

# Assessment of the feasibility of a trial of individualised placement and support for people unemployed with chronic pain

<b>Submission date</b> 15/11/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/12/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/01/2024	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Chronic pain is pain that continues over months or years and does not respond to usual pain care. It has many causes but is often musculoskeletal (e.g. back pain). Chronic pain negatively impacts on daily activities, relationships, mood, sleep, overall health and employment. In general, work is good for people: as well as financial wellbeing, it enhances self-worth and confidence and gives status and purpose in society. Unemployment is associated with poorer health and the children of workless adults in turn have poorer health and higher risk of long-term unemployment. Individualised Placement Support (IPS) has been shown to improve the employability of people with severe mental health conditions such as schizophrenia. Trained vocational advisers provide support to patients in finding and retaining a job using motivational interviewing techniques, problem-solving, identification of the skills and capabilities of the individual, and using knowledge of local employers and workplaces. Support can be supplemented with skills training such as CV workshops or counselling to overcome low self-esteem. Vocational support is combined with healthcare. The aim of this study is to find out whether IPS could benefit people with chronic pain who have many problems similar to those with severe mental illness.

### Who can participate?

People who have taken part in the IPS scheme, Employment Support Workers who are currently working in the IPS scheme, primary care staff involved with patients with chronic pain, and people with chronic pain who have been unemployed for more than 3 months as a result of their health condition and who want to work.

### What does the study involve?

People who have recently completed IPS are interviewed to understand what they think the benefits of IPS are so that they can be measured. Vocational advisers are also interviewed to identify what additional training they might need to provide IPS to pain patients and how to best integrate them with pain services. Focus groups are run with GPs to find out what the usual care is for unemployed people with chronic pain. IPS for chronic pain patients is then developed. People with chronic pain who are unemployed and want to work are randomly allocated to

receive either IPS supported by community pain services, or a booklet which signposts them to employment and healthcare services. The aims are to find out whether enough people can be recruited, whether they will stay in the study and complete questionnaires for 12 months, and how they feel about being randomly allocated, particularly if they do not receive IPS. A sample of the patients, the vocational advisers and the GPs are interviewed about their experiences.

What are the possible benefits and risks of participating?

There are no direct benefits to those participating but the main future benefit will be to inform healthcare providers, policy makers and employers so that any intervention is effective and appropriately tailored to the needs of those with chronic pain who wish to work. There are no foreseen risks to the participants but they are invited to contact the University of Southampton Research Governance Office if they have concerns.

Where is the study run from?

MRC Lifecourse Epidemiology Unit (UK)

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

September 2015 to March 2019

Who is funding the study?

Health Technology Assessment Programme (UK)

Who is the main contact?

Dr Cathy Linaker

chl@mrc.soton.ac.uk

## Contact information

### Type(s)

Public

### Contact name

Dr Cathy Linaker

### Contact details

MRC Lifecourse Epidemiology Unit

University of Southampton

Southampton General Hospital

Tremona Road

Southampton

United Kingdom

SO16 6YD

+44 (0)238 077 7624

chl@mrc.soton.ac.uk

## Additional identifiers

### Protocol serial number

HTA 15/108/02

# Study information

## Scientific Title

Manualising individualised placement support for people with unemployment due to chronic pain and testing the feasibility of a randomised controlled trial

## Acronym

In STEP (Individualised Support To Employment Participation)

## Study objectives

The aim of this feasibility research is to develop knowledge and understanding to inform the future delivery of an individually randomised controlled trial to assess the clinical and cost-effectiveness of Individualised Placement Support (IPS) for unemployed people with chronic pain who wish to work. There are five primary research questions for this feasibility phase of the research:

1. Can unemployed people with chronic pain be identified efficiently from primary care and what resource or logistic issues might be involved?
2. What are the barriers (e.g., practical, financial, motivational) to an individual's participation in a trial of a vocational (IPS) intervention for people with chronic pain?
3. What are the barriers (e.g., practical, financial, motivational) to a primary care practice's participation in a trial of a vocational (IPS) intervention for people with chronic pain?
4. What training and support is needed to enable Employment Support Advisers to work with individuals with chronic pain and integrate with pain services?
5. What should be 'treatment as usual' (TAU), in a future trial in the views of participants, ESWs, GPs and other members of the primary care team?

More details can be found at: <https://www.journalslibrary.nihr.ac.uk/programmes/hta/1510802/>

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The University of Southampton Faculty of Medicine Ethics Committee, 19/12/2016, ref: 23853

## Study design

Mixed-methods including qualitative work and a pilot randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Quality of life

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

Chronic pain and unemployment

## Interventions

The research includes mixed-methods in six work packages. Five of the 6 are qualitative work involving all the key stakeholders. Work package 4 involves carrying out a pilot trial including 80 participants, who will be randomised to one of two arms (treatment as usual vs the Individual

Placement and Support intervention). Data collected in this phase will only be evaluated for completion rates and user-friendliness to participants.

Before a definitive RCT of Individual Placement Support (IPS), we have a number of research questions that must be addressed around recruitment, the intervention, the comparator and the outcome measures, as well as needing to test the feasibility of delivery of IPS in the NHS. We propose that these questions can be addressed through qualitative and quantitative work in 6 iterative work packages (WPs):

WP1: Qualitative work with a sample of patients who have experienced the City Deals IPS to explore assessment of motivation to enrol, outcomes most important to patients, and beliefs which may be barriers to change.

