RETURN TO WORK USING INDIVIDUALISED SUPPORTED EMPLOYMENT (REISE)

STATISTICAL ANALYSIS PLAN

Version: 03.12.2025

Are Hugo Pripp[1,2], Pål André Amundsen[3], Martin Underwood[4], Margreth Grotle[1,5], Robert Froud[3,4]

1. Department of Rehabilitation Science and Health Technology, Faculty of Health Science, Oslo Metropolitan University, Oslo, Norway
2. Oslo Centre of Biostatistics and Epidemiology, Oslo University Hospital, Oslo, Norway
3. School of Health Sciences, Kristiana University College, Oslo, Norway
4. Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, Coventry, UK
5. Department of Research and Innovation, Division of Clinical Neuroscience, Oslo University Hospital, Oslo, Norway

ISRCTN:	85437524
Funding body:	Norwegian Research Council
Ethics approval:	Norwegian Regional Committee for Medical and Health Research Ethics (Reference no. 402918)
SAP version:	1.5
Date:	03.12.2025
Stage:	Final
Protocol version:	1.0 dated 31.01.2023

Contents

Section 1: Administrative Information

Title: Returning people with persistent pain to work using Individual Supported Employment placements (ReISE)

SAP Version	Date and timing of revision	Details of revision
1 – 1.1	9 Dec 20	Working drafts
1.2	23 Oct 21	Added Estimands framework details
1.3	18 Sep 25	Clarified the use of registry data Removed content related to process evaluation
1.4	06 Oct 25	Changes to text throughout for clarity
1.5	03 Dec 25	Final version

Roles and responsibility:

- AHP: Lead statistician
- MU: SAP contributor
- PA: SAP contributor
- MG: SAP contributor
- RF: Principal investigator

Protocol Version: 1.0 dated 31.01.2023, published in Trials *(2023) 24:179*

Section 2: Introduction

Background and rationale

Persistent (chronic) pain is the most frequent cause of sick leave and work disability in Norway; accounting for 11% and 9%, respectively (1). Most chronic pain is of musculoskeletal (MSK) origin (2). In 2019, around one-third of work days lost in Norway were due to MSK conditions (3). Increasing work participation in sick and disabled populations improves health outcomes, reverses adverse effects of worklessness, reduces poverty, and improves quality of life and well-being (4). In 2016, the costs of MSK conditions to the Norwegian health service were NOK 18 billion, and the total socio-economic costs were estimated to be NOK 255 billion (5). The average age of people reporting persistent pain in Norway is 48 (SD=16) (6). In people of this age, disability benefits increased between 2011 and 2020, and the percentage outside the labour market increased between 2018 and 2020 (in both cases by around 1.5%) (7, 8).

However, these people potentially have many remaining working years to contribute (9). For many people, a job is an essential part of self-identity; yet being out of work is too often their solution (4). There is uncertainty about how best to help unemployed people with persistent pain return to work (RTW). Usual care for people with persistent pain is interdisciplinary in Norway, featuring pain management services supported by physicians, psychologists, physiotherapists and nurses (10). Employment services take an individualised approach, and are flexible, including assessments of work ability, training, and vocational rehabilitation programmes involving traineeships in sheltered businesses (11). However, these services are not specifically tailored for people with pain. Effective vocational rehabilitation requires a combination of work-focused healthcare together with supportive workplaces; unfortunately, the two are generally not coordinated (12). Supported employment interventions, such as Individualised Placement and Support (IPS), are effective for helping people with mental health conditions to gain and retain employment (13). Considerable interest has been generated in adapting this style of intervention to help people with persistent pain (14-17). People who are unemployed due to persistent MSK pain face different obstacles to working than those with mental health conditions *per se,* requiring work-place accommodations in the physical task environment (18, 19). In contrast to IPS, where the user is largely passive and simply supported, engaging people with persistent pain in identifying their own individual (psychosocial) obstacles to work ability, agreeing on the actions to overcome those obstacles in a RTW plan, and combining pain management advice, may be more effective for this group. In 2020, we described the results of a

feasibility study of an adapted supported employment placement intervention, run in the UK, which featured work placement provision with case manager (CM) support (15). In this novel intervention, we trained case managers to act as a bridge between systems and institutions, engage people about obstacles to work, and collaboratively agree a RTW plan. We also provided supportive work placements of up to 16-hours per week and six-week durations. The developed intervention was acceptable and valued, with around 20% of the sample obtaining paid employment within the short six-month follow-up: self-perception of satisfactory functioning in role and management of identified obstacles, may be key to increasing confidence for this group. As the study focused on feasibility, the effectiveness and cost-effectiveness of the intervention are unknown. Without intervention, the probability of RTW after two years of unemployment is thought to be close to zero (15). RTW rates for traditional vocational rehabilitation in the unemployed (rather than sick-listed) pain population are unclear. In trials of interventions, outcome measures have often been expressed with employment success constituting as little as one day of paid work (20). A focus on sustained RTW will be more useful and relevant (21).

