PROTOCOL:

Manualising Individualised Placement Support for people with unemployment due to chronic pain and testing the feasibility of a randomised controlled trial

Abbreviations

DWP: Department for Work & Pensions

IPS: Individualised Placement Support

IT: Information Technology

KASRP: Knowledge and Attitudes Survey Regarding Pain

RCT: Randomised controlled trial

SOPs: Standard Operating Procedures

TAU: Treatment as usual

VAs: Vocational advisers

Background and Rationale:

Chronic pain is that which troubles a person all or most of the time over months/years and is defined as pain that persists beyond the normal period of healing, usually taken as three months, with a six-month cut-off being used for research purposes. It is a major health problem associated with mental illness, job loss, impaired function and poor quality of life. Epidemiological studies suggest that 31% of men and 37% of women have chronic pain at any point in time and prevalence increases with age (3). Chronic pain is more common and more severe among those with poorer socioeconomic status. Mental illness including depression and anxiety are significantly increased among people with chronic pain, with rates of prevalence as high as 70% among those with more severe pain. Between 20-27% of people of working age with chronic pain are unable to participate in their usual activities, including work, due to their pain (4). Healthcare costs associated with chronic pain are high: it has been estimated that chronic pain patients consult their GP up to five times more frequently than others, with almost 5 million GP appointments annually (5). The costs of chronic back pain, for example, have been estimated at £12.3 billion/year (6). In addition to direct medical costs, it has been estimated that as much as 48-88% of the total cost burden of chronic pain can be attributed to indirect costs arising from restricted productivity, sick leave, disability benefits and other aspects of work disability. Importantly, three out of the top ten conditions that impact on productivity are painful disorders (back/neck pain, other chronic pain and arthritic conditions) (7), and in a national audit, as many as 40% of people attending UK pain clinics were prevented from work (paid or voluntary) by pain (8).

Prolonged unemployment, for any reason, causes additional health problems (9). Those who lose their job suffer from worse mental health (10), poorer life expectancy (11), attend healthcare consultations more frequently with physical symptoms and report higher levels of pain (12).

Moreover, these effects transfer to the next generation such that the children of unemployed people also have poorer mental health and themselves experience higher rates of unemployment (13). Taken together, these findings illustrate the potential public health impact of rehabilitating people with chronic pain back into work.

There have been calls in the UK for improved services for chronic pain. For example, chronic pain was a focus of the Chief Medical Officer's Annual Report 2008 (4), emphasising the need for improved holistic pain services, and the Royal College of General Practitioners named chronic pain a clinical priority area in 2011-14 (14). A particular area of need highlighted by patient representative groups (15) was the poor availability of information and support about employment from healthcare professionals.

People unemployed with chronic pain have a number of compounding problems which include: reduced self-esteem and self-confidence; progressive loss of fitness and stamina through inactivity; outdated vocational skills; lack of suitable, sustainable employment opportunities; poor availability of "tailored" job-seeking and occupational advice and potential prejudice from employers against people with poor sickness records. These problems exactly parallel those faced by people with severe mental illnesses in whom rates of unemployment as high as 95% have been reported (16). Amongst people with severe mental illness, the traditional 'train and place' model of rehabilitation has been shown to have little success with many patients only obtaining employment in sheltered workshops. Being in paid work, as compared with being in supported work, is associated with higher self-esteem and higher levels of hope/optimism among people with mental illness, and is clearly the outcome of choice (17). Therefore, a new approach was developed in the USA in which the emphasis was on direct job placements, plus support to patient and employer, the so-called 'place-and-train' model. The model of 'place-and-train' that has been researched most intensively is Individualised Placement and Support (IPS) (1, 18-21). IPS is a systematic approach to helping people with severe mental illness obtain competitive employment. It involves allocation of carefully trained vocational advisers to people who wish to return to work, and equipping them with skills and health support as required. It relies upon 8 principles: eligibility dependent upon client choice; focus on competitive employment; close integration of medical care and employment services (22); work incentives planning, rapid job search, systematic job development and individualised job support. Although originally developed and tested in the US, IPS has since been shown to be effective in European countries (2), despite very different systems of welfare and job markets. It has been shown to translate to mental health patients in the UK (2,17), provided that it is implemented effectively (24) and a high rate of adherence to the fidelity principles is achieved (25). Pooled data from a 2012 systematic review suggest 47% of those unemployed due to severe mental illness can be returned to meaningful employment using IPS in Europe (2).

Chronic pain is one of the major causes of health-related worklessness in the UK, with marked impact on the individual, their family, healthcare providers and society. There is little evidence showing effectiveness of traditional 'train and place' rehabilitation interventions for chronic pain patients in the UK, partly because return to work is rarely the principal outcome. The results of one published study suggested that occupational rehabilitation can be integrated with pain management programmes producing a 38% return to work rate at 6 months (26), and showed that those already unemployed need a different approach from that used for those currently in work.

