IPS type services to the selected client groups have upon the self-reported health, the self-management of health and wider wellbeing?
3. What costs are incurred and what benefits arise (in respect of health, employment and wellbeing) from the provision of IPS type services to the selected client groups?
4. How are any impacts of the trial upon sustained employment, and health, achieved?

While there is good evidence that IPS is associated with positive outcomes for people living with severe and enduring mental illness, it is not well-evidenced for other health conditions and in other settings. The trial therefore has an underlying hypothesis that IPS will also work in wider health-settings, and for other health conditions and employment situations.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 23/10/2017, Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; Tel: +44 (0)207 104 8101; Email: NRESCommittee.EastofEngland-CambridgeEast@nhs.net), ref: 17/EE/0371

## **Study design**

Randomised; Both; Design type: Treatment, Complex Intervention, Cross-sectional

## **Primary study design**

Interventional

## **Study type(s)**

Other

## **Health condition(s) or problem(s) studied**

Mild to moderate mental health and/or physical health conditions

## **Interventions**

### **SUMMARY OF STUDY DESIGN AND METHODOLOGY**

The national evaluation will be using a mixed methods design using a randomised controlled trial, a process evaluation and an economic evaluation.

**RANDOMISED CONTROLLED TRIAL (RCT):** consenting individuals will be randomly allocated to either an intervention group (the new service) or a control group (support as usual). Data needed to answer the research questions will be collected on both groups from the following sources: (i) data collected by Employment Specialists delivering the new service; (ii) health service usage data collected and held nationally by NHS Digital; (iii) data about earnings, employment and benefits held nationally by HMRC and DWP; (iv) surveys of trial participants carried out in the course of the evaluation. The evaluation will use these data to reach assessments of the impact, benefits and costs of the trial.

An RCT method was selected to provide the best chance of gathering robust evidence about the impact of the trial on health and work outcomes, and thus the most appropriate methodology to answer the key research questions. Other approaches to building a counterfactual were considered (for example creating a matched control group using propensity score matching), but the RCT was found to be the approach which was most likely to generate a similar control group. The selection of this method, including a control arm where the service users will be able to receive service as usual, is justified on the basis that it is not known whether the SCR IPS service will be effective. Key outcomes – in terms of health, wellbeing and work – will be compared between the treatment and control group using data in datasets (held by NHS Digital, DWP, HMRC) and a survey administered to all trial participants.

**PROCESS EVALUATION:** alongside the quantitative analysis, the evaluation will invite trial participants in treatment and control groups to complete interim and follow-up user surveys. It will also involve and qualitative research (interviews) with users, staff and other stakeholders such as employers in each area, to understand how the trial is operating and to unpick the causal pathway to outcomes.

**ECONOMIC EVALUATION:** this looks at whether the benefits of the IPS service exceed the costs. The researchers will conduct a cost-benefit-analysis, i.e. a valuation of individual and wider social /economic impacts in monetary terms (including future discounted benefits), from which the costs of the service can be subtracted to derive an 'analysis of value for money', e.g. benefit-cost ratios.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Updated 31/03/2020:

These are the primary outcome measures noted in the statistical analysis plan and thus are dated 20/12/2019:

There are three primary outcomes at the interim report stage and four primary outcomes at the final report stage. The SAP gives a decision rule that will be used to define primary outcomes in the case of substantial treatment-control imbalance in the survey response rates.

Interim report:

1. Employment: employed 4 months after randomisation
2. Health assessed using EQ-5D-5L scale on mobility, self-care, usual activities, pain/discomfort and anxiety/depression, at 4 months after randomisation
3. Well-being assessed using Short Warwick-Edinburgh Mental Well-being Scale (SWEMWB) at 4 months after randomisation

Final report:

1. Sustained employment: 13 weeks or more in employment during the 12 months since randomisation
2. Earnings: total earnings in the 12 months since randomisation
3. Health assessed using EQ-5D-5L scale on mobility, self-care, usual activities, pain/discomfort and anxiety/depression, at 12 months after randomisation
4. Well-being assessed using Short Warwick-Edinburgh Mental Well-being Scale (SWEMWB) at 12 months after randomisation

Previous primary outcome measures as of 18/11/2019:

1. Employment: employed 4 months after randomisation (interim report); 13 weeks or more employment 12 months after randomisation (final report)
2. Health assessed using EQ-5D-5L scale on mobility, self-care, usual activities, pain/discomfort and anxiety/depression, at 4 months and 12 months after randomisation
3. Well-being assessed using Short Warwick-Edinburgh Mental Well-being Scale (SWEMWB), 4 and 12 months after randomisation

Current primary outcome measures:

1. Employment: employed 4 months after randomisation (interim report); 13 weeks or more employment 12 months after randomisation (final report)
2. Health assessed using EQ-5D-5L scale on mobility, self-care, usual activities, pain/discomfort and anxiety/depression, at 4 months and 12 months after randomisation
3. Well-being assessed using Short Warwick-Edinburgh Mental Well-being Scale (SWEMWB) at 4 and 12 months after randomisation

Previous primary outcome measures:

1. Employment: proportion spending 13 weeks or more in competitive employment at baseline, at +4 months after baseline, and at +12 months after baseline, at 31/07/2021

2. Health assessed using EQ-5D-5L scale on mobility, self-care, usual activities, pain/discomfort and anxiety/depression at baseline, at +4 months after baseline, and at +12 months after baseline
3. Well-being assessed using Short Warwick-Edinburgh Mental Well-being Scale (SWEMWB) at baseline, at +4 months after baseline, and at +12 months after baseline

### **Key secondary outcome(s)**

Updated 31/03/2020:

These are the secondary outcome measures noted in the statistical analysis plan and thus are dated 20/12/2019:

#### Employment:

1. Percentage employed in each month since randomisation, measured using HMRC data on the start and end dates of employment spells, observed in each of the 12 months following randomisation
2. Number of months employed since randomisation, measured using HMRC data on the start and end dates of employment spells, observed over a period of 12 months following randomisation
3. Earnings by month since randomisation, measured using HMRC data on gross pay from employment and the start and end dates of employment spells, observed in each of the 12 months following randomisation
4. Total earnings since randomisation, measured using HMRC data on gross pay from employment, observed over a period of 12 months following randomisation
5. Receiving out of work benefits by month since randomisation, measured using DWP data on the start and end dates of benefit spells, observed in each of the 12 months following randomisation
6. Number of months receiving out of work benefits since randomisation, measured using DWP data on the start and end dates of benefit spells, observed over a period of 12 months following randomisation
7. Amount received in benefits by month over the 12 months following randomisation
8. Employed and receiving benefits by month over the 12 months following randomisation
9. Percentage employed or self-employed (any hours), measured using survey question on current employment status, observed 4 and 12 months after randomisation
10. Percentage employed or self-employed for 16 or more hours a week, measured using survey question on current employment status, observed 4 and 12 months after randomisation
11. Number of weeks in paid work (any hours) in the four or 12 months since randomisation, measured using survey question on number of weeks in paid work for those currently working, observed 4 and 12 months after randomisation
12. Number of weeks working for 16 or more hours a week since randomisation, measured using survey question on number of weeks in paid work for those currently working, observed 4 and 12 months after randomisation
13. Number of continuous weeks working for 16 hours or more per week since randomisation, measured using survey question on whether the number of weeks in paid work for those currently working for 16 hours or more a week were continuous, observed 4 and 12 months after randomisation
14. Job search self-efficacy, measured using survey question using the 9-item Job Search Self-Efficacy scale. Scores on each of the individual items will be summed together and divided by the total number of items to derive the mean score on the job search self-efficacy index. Observed 4 and 12 months after randomisation

#### Health and well-being:

1. Musculoskeletal health, assessed using survey question using two items from the

Musculoskeletal Health Questionnaire (MSK-HQ) to calculate the proportion who have been bothered 'very much or extremely' by joint or muscle symptoms in the last two weeks. Observed 4 and 12 months after randomisation

2. Mental health, assessed using survey question using the sum of the General Anxiety Disorder 7-item score, and the sum of the Patient Health Questionnaire 8-item score to capture anxiety and depression. Observed 12 months after randomisation

3. Disability Discrimination Act definition of limiting health condition, assessed using Survey question on presence of a health problem which limits everyday activities, observed 4 and 12 months after randomisation

4. Life satisfaction, assessed using survey question using single item on life satisfaction from the Office for National Statistics Personal Well-being Questions. Observed 4 and 12 months after randomisation

5. Self-efficacy, assessed using survey question using the 10-item General Self-Efficacy Scale (GSE Scale). Observed 4 and 12 months after randomisation

Use of health services:

1. Total number of days in hospital since randomisation, assessed using Hospital Episode Statistics on the length of inpatient spells, observed over a period of 12 months following randomisation

2. Total number of health appointments attended since randomisation, assessed using Outpatients, Community Services Dataset, Mental Health Services Dataset and Improving Access to Psychological Therapies records on the date of appointments and whether the patient attended. Observed over a period of 12 months following randomisation

3. Percentage of health appointments attended since randomisation, assessed using Outpatients, Community Services Dataset, Mental Health Services Dataset and Improving Access to Psychological Therapies records on the date of appointments and whether the patient attended. Observed over a period of 12 months following randomisation

4. Total number of A & E visits since randomisation, assessed using Hospital Episode Statistics A & E data on A & E arrival date. Observed over a period of 12 months following randomisation.