Statistical objectives and estimands

Primary objective

- to establish whether whether a supported work placement intervention with biopsychosocial case management is more effective and cost-effective than usual care for improving sustained return to work in unemployed people with persistent pain who want to work.

Secondary objective

- to investigate the impact of being out of work with persistent pain on health-related quality of life; including measurements in the domains of physical function; anxiety; depression; fatigue; sleep disturbance; social function and activities; pain interference; bothersomeness; pain intensity; mental wellbeing; confidence in RTW and social care resources use.

Statistical estimands

The primary estimand

“Compared to those in the cohort study who were not offered the intervention, what is the effect of offering a supported employment intervention with biopsychosocial case management on sustained return to work in unemployed people with persistent pain?”

Secondary estimands

(1) "Compared to those in the cohort study who were not offered the intervention, what is the effect of attending at least the work familiarisation session on sustained return to work in unemployed people with persistent pain?"
(2) "Compared to those in the cohort study who were not offered the intervention, what is the effect of attending the work familiarisation session and receiving a placement offer on sustained return to work in unemployed people with persistent pain?"
(3) "Compared to those in the cohort study who were not offered the intervention, what is the effect of attending the work familiarisation session and at least two weeks of a placement on sustained return to work in unemployed people with persistent pain?"
(4) "Compared to those in the cohort study who were not offered the intervention, what is the effect of attending the work familiarisation session and who complete their placement, on sustained return to work in unemployed people with persistent pain?"

Section 3: Study Methods

Trial design and randomisation

We used a cohort randomised approach with national recruitment. Initially, all eligible and consenting participants were recruited to an observational cohort study of the impact of being unemployed with persistent pain. After baseline measurement, using minimisation (balancing for age on three levels (18 to 29; 30 to 49; and 50 and over) and gender on three levels (male; female; and 'prefer not to say') (22-24).

Randomisation was automated using a mix of Stata (StataCorp, College Station TX) and Bash scripting to keep personal data encrypted (within Tjenester for Sensitive Data (TSD), University of Oslo, Oslo). The first participant was randomly allocated (to receive an intervention offer) with equal probability across minimisation levels and then for each subsequent participant, there was initially a two-thirds probability that allocation would be to the group that best minimises the imbalance on the selected factors between groups at the time the allocation was performed. We randomly sampled a sub-group to whom we offered the intervention, requesting consent for intervention participation. The ratio used for random sampling changed over time from 1:3, to 1:2 to 2:1 (as intervention take-up rates were not as high as anticipated, and we sought more data to be able to address the third and fourth secondary estimands; *i.e.* the effect in those who attended placements) eventually leading to

approximately equally weighted trial arms at the end of the trial. The randomisation ratio in use at the time of randomisation was recorded as a dummy variable so that this could be subsequently modelled as a covariate in case people enrolled at different parts of the trial differed in important characteristics (25). Full details of the intervention can be found in the published protocol (26).

Between-group assessments will be made comparing to baseline, at three, six and 12-months of follow-up. The primary outcome of sustained return to work will be obtained from questionnaire or if available, registry data at 12 months.