Given its success for severe mental illness, IPS may work for chronic pain patients who suffer similar disability, social isolation and rates of unemployment and also have high levels of psychological comorbidity. Indeed, in an uncontrolled pilot study performed by members of our research team, IPS was offered through Remploy to 17 patients attending the local pain clinic. The results showed excellent employment rates and high rates of patient satisfaction with a social return on investment of £6.64 for every £1 invested (27). However, long-term funding for this service could not be secured after the pilot study due to lack of evidence from RCTs and insufficient data on cost-effectiveness to justify its widespread adoption.

IPS programmes are already being offered patchily in the UK by private sector and local-authority schemes. Given that IPS was manualised for a different patient group, providers will be approaching adaptation in different ways, particularly in relation to integration with pain management services. Whilst IPS is in the main a set of practical interventions in support of people seeking work, it may be that some people in pain are not ready for behavioural change, in terms of psychological and / or systemic factors. In this respect, IPS may be supported by well-evidenced psychological interventions which centre around engaging people in the process of change. Two such interventions are motivational interviewing (28) and values-based work (which is described in the context of contextual cognitive behavioural therapy (29)). The research process allows for the development of the IPS intervention to include those components which are associated with cognitive and behavioural change and establish a basis for integration of pain management.

It is important that we establish that the fidelity principles apply similarly in chronic pain patients because concordance with the fidelity principles is associated with better outcomes in severe mental illness. Crucially, a high-quality clinical and cost effectiveness analysis is needed if we are to justify the widespread adoption of this approach in this prevalent group of patients.

This application will test the feasibility of adopting IPS for people unemployed with chronic pain, and lay the groundwork for a definitive randomised controlled trial.

Aims and objectives:

In this feasibility research, our aim is to develop the knowledge and understanding required to inform the future delivery of a definitive individually randomised controlled trial, which would assesses the clinical and cost-effectiveness of IPS for people unemployed with chronic pain, who wish to work.

The specific objectives are to answer questions in the following areas:

1. **Recruitment/retention:**

    a. Can patients unemployed with chronic pain be identified efficiently from primary care?

    b. Would sufficient numbers of eligible participants consent to take part in a trial?

    c. What rates of drop out might occur during follow-up?

    d. How acceptable would such patients find randomisation?

e. What are the barriers to patients' and healthcare providers' participation in a future RCT (practical, financial, motivational)?

f. What would be the risk of "contamination" if individual-level randomisation were used?

2. Intervention:

a. In practice, what is needed to manualise IPS for chronic pain patients?

b. What adaptations are needed?

c. How do the fidelity principles perform and can they be translated across?

d. What training/support is needed for Vocational Advisers to integrate with pain services?

e. How feasible is it that this complex intervention can be delivered within the NHS?

3. Comparator:

a. What is treatment As usual?

b. What information should be in a booklet provided to 'control' subjects?

4. Outcomes:

a. What should be the primary outcome measure in a definitive trial (employment, health-related or economic)?

b. In addition to competitive employment outcomes, which in trials of IPS for severe mental health conditions, have consistently been improved:

i. What do patients think are the important outcome measures?

ii. What do employers think?

c. What is the distribution of the relevant outcome measures to calculate power for the trial?

We seek funding from HTA to address these questions by carrying out the following programme of work with patients, healthcare providers and employment advisers.

Research Plan:

We have developed the research plan based upon the research question for a future definitive trial of IPS being broken down into PICO format in the following way:

Population: Adults (aged >18 years and <65 years) identified from primary care with chronic pain from any cause who have completed their diagnostic pathway, for whom there is no expectation of change in the clinical course/prognosis during the next 12 months, who have been unemployed at least 3 months and who want to return to work.

Intervention: An Individualised Placement and Support (IPS) programme is currently funded in Southampton and Portsmouth through City Deals to provide support for people unemployed more than 2 years as a result of a long-term health condition. IPS is provided by vocational advisers (VAs) trained in a variety of techniques to bring about behavioural change (e.g. motivational interviewing), range of employability and skills development opportunities. Additionally, access is available to a paid 6-month placement hosted by a local employer and paid at minimum wage by the City Deal Programme, provided that the individuals stop claiming employment support allowance. Analysis of the first 100 participants suggests that more than 20% reported musculoskeletal pain (often back pain) as their primary health complaint and a further one-third reported multi-morbidities amongst which pain and mental illness were common. Uptake of the programme has been good and early results encouraging with critical components identified as a maximum caseload of 20 clients per VA at any one time and careful management of the transition off benefits. The initial results have attracted attention from the Department for Work and Pensions (DWP) who have requested a high-quality evaluation of the programme alongside other pilot initiatives in other parts of the country to inform government policy. The initial results have attracted attention from the Department for Work and Pensions (DWP) who have requested a high-quality evaluation of the programme alongside other pilot initiatives in other parts of the country to inform government policy. The Cities and DWP are funding this initiative as part of a social/policy agenda, evaluating its cost-effectiveness without consideration of benefits for health or healthcare costs. It makes considerable sense, and good use of public money, to combine analysis if all outcomes, vocational and health-related, not least because there is evidence that both are inextricably linked. Recognising this, the City providers have expressed willingness to widen the programme to people unemployed because of chronic pain for any time greater than 3 months and to collaborate with us in this research proposal to optimise both the quality of the programme and its evaluation.

