Individualised placement and support programme for people unemployed because of chronic pain: a feasibility study and the InSTEP pilot RCT

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Scientific summary

Background

Chronic pain is common and can have a significant impact on quality of life. There have been calls in the UK for improved services for chronic pain patients, particularly regarding employment. As many as 40% of people attending UK pain clinics were incapacitated for work.

Individualised placement and support is an evidence-based model of vocational rehabilitation. The programme places emphasis on an early supported work placement and has been shown to be clinically effective and cost-effective at increasing rates of employment among people with severe mental health conditions.

Given the high burden of worklessness in chronic pain, and the evidence around the effectiveness of individualised placement and support, we investigated the feasibility of undertaking a randomised controlled trial of individualised placement and support, investigating its impact on quality of life among people unemployed because of chronic pain.

Objectives

To develop the knowledge and understanding required to inform a future definitive individually randomised controlled trial to assess the clinical effectiveness and cost-effectiveness of individualised placement and support for people unemployed because of chronic pain who wish to work.

Recruitment/retention

- Can patients unemployed with chronic pain be identified in primary care?
- Would sufficient numbers of eligible participants consent to take part in a trial?
- What rate of dropout occurs during follow-up?
- How acceptable would such patients find randomisation?
- What are the barriers to patients’ and health-care providers’ participation in a future randomised controlled trial?
- What would be the risk of ‘contamination’?

Intervention

- In practice, what is needed to manualise individualised placement and support for chronic pain patients, and does individualised placement and support need to be adapted?
- What training/support is needed for employment support workers to integrate with pain services?
- How feasible is it that this complex intervention can be delivered within the NHS?

Comparator

- What is treatment as usual?
Outcomes

- What should be the primary outcome measure in a definitive trial?
- In addition to competitive employment outcomes, which previous trials of individualised placement and support for severe mental health conditions have consistently found to have been improved, what do:
  - patients think are the important outcome measures?
  - employers think are the important outcomes measures?
- What is the distribution of the outcome measures to calculate power for the trial?

Methods

We carried out mixed-methods research in six complementary work packages.

Work package 1

Aim
To understand barriers to and facilitators of participation in a trial of individualised placement and support.

Method
Qualitative interviews with people with long-term health conditions who took part in individualised placement and support through the Solent Jobs Programme.

Setting
City council employment offices.

Participants
People unemployed for > 2 years with a long-term health condition who had received individualised placement and support through the Solent Jobs Programme.

Outcomes
Insight into individualised placement and support participation, and views about trial participation and recruitment.

Work package 2

Aim
To understand barriers to and facilitators and training needs of employment support workers for a pilot individualised placement and support trial.

Method
Qualitative interviews.

Setting
City council employment offices.

Participants
Employment support workers who were delivering individualised placement and support as part of the Solent Jobs Programme.
Outcomes
Information about delivering individualised placement and support locally, insight into educational needs for working with chronic pain patients and views about a future trial.

Work package 3

Aim
To seek the views of primary care-based health-care professionals about the feasibility and resource implications of the identification of individuals with chronic pain, and hosting recruitment and acceptability of a trial.

Method
Focus groups with primary care-based health-care professionals in Southampton and Portsmouth.

Setting
General practices.

Participants
Primary care-based health-care professionals involved directly with the care of patients with chronic pain.

Outcomes
Views about a pilot trial, ideas about identifying people with chronic pain who are unemployed via general practice, and insights about the intervention and proposed treatment as usual.

Work package 4

Aim: pilot study (the InSTEP pilot trial)
To conduct a primary care-based pilot trial.

Method
A pilot longitudinal study [i.e. the Individualised Support To Employment Participation (InSTEP) pilot trial], recruiting people unemployed for > 3 months with chronic pain, and randomising to the active individualised placement and support intervention or treatment as usual. Follow-up at 3, 6 and 12 months by postal questionnaire.

Setting
Primary care and community pain services.

Participants
Individuals aged 18–64 years with chronic pain who were unemployed for at least 3 months and who wish to return to work.

Individualised placement and support intervention
An individualised placement and support programme integrated with a personalised pain management plan, formed in partnership with a pain occupational therapist. Employment support workers also assessed motivation, barriers to and readiness for work, and then supported people in accordance with local standardised individualised placement and support protocols. If clients were assessed as not yet ready for work, employment support workers were able to use a range of services and skills to develop clients’ work readiness before moving them into the job placement. Based on client choice and once the client was ‘work-ready’, employment support workers provided ongoing support and mentoring with the employer and employee, as required, for at least 6 months.
Control intervention: treatment as usual
Treatment as usual consisted of an appointment with the study co-ordinator (a health-care professional with no training in vocational rehabilitation) to take the participant through a treatment-as-usual booklet. These booklets were bespoke, created for each of the two cities, and provided easy-to-use guidance about how to self-manage pain and obtain access to local employment services. They were designed with and by our public and patient involvement group, who helped to make them accessible and user friendly.

