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What is the effectiveness and cost-effectiveness of using individual supported work placements to help people with persistent pain to return to work?

Submission date
30/03/2022

Recruitment status
No longer recruiting

Registration date
31/05/2022

Overall study status
Ongoing

Last Edited
14/08/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Many Norwegians are not able to work because of pain. This is often back, joint, or muscle pain. It can be hard for those affected to get back to work. We know that being in work is good for people's physical and mental health and that supported employment measures can help people with mental health problems get back into work. Many people who are unemployed and have persistent pain, potentially have many working years left to contribute. We want to know if an approach featuring work placements and trained case manager support (including support for matters related to pain) will help unemployed people with pain get back to work, and how much this might improve their overall health. We have already done a feasibility study in England where we found that a support package featuring work placements was well received by unemployed people with persistent pain. A full-scale study is now needed to compare this approach with the usual Norwegian support to get back to work.

Our objectives are to explore the impact on quality of life of being out of work with persistent pain and to examine the effectiveness and cost-effectiveness of a work placement intervention compared to usual care, for improving sustained return to work and quality of life in unemployed people who have persistent pain.

Who can participate?
We will recruit men and women in Norway who are between 18 and 64 years, who have been out of work for at least one month and had pain for more than three months. These people will initially asked only to be involved in a cohort study of the impact of being out of work with persistent pain; asking people to complete outcome measures asking them about their work ability, confidence in working, quality of life, if they have had any offers of employment and if they accept any of those offers. However, we will then randomly sample one in three to whom we will offer an intervention designed to facilitate return to work.

What does the study involve?
For those selected, a trained Case Manager will help identify obstacles to work and explore work aspirations and skills before matching a six-week part-time work placement. The case manager will then work with the person to help them navigate the identified obstacles to work within a specially created work plan that is discussed and approved by the manager at the placement. Before beginning the placement, we will provide a two-day work-preparation course, during which time the participant will be with other people who are also out of work with persistent pain, and review strategies for coping with pain and navigating common obstacles to working. Once the person begins their placement, the Case Manager will provide regular support to the participant and supervisor, and if needed, they may make referrals to existing health services. Three, six, and 12 months after joining we will ask people who were selected, and those who were not selected, to tell us if they are working, how bad their pain is, and report on their overall quality of life. By doing this we will be able to find out if our support package is worth offering to all those who are unemployed with persistent pain.

What are the possible benefits and risks of participating?
Where effective, involvement the study may offer participants the chance to find pragmatic ways around obstacles they perceived they have to work around such that this helps them to return to full paid work. This may bring not only financial benefits and security but associated improvements to health-related quality of life, social domains, and even general health. We anticipate few risks of being involved; there may be a slight risk of temporarily increased pain when the participant initially starts to work due to the person becoming more physically active. However, the trained case managers will continually monitor progress, function, and work environment, assessing risks, and referring to existing healthcare if it becomes appropriate.

Where is the study run from?
The study is run from Kristiania University College and takes place in Norway (various work placements across Norway for the intervention)

When is the study starting and how long is it expected to run for?
November 2021 to December 2025

Who is funding the study?
Norwegian Research Council

Who is the main contact?
Professor Robert Froud
Robertjames.froud@kristiania.no

Study website
https://kristiania.no/reise

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
NRC 326732

Study information

Scientific Title
Returning people with persistent pain to work using individual supported work placements

Acronym
ReISE

Study objectives
Cohort randomised controlled trial research question
What is the effectiveness and cost-effectiveness of a supported work placement intervention, compared to usual care, for improving sustained RTW and quality of life in unemployed people who have persistent pain?

Process evaluation research question
What are the delivered processes in the package; in terms of fidelity, context, reach, dose, continuity, participation, recruitment, engagement, and referrals?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/05/2022, Regional Committees for Medical and Health Research Ethics (REC) REK sør-øst (Post box 1130, Blindern, 0318 Oslo, Norway; +47 (0)22845522; rek-sorost@medisin.uio.no), ref: 402918

Study design
Cohort randomized controlled approach with random subsampling

Primary study design
Interventional

Secondary study design
Cohort randomised controlled approach with random subsampling

Study setting(s)
Home, Other therapist office

Study type(s)
Quality of life

Participant information sheet
https://www.kristiania.no/contentassets/7c3186cb86e946f2b3ecd8c8ba878964/digital_pil_cohort_nor_v6.0_main_trial.pdf

Health condition(s) or problem(s) studied
Helping unemployed people with chronic pain return to work.

Interventions
Individual Supported Employment Placements
The intervention comprises training therapists with prior experience of working with people with chronic pain, to be case managers (CM) and identify obstacles to RTW using the Psychosocial Flags Framework and a set of stem questions, culminating in a Return to Work (RTW) plan. The trained CM then contacts participants to explore work-aspirations and skills, and helps the participant to identify work obstacles. The CM matches the participant with a six-week part-time work placement, based on skills, aspirations, and suitability. The CM, the participant, and supervisor meet to collaboratively agree a RTW plan and discuss whether temporary accommodations are needed to overcome identified obstacles. Additionally, an initial familiarisation period will help embed the person into their role and discuss work-focussed pain management. The CM provides regular support to the participant and supervisor, and may make referrals to existing health services if needed where the CM will aid work-focused health-care through provision of existing evidence-based resources.