Sample size

The sample size calculation was based on detecting a difference of 20% in cumulative incidence of sustained RTW between the intervention group and those in the remaining cohort who would be receiving usual care. We defined sustained return to work as the first four weeks of ≥50% work. A priori we assumed a 1:3 allocation ratio, and a usual care RTW rate as high as 10%; with a power of 80% and a 5% significance level, and thus needed data on 176 participants (132 control and 44 intervention) (15). Allowing 20% loss to follow-up, and a crude 14% inflation in the intervention group for an unknown (due to the lack of an ICC) design effect for clustering by case manager; we estimated an average cluster size of 15 across three case managers, an ICC of 0.01, smallest cluster size of 5 and largest of 18, and so a design effect of about 1.14. We therefore aimed to recruit 228 people (27). The ratio needed to be changed, first to 1:2 to provide sufficient throughput for us to regularly form small groups of people for the work preparation session due to the proportion of people not accepting the intervention being high, and then to 2:1 following guidance from our Data Monitoring Committee and Trial Steering Committee to increase the number of people accepting the intervention and then being offered a placement (*i.e.* to ensure power to assess down to at least the second secondary estimand). In the case of balanced randomisation, the comparative overall required sample size would be reduced to 190 in total, with the above inflations (and with the same assumptions, the estimated design effect would be 1.11 in that case).

Framework

The framework of the trial is superiority however we will use two-sided hypotheses testing and all point estimates will be expressed with 95% confidence intervals (CI The intervention will be compared with the usual care group on all predefined and prespecified variables. All subgroup analyses are also prespecified.

Pilot analysis, interim statistical analyses and DMC stopping guidance

When the internal pilot study target sample size reached 66 participants with 17 allocated to the intervention, feasibility of pilot objectives was assessed and described in the published pilot paper (28).

An independent Data Monitoring Committee (DMC) was convened to review material in relation to these objectives, reporting to an independent (by majority) Trial Steering Committee (TSC) who advised on progression to full-scale trial.

The DMC and TSC advised on when and how regularly it would like to review progress, and prior to this meeting interim analyses will be performed for the DMC, with all of the group other than the statistician blind to results. The results of such interim analyses determined if the study continued or would be prematurely terminated, either due to infeasibility detected at the pilot phase, or stopping for futility, for example. The DMC monitored quality, for futility or overwhelming success (See Spirit item 21a), with their first meeting being at the end of the pre-pilot phase.

Timing of final analysis

The database will be frozen for the final analyses when all data have been collected from participants at 12-months, with any paper entries also entered onto the database, data are fully validated and cleaned, and the statistical analysis plan published or lodged in repository.

Section 4: Statistical Principles

Confidence intervals and p-values

The study hypotheses are formulated using the superiority framework; however all statistical tests will be two-sided, and we will use significance level of 5%. The point estimate, 95% confidence interval (95% CI) and p-value will be reported for each test undertaken. As outcomes are considered largely to be statistically independent, no adjustment to p-values will be made for multiple testing.

Adherence and protocol deviations

We will assess two levels of intervention adherence in this study: minimal and full adherence (*i.e.,* secondary estimands three and four). Minimal adherence with the intervention is defined as the

participant attending two of the six-week placements and full the full six-week placement. Both levels of adherence will inform the complier averaged causal effect (CACE) analysis (29).

Analysis principles

All analyses will be performed according to 'Intention-to-treat' (ITT) principles. Participants will be analysed according to the group they were randomised to, irrespective of the intervention they actually received. All participants will be included in the analysis, regardless of whether they adhered to the protocol.

Section 5: Trial Population

Inclusion and exclusion criteria

The inclusion criteria were that participants should be aged between 18 and 64, unemployed for at least one month, had pain for more than three months, lived in Norway and wanted to work. Exclusion criteria covered those over 65 years of age, and those insufficiently fluent in Norwegian or English to give consent.

Eligibility will be summarised using frequencies and percentages to describe how many people were:

- Eligible and randomised
- Eligible and not randomised
- Ineligible and randomised (in error)
- Ineligible and not randomised, summarising the main reasons for exclusion

Recruitment

The CONSORT diagram will illustrate the flow of participants throughout the trial. This will include:

- Number screened
- Of those screened, how many were ineligible or declined
- Number randomised
- How many withdrew, died and were lost to follow-up at each follow-up time-point
- How many included in the final analyses at the primary endpoint listing reasons why participants were excluded

Withdrawal/follow-up

All withdrawals will be summarised by group using frequencies and percentages.

Level of withdrawal and intervention discontinuation will be summarised by treatment group, *i.e.* how many discontinued from the intervention alone but remained on follow-up and/or how many withdrew completely.

Timing of withdrawals and discontinuation will be summarised by treatment group as follows:

- Withdrawals or discontinuations after randomisation but before initial assessment (intervention arm only);
- Withdrawals or discontinuations during placement (intervention arm only);
- Withdrawals or discontinuations from follow-up - (i) prior to three-month follow-up (ii) after three-month follow-up but before six-month follow-up (iii) after six-month follow-up but before 12-month follow-up

Withdrawal or discontinuation decisions will be reported i.e. decisions made by participant or ReISE study team, will be summarised by group.

