ISRCTN17267942 https://doi.org/10.1186/ISRCTN17267942

West Midlands Combined Authority health-led trial

Submission date	Recruitment status	[_] Prospectively registered
02/09/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
28/10/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/05/2023	Other	

Plain English summary of protocol

Background and study aims
The West Midlands Combined Authority is working with NHS England, the Department of Work and Pensions and the Department of Health to trial a new model for providing health and employment support in one service. The aim is to test whether this model can deliver improvements in people's employment, health and wellbeing. The trial is referred to locally as the 'Thrive into Work' trial. The new service involves Employment Specialists working one-to-one with people to help them find a job and then support them once they find work. The new service is based on the Individual Placement and Support (IPS) model. IPS services are already used and well-evidenced internationally and have been shown to be effective for people with severe mental illness in community mental health settings. The study aims to test whether a modified version of the IPS model will work in other health settings and for a broader group of service users.

Who can participate?
Patients aged 18 or older with a self-defined health condition or disability which presents obstacles to them gaining work, who have been out of work for 4 or more weeks and have expressed an interest in finding paid employment, and are registered with a GP practice in one of the following areas at the point of the initial meeting: Wolverhampton; Dudley; South and Central Birmingham; Sandwell and West.

What does the study involve?
Participants are randomly allocated to either a treatment group (the new service) or a control group (support as usual). Participants provide data before random allocation and agree to administrative data being drawn down for their case at this point. Following this they are then invited to take part in follow-up surveys and some are 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.

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 new service is expected to be implemented in Sandwell and West Birmingham, Birmingham and South Central, Dudley and Wolverhampton.

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 and Department of Health 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: 35170

Study information

Scientific Title
West Midlands Combined Authority health-led trial

Study objectives
The West Midlands Combined Authority is working with NHS England, the Department of Work and Pensions and the Department of Health to trial a new model for providing health and employment support in one service. The aim is to test whether this model can deliver improvements in people's employment, health and wellbeing. The trial is referred to locally as the 'Thrive into Work' trial.

The new service involves Employment Specialists working one-to-one with people to help them find a job and then support them once they find work. It is expected to be implemented in Sandwell and West Birmingham, Birmingham and South Central, Dudley and Wolverhampton.

The programme will be evaluated using a randomised control trial, which means that, on referral, individuals will be randomly allocated to either a treatment group or a control group (support as usual). 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 and Department of Health unit) and NHS England. The evaluation will run from October 2017 to March 2019.

The new service is based on the "Individual Placement and Support (IPS) model". IPS services are already used and well-evidenced internationally and have been shown to be effective for people with severe mental illness in community mental health settings. The new service aims to test whether a modified version of the IPS model will work in other health settings and for a broader group of service users.

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.

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/0364

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
Health and employment support

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 a treatment 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 WM 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
Other

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

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
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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. Registered with a GP practice in one of the following health geographies at the point of the initial meeting: Wolverhampton; Dudley; South and Central Birmingham; Sandwell and West. 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
2. 18 years or older
3. Have a self-defined health condition or disability which presents obstacles to them gaining work
4. Has been out of work for 4 or more weeks and have expressed an interest in finding paid employment

Issues around informed consent and capacity are of course key gateways into the WM IPS service trial, but these are not part of the inclusion criteria, which are primarily aimed at referring professionals. Informed consent and capacity are essential, but are assessed by the Employment Specialist at the first meeting, if the individual meets other inclusion criteria.

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 (the WM IPS service would like 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: 5300; UK Sample Size: 5300

Total final enrolment
3682

Key exclusion criteria
1. Not registered with a GP in one of the outlined areas
2. Less than 18 years' old
3. Not capable of undertaking/attending for the study procedures due to any long-standing condition (e.g. moderate to severe learning disability or presenting with late stage dementia)

4. People who are not out of work
5. People who have been out of work for less than 4 weeks
6. People in work but job in jeopardy (e.g. long-term sick leave)
7. People who have a job offer
8. People who are currently on a state-funded employment programme (apart from Job Centre Plus or programmes where employment is not the primary focus) or relevant research programme

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.) or those with a condition likely to improve rapidly (e.g. currently temporarily impaired after successful treatment) should be included or excluded. It was decided not to include these factors in the inclusion/ exclusion criteria. In relation to the former, with medical treatment people with these conditions can make functional gains and may wish to return to work - and would need support to do so. In relation to the latter, the criteria for inclusion specifies long-term health conditions or disabilities, and it is unlikely that this criteria would be interpreted by a health professional as a brief stint of ill health.

Date of first enrolment
08/05/2018

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Dudley Group NHS Foundation Trust
C Block
Russells Hall Hospital
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

Study participating centre
Dudley and Walsall Mental Health Partnership NHS Trust
Trafalgar House
47-49 King Street
Dudley
United Kingdom
DY2 8PS

Study participating centre
Black Country Partnership NHS Foundation Trust
Delta Point
Greets Green Road
West Bromwich
United Kingdom
B70 9PL

Study participating centre
Heart Of England NHS Foundation Trust
Birmingham Heartlands Hospital
Bordesley Green East
Birmingham
United Kingdom
B9 5ST

Study participating centre
NIHR CRN: West Midlands
United Kingdom
-

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Trust HQ
PO Box 9551
Queen Elizabeth Medical Centre
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Birmingham and Solihull Mental Health NHS Foundation Trust
Unit 1
50 Summer Hill Road
Birmingham
United Kingdom
B1 3RB

Study participating centre
Birmingham Community Healthcare NHS Foundation Trust
3, Priestley Wharf
Holt Street
Birmingham Science Park
Aston
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United Kingdom
B7 4BN

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

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
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?
Protocol file	version v4	13/02/2018	28/10/2019	No	No
Statistical Analysis Plan		19/12/2019	20/12/2019	No	No
Funder report results		20/04/2023	12/05/2023	No	No
HRA research summary			28/06/2023	No	No