Cohort: Usual care
Cohort will be observed as they follow usual care. Usual care for people with persistent pain is interdisciplinary in Norway, featuring pain management services supported by physicians, psychologists, physiotherapists and nurses. Employment services take an individualised approach, and are flexible, including assessments of work ability, training, and vocational rehabilitation programmes involving traineeships in sheltered businesses. However, these services are not specifically tailored for people with pain.

Intervention Type
Behavioural

Primary outcome measure
1. Sustained return to work (defined as the first continuous four-week period of 50-100% RTW) measured using Registry data from Norwegian Labour and Welfare Administration (NAV) at

baseline and at 3, 6 and 12 months.
2. Cost effectiveness measured using Health care registry from Norwegian Patient Registry (NPR) at baseline, and at 3, 6 and 12 months.

Secondary outcome measures
1. Health-related Quality of Life measured using questionniares; EQ-5D-5L, Warwick-Edinburgh Mental Well-being Scale, and PROMIS-29 at baseline, and at 3, 6 and 12 months.
2. Work Ability measured using the Work Ability Score (as taken from the Work Ability Index), at baseline, and at 3, 6 and 12 months, and for the intervention group; work-role functioning and return to work self-efficacy, at baseline, and at 3, 6 and 12 months.
3. Details of care received and services used measured by data collected from Case Report Forms and registry data (NPR and NAV) at baseline, and at 3, 6 and 12 months.
4 . Pain and Pain intensity measured by items from the PROMIS-29, and for intervention group; study questionnaire on whether work makes pain worse. Measured at baseline, and at 3, 6 and 12 months.
5. Adverse events data collected from Case Report Forms throughout the study
6. Satisfaction with placement or job (for those who return to work) measured using a single item five-point categorical scale ranging from 'Very dissatisfied' to 'Very satisfied' in response to the wording 'How satisfied are you with your job in general?' at 3, 6 and 12 months after baseline
7. Fidelity, context, reach, dose, continuity, participation, recruitment, and engagement measured using observation techniques, data from field notes, interviews, focus groups with participants, case managers (CM), and placement managers, diary records kept by CMs, and registry data at the end of the study

Overall study start date
01/11/2021

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/09/2022:
1. Aged between 18-64 years, living in Norway
2. Want to work, and have been out of work for at least 1 month
3. Had pain for more than 3 months that is judged to interfere with work ability

Previous inclusion criteria:
1. Aged between 16-64 years
2. Want to work, and have been out of work for at least 1 month
3. Had pain for more than 3 months that is judged to interfere with work ability

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
557

Key exclusion criteria
1. People aged 65 years or over as their future time in work would be relatively limited.
2. People insufficiently fluent in Norwegian or English to give consent

Date of first enrolment
08/09/2022

Date of final enrolment
21/06/2024

Locations

Countries of recruitment
Norway

Study participating centre
Kristiania University College
Kirkegata 24-26
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Sponsor information

Organisation
Kristiania University College

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Sponsor type
University/education

Website
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Funder(s)

Funder type
Government

Funder Name
Norges Forskningsråd

Alternative Name(s)
Forskningsrådet, Norwegian Research Council, Research Council of Norway

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Results and Publications

Publication and dissemination plan
To maximise impact and use of findings, we have established a comprehensive communication and exploitation plan across four target areas/groups for the whole ReISE project

I. scientific, health, and education communities (informing research, practice, and teaching);
II. people with persistent pain (who will benefit from the scheme and/or adapted materials);
III. NAV (who will benefit from knowledge about what works, when, and for whom); and
IV. policy makers (for whom results will inform tailored policy making).

We aim to publish four articles in high-impact journals. Articles will comprise a protocol; a report on the internal pilot study; the main trial and cohort results paper; and a process evaluation. We will target a journal with a very high impact factor for the trial report, such as the BMJ or Lancet, We will include user representatives as authors to ensure lay summaries and abstracts are accessible and user-relevant. We will present results at national and international conferences.

Intention to publish date
31/10/2025

Individual participant data (IPD) sharing plan

Current IPD sharing statement as of 15/06/2022:
After completion of the ReISE project and all peer-reviewed publications and disseminations will be complete and published, anonymised/de-identified data will be available upon reasonable request to the data custodian at Kristiania University College. De-identified data will be stored in a secure database for this purpose. Protocol, data from intervention, and statistical analysis plan can be delivered upon reasonable request to the principal investigator Prof. Robert Froud (rob.froud@kristiania.no).

Previous IPD sharing statement:
After completion of the ReISE project and all peer-reviewed publications and dissiminations are complete and published, anonymised/deidentified data will be available upon reasonable request to the data custodian at Kristiania University College. Deidentified data may be stored in a secure database for this purpose. Consents for processing for these purposes will be sought from participants at the outset of the study. Protocol, data from intervention, and statistical analysis plan can be delivered upon reasonable request to principal investigator. nina.pettersson@kristiania.no

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)		16/02/2023	28/02/2023	No	No
Protocol article		11/03/2023	13/03/2023	Yes	No
Interim results article	Internal pilot study results	13/08/2024	14/08/2024	Yes	No