Therefore, the intervention will be IPS delivered in the community by vocational advisers (VAs) funded through the City Deals programme and integrated with a personalised, responsive pain management plan which will consider the need for further diagnostic investigations, the need for minimisation of the cognitive and physical impact of medicines and non-pharmacological methods of pain relief, supported self-management to increase self-efficacy and psychologically-based interventions to facilitate adjustment to chronic pain based upon best practice guidance (30). This plan will be backed up by communication with the GP and rapid access to community-based pain services as required.

Comparator: There is no evidence-based widely-used NHS alternative that is designed to improve health and the ability to work so we will compare NHS treatment as usual (TAU), supplemented with a standardised booklet to signpost the patient and their GP to local employment and healthcare services.

Outcomes: There are many potentially relevant outcomes for the definitive trial:

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 (31), financial wellness, debt.

Health: General self-efficacy (32), Modified enablement questionnaire (33), self-rated health, IMMPACT measures of chronic pain (34) including function, pain self-efficacy (35,36), 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

Economics: Health and social care costs, benefits costs, cost-effectiveness from societal perspective

The final choice of primary and secondary outcomes will be determined in the light of findings from the feasibility study that is now proposed".

Methodology for the feasibility research

This feasibility research will use a mixed-method approach and is designed and will be carried out in such a way that we can develop our thinking iteratively, using each aspect of the research programme to inform the other aspects. Individualised Placement Support (IPS) is a complex intervention and we recognise that this feasibility work needs to be flexible and responsive to insights received from the different research contributors (patients, healthcare providers, employers) so that we can develop the research as we go along. The programme as described below is not linear and work packages (WPs) will take place in parallel so as to inform each other. Ultimately we will address all of the objectives as defined above.

WP1: We will carry out qualitative work with a sample of approximately 10 of the 100 people who have taken part so far in the City Deals IPS programmes in Southampton / Portsmouth. The semi-structured interviews, carried out by a trained psychologist, will focus on their motivation for participation, their perceptions of the benefits that they experienced and how those benefits could be best captured as outcome measures. We will also seek their views about participation in any trial and what barriers they perceive. It may be important to identify types of beliefs held by patients about barriers to work and the intervention itself, which may impede engagement. As part of a qualitative assessment, patients may be asked to list the kinds of thoughts which raise anxieties about the prospect of returning to work. Ethnographic research suggested that motivation to return to work is an important factor in determining outcomes of interventions, at least in patients with severe mental illness (17,37). With this group, we will also test out approaches to assessing motivation of individuals to return to work: 'active job seekers' as compared with 'passive job seekers' (37).

WP 2: We will carry out qualitative work with those vocational advisers (VAs) currently working in the IPS programme with the City Deals programme. We will seek their views about the service, about integration with pain services and about the outcomes of importance. We will aim to understand what training needs they perceive in order to work with chronic pain patients and facilitate a pain management plan. We will work with them and City Deals to develop and manualise the intervention and cross-reference to the fidelity principles as published (24,38), adapting them as required.

WP 3: We will carry out focus groups with members of the primary care team (e.g. GPs, nurses, physiotherapists). We will seek their views about identification of people with chronic pain from

primary care. We propose an initial recruitment strategy which includes a practice meeting with GPs and their teams supplemented by a database search for chronic pain Read codes e.g. referral to pain service, prescription of long-term strong analgesics. We will discuss the feasibility of this approach, its refinement and its resource implications with the primary care teams. We anticipate that GPs will screen the names of potential participants and if appropriate, authorise the sending of a letter to the patient on practice headed paper with information about the study, responses from which would be sent to the study team. We will explore the resource implications and gain their input into content of any patient information that might be sent. We will also discuss 'TAU' and develop their ideas about what a "control" booklet should contain. Stimulus questions will ask about awareness of services and likely referral. A thematic analysis will be conducted to identify beliefs and behaviours. The 'control' leaflet will be developed with professionals and PPI and its acceptability and usefulness assessed in practice in WP 4.

