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

Submission date
15/11/2016

Recruitment status
No longer recruiting

Registration date
01/12/2016

Overall study status
Completed

Last Edited
10/01/2024

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 though 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 measure
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

Secondary outcome measures
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, IMMPACT 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

Overall study start date
21/09/2015

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

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
30 staff and 80 patients for dummy trial

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
England

United Kingdom

Study participating centre
MRC Lifecourse Epidemiology Unit
University of Southampton
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Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

1. Communication with researchers in pain medicine, occupational medicine and vocational rehabilitation through scientific publications and conference presentations
2. Communication with healthcare professionals through publications and conferences (RCGP annual conference, Pain Society Conference)
3. The PI is a member of the UK Fit for Work Coalition and will disseminate findings to inform members of the Health Select Committee and Work and Pensions Select Committee
4. Communication with established PPI group, local employers and relevant charities (Arthritis Research UK, Pain UK, Arthritis Care)

Intention to publish date
31/12/2021

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?
Other publications	stakeholder evaluation	04/04/2020	09/12/2020	Yes	No
Results article	qualitative results	25/08/2020	18/01/2021	Yes	No
Results article	results	01/01/2021	28/01/2021	Yes	No
Results article		22/07/2022	10/01/2024	Yes	No