Previous secondary outcome measures:

Employment:

1. Percentage employed in each month since randomisation, measured using HMRC data on the start and end dates of employment spells, observed in each of the 12 months following randomisation

2. Number of months employed since randomisation, measured using HMRC data on the start and end dates of employment spells, observed over a period of 12 months following randomisation

3. Earnings by month since randomisation, measured using HMRC data on gross pay from employment and the start and end dates of employment spells, observed in each of the 12 months following randomisation

4. Total earnings since randomisation, measured using HMRC data on gross pay from employment, observed over a period of 12 months following randomisation

5. Receiving out of work benefits by month since randomisation, measured using DWP data on the start and end dates of benefit spells, observed in each of the 12 months following randomisation

6. Number of months receiving out of work benefits since randomisation, measured using DWP data on the start and end dates of benefit spells, observed over a period of 12 months following randomisation

7. Percentage employed or self-employed (any hours), measured using survey question on current employment status, observed 4 and 12 months after randomisation

8. Percentage employed or self-employed for 16 or more hours a week, measured using survey question on current employment status, observed 4 and 12 months after randomisation
9. Number of weeks in paid work (any hours) in the four or 12 months since randomisation, measured using survey question on number of weeks in paid work for those currently working, observed 4 and 12 months after randomisation
10. Number of weeks working for 16 or more hours a week since randomisation, measured using survey question on number of weeks in paid work for those currently working, observed 4 and 12 months after randomisation
11. Number of continuous weeks working for 16 hours or more per week since randomisation, measured using survey question on whether the number of weeks in paid work for those currently working for 16 hours or more a week were continuous, observed 4 and 12 months after randomisation
12. Job search self-efficacy, measured using survey question using the 9-item Job Search Self-Efficacy scale. Scores on each of the individual items will be summed together and divided by the total number of items to derive the mean score on the job search self-efficacy index. Observed 4 and 12 months after randomisation

#### Health:

1. Musculoskeletal health, assessed using survey question using two items from the Musculoskeletal Health Questionnaire (MSK-HQ) to calculate the proportion who have been bothered 'very much or extremely' by joint or muscle symptoms in the last two weeks. Observed 4 and 12 months after randomisation
2. Mental health, assessed using survey question using the sum of the General Anxiety Disorder 7-item score, and the sum of the Patient Health Questionnaire 8-item score to capture anxiety and depression. Observed 12 months after randomisation
3. Disability Discrimination Act definition of limiting health condition, assessed using Survey question on presence of a health problem which limits everyday activities, observed 4 and 12 months after randomisation
4. Life satisfaction, assessed using survey question using single item on life satisfaction from the Office for National Statistics Personal Well-being Questions. Observed 4 and 12 months after randomisation
5. Self-efficacy, assessed using survey question using the 10-item General Self-Efficacy Scale (GSE Scale). Observed 4 and 12 months after randomisation

#### Use of health services:

1. Total number of days in hospital since randomisation, assessed using Hospital Episode Statistics on the length of inpatient spells, observed over a period of 12 months following randomisation
2. Total number of health appointments attended since randomisation, assessed using Outpatients, Community Services Dataset, Mental Health Services Dataset and Improving Access to Psychological Therapies records on the date of appointments and whether the patient attended. Observed over a period of 12 months following randomisation
3. Percentage of health appointments attended since randomisation, assessed using Outpatients, Community Services Dataset, Mental Health Services Dataset and Improving Access to Psychological Therapies records on the date of appointments and whether the patient attended. Observed over a period of 12 months following randomisation
4. Total number of A & E visits since randomisation, assessed using Hospital Episode Statistics A & E data on A & E arrival date. Observed over a period of 12 months following randomisation

#### Completion date

31/03/2022

# Eligibility

## Key inclusion criteria

1. Individuals giving informed consent to participate in the trial and share data for the evaluation
2. 18 years or older
3. Registered with a GP practice in one of the following areas: Barnsley; Bassetlaw; Doncaster; Rotherham; Sheffield (If a trial participant moves out of the area, they will continue to receive the service, if feasible. If not feasible, they will be considered to have dropped out)
4. Wants to participate in voluntary support to sustain paid work
5. May or may not be in receipt of DWP benefits and with a self-defined low/moderate mental health and/or physical health condition which is an obstacle to them finding or keeping work
6. Individuals in work but off sick or struggling in the workplace due to a self-defined low/moderate mental health and/or physical health condition
7. Individuals not currently receiving employment support other than from JobCentre Plus
8. Not on a Care Programme Approach, receiving Community Mental Health Team (CMHT) support or identified on a Serious Mental Illness (SMI) register

It was decided that the following would not feature as part of the inclusion criteria: having sufficient command of English to take part in the procedure (because this could possibly be discriminatory and a small proportion of those referred may have limited levels of English, given the local demographic); physically capable of undertaking the study procedures (the 'spirit' of IPS is not to discriminate or base assessment on any factors other than the individual's perception of their own capability); likely to be available for the planned duration of the study (in order to keep the criteria simple, this could be hard for a referring clinician to assess).