WP 4: We propose to carry out a primary-care based longitudinal study in a sample of 80 patients with chronic pain, to assess some of the methods that might be used for recruitment, delivery of an intervention and assessment of outcomes in a subsequent RCT (39,40). A sample of GPs in Portsmouth and the Wessex Primary Care research network have agreed to work with us to 'trial' the identification of suitable patients in their practices and will help us to refine it as necessary to test if we can identify appropriate patients in sufficient number. We will 'test' the patient information and consent processes by comparing the rates of 'interested' letters returned with the numbers sent out by practices. We will explore the acceptability of randomisation by 'randomising' 40 patients to each of the two arms (by pre-arranged algorithm known only to the researchers) but will aim to have some people in the same practice 'randomised' to different arms in order to evaluate the risk of 'contamination', although we anticipate that this risk is small. All 80 participants will have a baseline interview collecting some qualitative and quantitative information. Those allocated to the intervetion will have assessment by the VAs and a pain clinician to establish the pain management plan and the process for this will be refined and developed as we go along. The VAs will then work with these 40 patients as per the City Deal programme. We will send follow-up questionnaires on measures of process and potential outcomes to all 80 participants on at least 3 occasions (optimum timings to be defined) over 12 months to assess rates of completion and adherence to protocol. Questionnaires will be distributed and collected back, not to evaluate the outcome measures but rather to assess whether people can and do complete the questionnaires as intended. A sample of 'control' subjects will be interviewed during the 12 months to assess the acceptability of randomisation, and uptake and utility of the control information. It is our view that we have an ethical responsibility to offer information to those randomised to the control arm although everybody in the local area who is unemployed with a long-term health condition for >2 years will become eligible for intervention through the local authority-provided IPS.

WP 5: Focus groups will be held with participants, healthcare providers and VAs who were involved in the longitudinal study, to evaluate study experiences and lessons learned. This work will inform manualisation of the intervention for a future trial and the design and principal outcome measures for a pilot trial. From the patients and vocational advisers, we will understand which skills must be developed and how optimally to integrate a pain management plan and pain service providers.

WP 6: Ultimately, we will pool the information collected from WPs 1-5 to manualise the intervention and refine the fidelity principles as appropriate as well as define a protocol for a future trial, create the standard operating procedures and data collection tools.

Health technologies being assessed:

Individualised Placement Support (IPS) was developed for people with severe mental illness as a vocational rehabilitation intervention. It has been manualised for this patient group. To date however, IPS has not been formally evaluated among patients with any other health condition. Although developed originally in the US, there have now been a number of studies showing that its effectiveness among mental health patients translates to European countries, including the UK (2), and these European studies have been meta-analysed (1). Therefore, this research falls within the remit of HTA as it seeks to assess the value of an established health technology but in a different group of patients (chronic pain instead of severe mental ill-health). There is both a sound theoretical basis for the transferability of IPS to chronic pain patients and evidence from a locally-run project, nested within community pain services, which found excellent levels of satisfaction and high rates of competitive employment with a social return on investment of £6.64 for every £1 invested (27). Moreover, the Cities of Portsmouth and Southampton have been funded through their City Deal agreement to deliver IPS to 1000 people who are unemployed for more than two years due to any long-term health condition. There is currently no established alternative to IPS available and therefore we propose to evaluate treatment as usual (TAU). However, it is our first impression that we have an ethical responsibility to offer some information about relevant services to people in order to encourage their participation in such a trial and this premise will be investigated within the feasibility work.

Design and theoretical/conceptual framework:

We propose to use a mixed-methods iterative approach to develop this feasibility work. The qualitative work will be supplemented with a longitudinal study, in which patients are asked to give consent to be allocated to one of two arms, but in which allocation is not truly random, allowing the practical testing of some of the concepts of recruitment, consent, randomisation, attrition and aid the choice of primary outcome measures.

Target population:

Men and women aged > 18 years and < 65 years unemployed as a result of chronic pain for more than 3 months who wish to work.

Inclusion/Exclusion Criteria:

These will be clarified as part of this feasibility work but exclusions will include:

- Previously referred for IPS as part of City Deal
- Inability to provide written, informed consent
- Unexplained chronic pain still undergoing diagnostic work-up
- Chronic pain where some recovery is likely within the next 12 months

- Unwillingness to return to work

Setting/context:

Community /primary care

Sampling:

We will sample healthcare providers, vocational advisers and people with chronic pain from the cities of Southampton and Portsmouth. The HTA brief requested that we aim to test the feasibility of recruitment of research participants through primary care and therefore, this will define our sampling frame. For this feasibility work, we have chosen a sample size of 80 people, 40 in each arm, to furnish sufficient numbers to assess recruitment rates, rates of attrition in each arm, and 'contamination' of participants.