Outcomes
Outcomes included rates of identification of eligible participants; recruitment and retention rates; acceptability of randomisation and treatment as usual; questionnaire data completeness; acceptability of questions on topics including pain, employment and financial circumstances; and risk of contamination.

Work package 5

Aim
To evaluate the experiences of key stakeholders involved in the InSTEP pilot trial.

Method
Focus groups and interviews with participants, employment support workers, primary care-based health-care professionals involved in work package 4, analysis of qualitative feedback from postal questionnaires and analysis of interviews with employers who offered work placements.

Setting
City council employment offices, general practices and community pain services.

Participants
Employment support workers, primary care-based health-care professionals and pain service staff involved with recruiting to the InSTEP pilot, participants in the InSTEP trial and employers offering placements within the trial.

Outcomes
Outcomes included the barriers to and facilitators of a future trial. Specifically, to understand the learning needs of employment support workers so that they would be able to work with people with chronic pain.

Work package 6

Aim
To manualise the individualised placement and support intervention, and define a protocol for a future trial.

Setting
City council employment offices, general practices and community pain services.

Participants
The Trial Management Group, employment support workers and pain team.

Outcomes
Manualised individualised placement and support for chronic pain.
Results

**Work packages 1-3**
All stakeholders viewed the trial as feasible and were supportive of its importance and relevance. The treatment-as-usual booklet was endorsed, along with its proposed method of delivery. All stakeholders were enthusiastic about the proposed intervention. Employment support workers indicated that training about chronic pain would be important.

**Recruitment**
Primary care-based health-care professionals thought that recruitment through primary care was possible and defined methodologies to be trialled as follows: Read code searching based on codes for prescriptions and chronic pain, followed by mailshot to those identified; opportunistic recruitment during appointments; targeted recruitment based on primary care-based health-care professionals’ knowledge; posters in surgeries; and hand-searching patients’ records. Clients proffered different views about general practitioners’ involvement (one felt more likely to participate if their general practitioner recommended it, whereas another felt that they would be unhappy if their general practitioner suggested an employment intervention). Clients also indicated that their general practitioners did not know their employment status.

**Intervention**
Clients viewed it as excellent that the individualised placement and support programme would be offered much earlier after becoming unemployed (the existing Solent Jobs Programme required that the participants be unemployed for >2 years before being offered individualised placement and support). Clients also emphasised the importance of the relationship with the employment support worker for success of the intervention, although they recognised that employment support workers were already overstretched with their current client numbers.

**Work package 4 pilot trial (the InSTEP pilot trial)**
We estimated that four general practices would be needed to recruit a maximum of 80 pilot study patients. In fact, to recruit the final total of 50 subjects, we involved nine general practices (serving an estimated 200,000 people) and then, with the agreement of the Trial Steering Committee, broadened our strategy to allow recruitment from community-based pain services. We trialled all of the approaches suggested in work packages 1–3 to understand (1) which was most clinically effective and (2) which was most efficient.

**Recruitment**
Read code searches were easy to carry out. However, the searches yielded large numbers of ineligible participants and non-responders, and so proved very inefficient (26 recruited from 1017 packs sent). Hand-searching notes was time-consuming and resource-intensive, but yielded six eligible participants, all of whom were recruited. Opportunistic recruitment during the consultation was also slow, but efficient, yielding five eligible participants who consented to participate. Given the challenges in recruiting, our study timelines were affected and we found ourselves nearing the end of the time over which individualised placement and support was available. Therefore, we widened recruitment to identify eligible people through community pain services opportunistically during consultations. This referral route yielded the highest rate of eligible participants who consented to take part (n = 13). In total, 50 people were recruited.

**Randomisation**
Given the limited availability of the individualised placement and support intervention caused by slow recruitment, we allocated as many of the earlier recruits as possible to individualised placement and support, until it was no longer available, and then allocated the remaining recruits to treatment as usual. However, in all cases, the participants were recruited to a randomised controlled trial and gave written informed consent for randomisation. Nobody expressed dissatisfaction with randomisation or their allocation. In total, 22 subjects received individualised placement and support, and 28 subjects received treatment as usual. Treatment as usual was acceptable to participants and they expressed satisfaction with the booklet and its purpose/aims.
Response rates and retention
At 3 and 6 months, excellent rates of return were achieved for follow-up questionnaires among treatment-as-usual participants. However, rates dropped somewhat among this group at 12 months. Two of the 22 individualised placement and support participants obtained employment rapidly, but only by moving out of the area. These participants withdrew from follow-up. An additional four participants failed to return any of the follow-up questionnaires, despite engaging with the individualised placement and support programme. Even with a system of reminders and an incentive payment for returning questionnaires, insufficient rates of return were attained in the individualised placement and support arm. It appeared that return rates dropped once the individual obtained employment.