WP2: Qualitative work with City vocational advisers (VAs) to understand their experiences of IPS, their knowledge of and attitudes to chronic pain and their training needs to implement IPS in practice.

WP3: Focus groups with primary care teams to develop recruitment strategies and inform outcome measures and to assist with developing patient materials for WP4.

WP4: A primary-care based longitudinal study involving the development of the RCT protocol in a sample of 80 patients. We will aim to recruit participants from primary care. A sample of GPs in Portsmouth and the Wessex Primary Care research network have agreed to use our proposed two-part search strategy to assess identification of appropriate patients in sufficient number. We will test the procedures for consent and randomisation in the sample of 80, randomising 40 to each arm (by pre-arranged algorithm known only to the researchers). All 80 will complete a baseline interview. Cases will have assessment by the VAs and by a pain clinician to establish a pain management plan. The pain plan will be dynamic and responsive, can be reviewed at any time and can be supplemented by rapid access to the pain management clinic. Specialist pain psychology supervision will also be provided where pain is acting as a barrier to moving forwards with employment. The VAs will work with the 40 patients as per the City Deals programme. Among participants, we will measure adherence to protocol and rates of drop-out. Questionnaires will be distributed and collected back, not to evaluate the main outcomes of the RCT but rather to assess whether people can and do complete the questionnaires as intended. The distribution of the outcome measures (employment, health-related and economic) will be assessed to inform a future power calculation. The 40 control subjects will be surveyed and a sample interviewed to assess acceptability of randomisation and uptake of the control booklet.

WP5: Qualitative research with a sample of WP4 participants, their healthcare providers, and VAs to evaluate the study and lessons learned.

WP6: Manualise the integrated IPS /chronic pain and review fidelity principles if required, last refinement of study protocol and SOPs and data collection tools based on feedback from Phase V.

We have allowed 6 months to set up WP4, including obtaining approvals. Once setup, we will complete WP4 over 18 months. WPs 1-3 will be initiated during the first 6 months. WPs 5 and 6 will take an additional 6 months timed towards the end of WP4 so that we can obtain maximum insight (total 27 months).

## **Intervention Type**

Behavioural

### **Primary outcome(s)**

1. Feasibility of recruitment, assessed using qualitative focus group/semi-structured interviews in January-June 2017
2. The acceptability of randomisation, assessed by descriptive analysis of the pilot trial data (the proportion who agree to take part) in April 2017-September 2018
3. Drop outs from intervention/control arms, assessed by descriptive analysis of the pilot trial data (rates of attrition from each arm of the trial) in April 2017-September 2018
4. Drop outs over the follow-up period, assessed by descriptive analysis of the pilot trial data (rates of attrition during the trial) in April 2017-September 2018

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

This pilot trial will explore the acceptability and feasibility of use of a range of relevant outcome measures which would usefully inform the future definitive trial. Some of the development work for this will take place during WPs 1-3 and therefore a definitive list cannot be provided at this stage. However, measures that are currently planned to be used include:

1. Work: Competitive employment outcomes (obtaining an interview, obtaining a job, duration of employment, hours of employment achieved, productivity, intensity of work participation, presenteeism, sickness absence), job satisfaction, job search self-efficacy questionnaire (Vinokur 1991), financial wellness, debt
2. Health: General self-efficacy (Luszczynska 2005), Modified enablement questionnaire (Howie 1998), self-rated health, IMMFACT measures of chronic pain (Dworkin 2005) including function, pain self-efficacy (Nicholas), mental health, pain medication use, adverse events, healthcare use (A&E visits, Ambulance calls, hospital visits, inpatient days, GP appointments), health-related quality of life, EQ-5D, social and emotional wellbeing, self-esteem and beliefs about coping, positive functioning, optimism, resilience
3. Economics: Health and social care costs, benefits costs, cost-effectiveness from societal perspective

### **Completion date**

31/12/2019

## **Eligibility**

### **Key inclusion criteria**

1. Participants who have taken part in the Individualised Placement Support scheme in Southampton or Portsmouth
2. Employment Support Workers who are currently working in the IPS scheme in Southampton and/or Portsmouth
3. Primary care staff will be invited to the focus group sessions if they are currently part of a team involved with patients with chronic pain in Southampton and/or Portsmouth
4. People with chronic pain who are unemployed for more than 3 months as a result of their health condition and who want to work

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

**Key exclusion criteria**

Individuals who are unable to speak English

**Date of first enrolment**

09/01/2017

**Date of final enrolment**

30/09/2018

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**MRC Lifecourse Epidemiology Unit**

University of Southampton  
Southampton General Hospital  
Southampton  
United Kingdom  
SO16 6YD

## Sponsor information

**Organisation**

University of Southampton

**ROR**

<https://ror.org/01ryk1543>

## Funder(s)

**Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

## Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Cyrus Cooper (cc@mrc.soton.ac.uk).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	qualitative results	25/08/2020	18/01/2021	Yes	No
<a href="#">Results article</a>	results	01/01/2021	28/01/2021	Yes	No
<a href="#">Results article</a>		22/07/2022	10/01/2024	Yes	No
<a href="#">Other publications</a>	stakeholder evaluation	04/04/2020	09/12/2020	Yes	No