Data collection:

Given the mixed methods, we will collect quantitative and qualitative data. Qualitative data will be gathered from patients and professionals involved in the study. Patients will be asked about their experiences of the intervention and the supporting systems, and perceived barriers to recovery addressed by the intervention. Professionals will be asked about perceived benefits and barriers to effective referral. Focus groups and individual interviews will be used to gather data from no more than ten patients and ten professionals (or until saturation of data has been reached). Focus groups and interviews will last around an hour. Participants for the qualitative methods will be selected from each group at random.

In addition to scales underpinned by psychometric data, we plan to use observed and reported behavioural incidence measures, pertaining to the individual. These may (or may not) be linked to intervention discussions around 'behaviours in the service of values'; i.e. Patients are engaged in a discussion around their values and what they could do to serve those values. These behaviours can then be measured in terms of reported incidence.

The following describes the approach to the differing packages:

WP 1: Qualitative data will be collected from a sample of approximately 10 patients (dependent upon saturation of themes) who have completed the City deals IPS programme. Thematic analysis will be used to assess motivation and barriers to participation in an IPS programme and in a trial and to understand what motivated them to embark upon IPS and what benefits they feel that they have experienced from participation to inform outcome measures for a trial. We will test out different ways of assessing willingness to engage with IPS. In the previous local pilot, Remploy used a grading matrix for this and we will compare the performance of this with other measures discussed in RCTs of IPS in mental illness (37).

WP2: Qualitative data will be collected from vocational advisers and thematic analyses carried out to understand: the confidence of Vocational Advisers to work with pain patients and to deliver the intervention; this will be supplemented with administration of an instrument designed to assess attitudes and beliefs towards pain e.g. the Knowledge and Attitudes Survey Regarding Pain (KASRP) (41)

WP3: Qualitative data will be collected from focus groups in primary care and thematic analyses will be applied to explore: strategies for recruitment of chronic pain patients, their views about the interventions planned and a future trial, supplemented by the Knowledge and Attitudes Survey Regarding Pain (KASRP) (41)

WP 4: testing of the feasibility of our preliminary RCT protocol (Figure 1). We will collect quantitative data to be summarised by descriptive statistics. To test out the feasibility of recruitment, we will compare the rates of invitations sent by GP surgeries with the responses from patients received by the study team. We will record the rate of consent to participation once eligible individuals have been invited to provide consent. To test the acceptability of randomisation for a definitive trial, participants will be asked to give written informed consent explaining that they have a 'random' chance of being allocated to each arm although allocation will be allocated by the research team in order to ensure that patients recruited from the same GP surgery will be allocated to different arms to assess the risk of contamination if an individual-level RCT is carried out. We will observe the drop-out rates from both arms (control and active arms). A questionnaire pack based upon the outcome measures described above will be tested out for participant engagement, ability to complete fully, comprehension and willingness to engage with questionnaires at three stages of follow-up. The content will also have input from the Study Patient Public Involvement (PPI) group, as well as the research team, before WP4 starts and will be developed iteratively as the study progresses. To assess the quality of the intervention received in the 'active' arm, and to investigate whether or not the fidelity scale needs adaptation for this client group, we will assess the IPS intervention against the published fidelity scale, developing it if required.

WP 5: Qualitative work with participants in the study (from both arms, GPs and VAs. Thematic analysis will focus on what lessons need to be learned to inform any future definitive trial.

WP 6: Manualisation of intervention based upon the results of the qualitative data and the findings from the fourth work package. :

Data analysis:

Quantitative data from WP4 will be summarised by descriptive statistics. As well as response and completion rates, we will summarise the distributions of outcome measures among controls in the absence of the intervention to inform power calculations for a definitive trial.

All qualitative data will be analysed using a formal thematic analysis to assess overarching themes. Thus patient and professional experience of the intervention will be directly assessed, to inform the way in which the interventions can be delivered in terms of content, form and service delivery.

Across the participant population, the behaviours incidence measures can be aggregated into themes (e.g. social, personal, work), or left as a domain of values-driven behaviours. Thus a key outcome will be around behaviours which are meaningful to the individual. Such methods and measures to support it are routinely employed in the pain management psychological therapies service to bring about meaningful change.

WP 1: Thematic analysis of the qualitative data collected from recent participants in the local IPS programme which will allow us to understand their motivation and barriers to participate in IPS and

a trial. We will compare the performance of the Remploy grading matrix with other measures identified from the ethnographic literature (37).

WP 2: Thematic analysis of qualitative data collected from Vocational Advisers which will lead us to understand what training or behavioural skills are needed to enable the VAs to work with chronic pain patients to deliver IPS. We will undertake thematic analysis of the KASRP scores (41) summarising the percentage of complete scores items with the least number of correct responses and those items with the best scores to guide educational needs.

WP 3: Thematic analysis of the qualitative research with GPs and other members of the primary care team. Analyses will focus on: their views about recruitment strategies, their views about the IPS intervention and the practicalities of a future trial and their views on the relevant outcome measures.