Contamination
Some participants from the same general practice were allocated to each arm of the trial to investigate the risk of contamination. Although numbers were small, the risk of contamination was assessed to be low, as primary care-based health-care professionals confirmed that they did not hear about the intervention or treatment as usual from any of their patients.

Outcome measures
The questionnaires, despite being quite lengthy, were well completed by those who returned them. Self-efficacy for return to work appears promising for use as a primary outcome in a definitive trial.

Work package 5
Recruitment
Primary care-based health-care professionals reported that it was straightforward to run Read code searches and to mail out trial information. Unfortunately, however, the searches yielded large numbers of ineligible participants, some of whom telephoned the practice to complain. Employment support workers reported frustration at how slow recruitment had been through primary care and reflected that recruitment was smoother through pain services, not least because every consultation in pain services specifically asked about employment. The employment support workers did, however, reflect that the participants recruited through primary care tended to be nearer to their last job and it was simpler to assist them on the return to work journey, whereas those recruited through pain services had more complex needs and were more challenging to re-engage with work. The employment support workers perceived that some practices were more enthusiastic than others, and that involvement and recognition of the importance of working (to benefit health) had resulted in improved recruitment rates and engaged more suitable patients.

Outputs
Employment support workers were very positive about the trial and working with people with chronic pain. They reported that the initial training about chronic pain was helpful. Employment support workers and the pain occupational therapist valued the joint consultations and found them helpful in understanding chronic pain and the limitations it imposed on working. When identified, they enjoyed working with people who were more recently unemployed and found, in some cases, that this enabled them to help such individuals re-engage with work quite easily. In contrast, some participants were initially a long way from a placement and needed time to build confidence and develop rapport with the employment support worker to facilitate work-readiness before a placement could even be contemplated. Participants’ needs were often complex and the fluctuations of chronic pain were particularly difficult to accommodate in paid work settings. The trial had correctly identified people who were motivated to and wanted to return to work, but employment support workers thought that some participants had rather unrealistic expectations, as they had considerable barriers to working. They reported that it took more than one meeting with most participants to fully assess their needs and aspirations. Pain services were supportive of the trial and intervention, but would have liked more rapid progress with integration of the individualised placement and support service within their setting.
Employers were extremely positive about individualised placement and support work placements. They described the health benefits to their employee and that employees had become valued members of their team. Employers described benefits to their organisation of employing individualised placement and support clients. Follow-up support by employment support workers was valued by employers and their employee. The employers showed themselves very willing to offer flexibility to accommodate the needs of the employee. One employer reflected that it was nice to ‘give back to the community’.

**Work package 6**
From the records of the pain occupational therapist and the employment support workers, as well as the qualitative outputs, individualised placement and support has been manualised for a trial.

**Conclusion**

All stakeholders with whom we engaged thought that a trial was relevant, needed and important. A future trial would not be feasible recruiting through primary care until employment status is routinely collected as part of the health-care record or linkage of health and employment databases is facilitated. A trial could be set within pain services to recruit the numbers required, but (1) not all patients with chronic pain are seen in pain services, (2) when they are seen, it is not usually over long-term follow-up and (3) those referred to such services may be more complex and further from the workplace, providing greater challenges in re-engaging them in paid work and retaining them for follow-up.

Existing individualised placement and support services can be easily adapted for people with chronic pain, but (1) employment support workers need prior training about chronic pain and (2) combining at least one consultation with employment support workers and pain expertise (provided in this study by an OT from the pain management team) is helpful to all parties. Integration of the employment support with the pain management is beneficial in yielding the best work and health outcomes for patients; however, it is challenging to achieve, given the current organisation of such services.

For a successful trial, more work is needed to retain participants through follow-up, particularly if they obtain work. It may be that additional contact is needed at 9 months, or that text messages or e-mails could be used, but our results suggest that if people find work, then their time and energy for questionnaires diminishes.

Paid competitive employment is the prime goal of individualised placement and support but it is not the key outcome for patients. Self-efficacy for return to work would appear to show promise as a principal outcome measure.

**Trial registration**

This trial is registered as ISRCTN30094062.

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This report

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