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## Total final enrolment

6117

## Key exclusion criteria

1. Not giving informed consent to participate into the trial
2. Less than 18 years' old
3. Not registered with a GP in one of the outlined areas
4. Does not want to participate in voluntary support to sustain paid work
5. People who are out of work but do not have a self-defined low/moderate mental health and/or physical health condition which is an obstacle to them finding or keeping work

6. Individuals in work but not off sick or struggling in the workplace due to a self-defined low/moderate mental health and/or physical health condition
7. Individuals currently receiving employment support other than JobCentre Plus
8. Individuals in the control group of the IPS Trial
9. On a Care Programme Approach, receiving Community Mental Health Team (CMHT) support or identified on a Serious Mental Illness (SMI) register

With regards to the exclusion criteria, consideration has been given as to whether individuals with a progressive condition (such as cancer, degenerative neurological disease etc.). The researchers decided not to include this as such individuals would not be likely to meet the inclusion criteria (the problem causing a person to be out of work, off sick or struggling at work must be a mild or moderate condition), but this would be assessed case-by-case and people with such conditions are not automatically excluded.

Individuals taking part in another similar employment trial at the point of referral would not be eligible to continue to randomisation. This will be determined by a question to the service user at the initial meetings. Service users will be encouraged to let their Employment Specialist know if they are offered other similar interventions.

**Date of first enrolment**

08/05/2018

**Date of final enrolment**

31/10/2019

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Sheffield Health & Social Care NHS Foundation Trust**

Fulwood House  
Old Fulwood Road  
Sheffield  
United Kingdom  
S10 3TH

**Study participating centre**

**Rotherham Doncaster and South Humber NHS Foundation Trust**

St Catherine's House  
St Catherine's Hospital  
Tickhill Road

Doncaster  
United Kingdom  
DN4 8QN

**Study participating centre**  
**South West Yorkshire Partnership NHS Foundation Trust**  
Trust Headquarters  
Fieldhead  
Ouchthorpe Lane  
Wakefield  
United Kingdom  
WF1 3SP

**Study participating centre**  
**Nottinghamshire Healthcare NHS Foundation Trust**  
The Resource, Trust HQ  
Duncan Macmillan House  
Porchester Road  
Nottingham  
United Kingdom  
NG3 6AA

**Study participating centre**  
**Sheffield Teaching Hospitals NHS Foundation Trust**  
Northern General Hospital  
Herries Road  
Sheffield  
United Kingdom  
S5 7AU

**Study participating centre**  
**The Rotherham NHS Foundation Trust**  
Moorgate Road  
Rotherham  
United Kingdom  
S60 2UD

**Study participating centre**  
**Barnsley Hospital NHS Foundation Trust**  
Gawber Road  
Barnsley

United Kingdom  
S75 2EP

**Study participating centre**

**Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust**

Doncaster Royal Infirmary  
Armthorpe Road  
Doncaster  
United Kingdom  
DN2 5LT

**Study participating centre**

**NHS Barnsley CCG**

Hillder House  
49-51 Gawber Road  
Barnsley  
United Kingdom  
S75 2PY

**Study participating centre**

**NHS Sheffield CCG**

722 Prince Of Wales Road  
Darnall  
Sheffield  
United Kingdom  
S9 4EU

**Study participating centre**

**NHS Rotherham CCG**

Oak House  
Moorhead Way  
Bramley  
Rotherham  
United Kingdom  
S66 1YY

**Study participating centre**

**NHS Doncaster CCG**

Sovereign House  
Ten Pound Walk  
Doncaster

United Kingdom  
DN4 5DJ

**Study participating centre**  
**NHS Bassetlaw CCG**  
Retford Hospital  
North Road  
Retford  
United Kingdom  
DN22 7XF

## Sponsor information

**Organisation**  
Department for Work and Pensions

**ROR**  
<https://ror.org/0499kfe57>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Department for Work and Pensions (UK)

**Funder Name**  
Department of Health (UK)

**Funder Name**  
NHS England

## Results and Publications

Individual participant data (IPD) sharing plan

Current individual participant data (IPD) sharing statement as of 23/03/2022:  
The intention is to store the final data set with the Office for National Statistics SRS for a period of three years.

Previous individual participant data (IPD) sharing statement:  
The intention is to store the final data set with the Administrative Data Research Network for a period of three years.

## IPD sharing plan summary

Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Funder report results</a>		20/04/2023	12/05/2023	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 4	13/02/2018	17/08/2022	No	No
<a href="#">Statistical Analysis Plan</a>		19/12/2019	20/12/2019	No	No