WP 4: We will use descriptive statistics to summarise the proportion of patients identified in primary care who are eligible for the study; the proportion that agree to take part; the rates of attrition in each arm of the trial; the rates of satisfactory completion of questionnaires in each arm and the distribution of potential outcome measures through analysis of the questionnaire responses among participants in the control arm, which will inform the choice of primary and secondary outcome measures in a definitive trial.

WP 5: Thematic analysis of qualitative data collected from participants, VAs and primary care colleagues specifically in relation to lessons learned about: recruitment; participation and engagement and outcomes.

Dissemination and projected outputs:

This research will have a number of outputs:

1) Developed and manualised IPS for this patient group and revised the fidelity principles as appropriate to operationalize them for a future trial.

2) Clarification of outcome measures (primary and secondary) for a definitive trial

3) Information about the acceptability, engagement and likely participation of patients and healthcare providers in primary care in a future trial

4) Establish the feasibility of the delivery of this intervention in the NHS

There are a number of stakeholders with whom we will wish to share our results:

1) **Participants**

We will discuss with our research advisory group how optimally to communicate our findings to research participants so as to retain their confidentiality but enable them to understand what an important role they have played and what our findings mean to people like them.

2) **People with chronic pain**

This research will be informed by people with chronic pain and we will aim to ensure that any new information discovered will be circulated to them. We will consult our lay applicant and research advisory group for local and regional meetings or publications and we will share information with relevant charities (e.g. Arthritis Care, Pain UK), providing interviews or written reports. Additionally, the stakeholder group of the Arthritis Research UK/MRC Centre for Musculoskeletal Health and Work was convened last week by Arthritis Research UK and this group reviewed the research plan and are keen to assist with dissemination of our findings. We will consult throughout with our lay co-applicant and hope that they will be able to present in some of these settings.

3) **Healthcare professionals** - These results will be of particular importance to GPs and allied healthcare professionals. We will seek to publicise our research through the Royal College of GPs, the annual RCGP conference and Journal of the Royal College of GPs and at the annual British Pain Society Conference and their journal, newsletters and websites. We will also make contact with physiotherapists, occupational therapists and nurses with an interest in pain and vocational rehabilitation.

4) **Policy makers** – The Department for Work & Pensions (DWP) has already expressed interest in the City Deals initiative and its evaluation and we will wish to share our results with them. Additionally, The PI is a member of the UK Fit for Work Coalition, which includes members from a range of stakeholders including musculoskeletal and pain charities, representatives from Royal College of GPs and Royal College of Physiotherapists. We will disseminate our findings through this group using its social media, website (http://www.fitforworkeurope.eu/UK) and blogs as well as taking opportunities through the coalition to inform members of the Health Select Committee and Work and Pensions Select Committee. We will share our results with the relevant departments at DWP and the newly formed DWP/Department of Health 'Health and Work Joint Unit'.

5) **Employers** – through links with employers, Business South, Federation of Small Businesses and the Hampshire Chamber of Commerce, we will explore how best to share results

6) **City deals** – as key collaborators, we will report comprehensively on all our findings to the City deals commissioners and assist them in developing any outputs they require for DWP.

7) **Scientists** - we will communicate with pain researchers through the Arthritis Research UK national pain Centre, British Pain Society and its national conferences, and in occupational medicine and vocational rehabilitation through publications and conferences.

Plan of investigation and timetable:

	Year 1 (Jan 2017-Dec 2017)	Year 2 (Jan 2018-Dec 2018)	Year 3 (Jan 2018-Mar 2018)

