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Sheffield City Region Health-led Trial

Submission date
02/09/2019

Recruitment status
No longer recruiting

Registration date
28/10/2019

Overall study status
Completed

Last Edited
12/05/2023

Condition category
Other

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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
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 measure
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

Secondary outcome measures

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

Overall study start date
14/10/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 7500; UK Sample Size: 7500

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
England

United Kingdom

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
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United Kingdom
DN22 7XF

Sponsor information

Organisation
Department for Work and Pensions

Sponsor details
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Sponsor type
Government

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

Publication and dissemination plan
The trial is sponsored by the Department for Work and Pensions and the Department of Health. These bodies are committed to publication. Detailed research reports will be made public first with interim findings in Autumn 2020, and final findings in Winter 2022.

1. Peer-reviewed scientific journals
2. Internal report
3. Publication on website

Intention to publish date
31/12/2022

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?
Statistical Analysis Plan		19/12/2019	20/12/2019	No	No
Protocol file	version 4	13/02/2018	17/08/2022	No	No
Funder report results		20/04/2023	12/05/2023	No	No
HRA research summary			28/06/2023	No	No