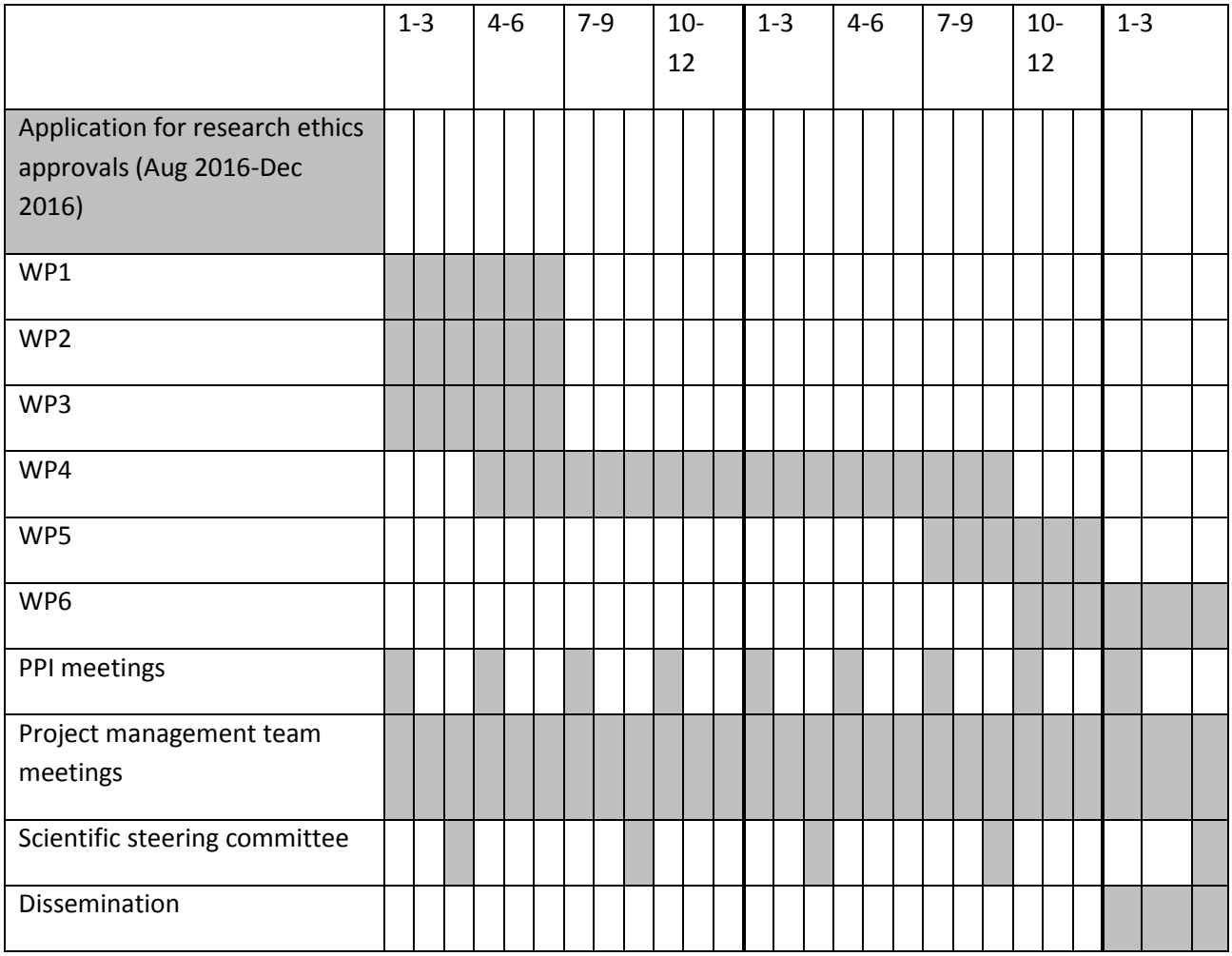

Figure 1 GANTT chart showing monthly project milestones and timings of work packages and meetings

We have planned a start date of 1.1.17. After notification of the decision of the HTA funding board, we will prepare and apply for a full research ethics submission through IRAS. This will allow 4 months to put the approvals in place before the start of funding. We have calculated an 18-month duration for carrying out work package 4, including full recruitment and 12-month follow-up of all participants. WPs 1-3 are allocated 6 months and WPs 5-6 an additional 6 months. It is our intention that there will be overlap so that each work package can inform the others and enable the development of our thinking. Therefore, we have created flexible timetable which allows 30 months in total building in a little time for any unexpected delays and 6 months for analysis and write up of our final conclusions (see Figure 2 for details).

Project management

All co-applicants will be members of the Project Steering Committee, which will meet formally on a 6-monthly basis to review progress against our planned objectives. These meetings will be formally minuted with action points to confirm progress. We will also configure a project management team,

who will meet monthly. Membership of this team will include the lead applicant, Dr Linaker as research programme coordinator, Dr Price or Sue Bingham (pain nurse) as lead for the chronic pain team, Dr McGuire or the post-doctoral psychologist as lead for the psychology team, Dr Fraser as lead for the public health and primary care team and our lay co-applicant and representatives from the pain team, and City deals. Chaired by the Lead applicant, this group will take responsibility for submission of ethical approvals, reviewing research progress against our project milestones and ensuring completion of the work packages in a timely manner. Meetings will be minuted with action plans against which members can be held accountable. Additionally, we will meet with our PPI team every 3 months to update them on progress and obtain their feedback. The project management team will be set up to be flexible so that members of relevant organisations/researchers can be brought in when appropriate e.g. the lead for the Wessex CRN, GPs or other colleagues from primary care, health economics or public health or occupational health leads. We will endeavour to follow the NIHR carbon footprint guidelines by minimising attendance at meetings when agenda items are not relevant.

Approval by ethics committees

This research raises a number of ethical issues: recruitment of patients with chronic pain; respecting patient confidentiality; collection, entry and storage of healthcare data; treatment of 'control' subjects in the 'control' arm of work package 4; and collection of written, informed consent.

The University of Southampton has agreed to act as sponsor and we will apply for ethical approval for the six work packages, aiming to secure the approvals before official commencement September 2016.

Storage and handling of confidential data will be done in accordance with Medical Research Council data handling policies, overseen by the MRC Lifecourse Epidemiology Unit data protection manager, Ms Vanessa Cox. All data are anonymised and stored with unique identifiers on computers which are encrypted. Questionnaires will be double-entered and then the hardcopies (without names addresses or dates of birth) stored in locked filing cabinets within the MRC Lifecourse Epidemiology Unit, Southampton General Hospital.

Written informed consent will be obtained by trained research nurses at an appointment after sending written information in advance. Patients will be able to withdraw at any time without needing to give a reason and without any effect on their primary care provision.

All patient resources will be developed with our PPI group and lay co-applicant and will be scrutinised by the research ethics committee.

Patient and Public Involvement

20 chronic pain patients (new patients and people completing a self-management course) participated in 3 workshops to review this proposal, two before the first-stage and one last week to review the full application. Participants were male and female, age 20-86 years and the group included people: currently in work; retired from professional/managerial work; not working on grounds of ill-health; currently signed off sick from work and actively seeking work/voluntary work. Confidence to work ranged from 0 (no confidence) to 6 (completely confident) as measured by the Pain Self Efficacy Scale (35,36).

Overall the response was positive about the research: “Brilliant and necessary”. They hoped for a reduction in anxiety and depression. The groups wanted vocational advisers to have a better understanding of the impact of pain medications and flare-ups. Important vocational interventions included skills training in CV-writing and interviewing. They expressed concern that it may be difficult to recruit the control group as intensive support was viewed as very necessary.

The groups thought that barriers to recruitment were: low confidence; fear of loss of benefits; flare-up of pain symptoms. “This is obvious must – why do we need the research to prove it?"

We were able to convene a third PPI group last week, including 8 people with chronic pain, only two of whom had been involved in groups prior to the first stage application. Together, we reviewed the near-complete application. Bringing a range of different employment experiences, they spent more than two hours critically appraising the application, with particular focus on WP4. They examined WP4 from the perspective of people like them being recruited to both arms. The group expressed particular concern about the recruitment of 40 people to receive what was perceived by them as vastly inferior (treatment as usual 'TAU'). However, when the group understood that TAU was in effect current real life (and several members of the group confirmed this fitted with their own experiences) they expressed: 'you have no choice, it has to be done that way'. Their other concern was about recruitment from primary care. There were strong views expressed from some members that their GPs had limited knowledge of their employment status. However, there were other group members who reported that they had received a lot of support from their GP in relation to unemployment and employment support.

Overall, they were extremely supportive of the proposed research and agreed the principles underpinning our proposed research plan. Their comments are reflected in the submitted application. They committed to ongoing support over the duration of the research, should funding be forthcoming and it is planned that they will convene three-monthly with members of the research project management team.

Expertise and justification of support required

Professor Coggon and Dr Madan are experienced academic occupational physicians with considerable clinical experience and a track record of occupational research including clinical trials in workplace settings. Dr Madan is currently the Lead Applicant on an NIHR-funded randomised controlled trial of a behavioural intervention to prevent hand dermatitis in nurses (the SCIN trial) (http://www.scintrial.org/). Dr Price is Clinical Director of community pain services in Wessex and has successfully led clinical trials in pain settings. Moreover, she led the successful pilot project embedding IPS in the community pain clinic which was very successful and on which this application is based. Kathryn Rankin has agreed to be a co-applicant on this application because she coordinates the City Deals vocational programme currently in progress in Portsmouth and Southampton. The vocational advisors are employed by and report to her and she has agreed to support this application to obtain high-quality evaluation of IPS locally. Prof Little and Dr Fraser bring the primary care and public health perspective to this research including study design, set up with primary care colleagues and analysis and implementation. Dr McGuire brings the essential health psychology input that is needed for the qualitative parts of this project, involving participants, and the healthcare professionals. He will supervise the post-doctoral researcher in undertaking analysis of the focus group work. Dr Linaker is a post-doctoral research nurse with considerable experience

leading and coordinating clinical research including trials: she will coordinate this programme. Former Lead for the MRC Population Health Sciences Research Network, Prof Cooper brings particular expertise in evaluating complex interventions. Dr Pinedo-Villanueva has joined our team as a health economist experienced in evaluations from NICE's perspective and measuring health-related quality of life in people with musculoskeletal disease. Mr Gareth Davies has agreed to join the team as lay co-applicant to provide the 'employer' perspective on this research programme. He has worked in the local economy for a long time and has been a local employer. Moreover, he is an experienced lay advisor to other local healthcare organisations including healthcare charities and Health Education Wessex.

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