Withdrawal or discontinuation reason will also be summarised where available.

Follow-up rates will be calculated based on case report form (CRF) completion at follow-up time points and summarised as follows: Follow-up (at time *t*) = (Number of participants assessed at time *t*, divided by total number of participants that should have been assessed at time *t*) x 100%. Follow-up rates will be calculated at the three-, six- and 12-month follow-up time-points. At each time point, a participant is defined as being lost to follow-up if not returning their CRF within six weeks of their follow-up due date.

Section 6: Statistical Analyses

Outcome definitions

Primary outcomes

The primary outcome is 'sustained return to work'. There is no consensus in the literature about what constitutes sustained RTW. In this study, the primary outcome is defined as the first four-weeks of ≥50 work.

Secondary outcomes

Secondary outcomes will include health-related quality of life, work ability, pain and pain intensity, and satisfaction with care. The EQ-5D-5L will be used to measure potential changes in participants' self-reported health-related quality of life within five domains: Mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The short form Warwick-Edinburgh mental wellbeing scale (WEMWBS) measures mental wellbeing (30), while the PROMIS-29 will be used to assess the following variables: anxiety, depression, fatigue, pain (intensity and interference), physical function, sleep disturbance, and social participation (31). Work-related outcomes include numeric scale measures in confidence in return to work and work ability, a RTW self-evaluation and offers of employment. For those who have returned to work measures include usual work patters, job satisfaction, and the Work Role Functioning Questionnaire (WRQF) which is an outcome measure linking a persons' health to the ability to meet work demands (32).

Cost-effectiveness

Details of the planned health economic analysis are not in the scope of this statistical analysis plan for assessing trial effectiveness. However, briefly, we note that we plan to use registry data (NPR (*Norsk Patientregister*), KPR (*Kommunalt pasient- og brukerregister*), and KUHR (*Kontroll og utbetaling av helserefusjoner*) used to estimate hospital and community health and social care resource use from three months prior to baseline measurement, and three, six and 12 months after baseline measurement. To support the economic evaluation, our own questionnaires include items of health and social care use in a wider sense than collected registry data. The cost-effectiveness will be conducted from the personal social services (PSS) perspective (33). Current Norwegian unit costs (if available) will be applied to value total resource use in both groups. Responses to the EQ-5D-5L will be converted into multi-attribute Norwegian utility scores (if available - at the time of writing Norwegian value sets are under development and it is recommended that the UK value sets are used in the meantime) (34, 35). Results will be presented using incremental cost-effectiveness ratios (ICERs) and cost-effectiveness acceptability curves (CEACs). This accommodates sampling uncertainty and varying levels of willingness to pay for an additional quality adjusted life year (QALY).

Analytical methods

Participant characteristics and outcomes will be summarised as mean and standard deviation (SD) for continuous variables, and frequency and percentage for categorical variables, stratified by study group (*i.e.* those offered the intervention and those not offered the intervention). The median and interquartile range (IQR) will be presented for variables with skewed distributions.

The primary analysis (the primary estimand) assesses the between group difference between those being offered the intervention and those in the cohort study only in terms of sustained RTW and will be conducted according to ITT principles.

To account for the trial design featuring clustering in the intervention arm, generalised linear mixed effects models (GLM) with partial clustering will be used to estimate treatment effects for both primary and secondary outcomes; with a random intercept for case manager. As the main outcome is a binary variable, we will analyse between-group differences in sustained RTW using a GLM model with logit link function, adjusting for age, gender, and duration of pain, and fitting a random effect in CM allocation. The results will be expressed as odds ratios for RTW in the intervention group compared with the standard care group using a point estimate with 95 % confidence interval. In the event of a statistically significant between group difference we will present data on numbers needed to treat to aid interpretation of our finding.

If possible, secondary outcomes will also be analysed using generalised mixed models, using link functions that are appropriate to the outcome (*e.g.* the logit for categorical outcomes and canonical or identity link functions for continuous data as appropriate). In all cases, we will adjust for the same covariates; age, gender, duration of pain, and the dummy variable for randomisation ratio. The results will be expressed as odds ratios or between group differences in changes from baseline using point estimates with 95 % confidence interval, as appropriate.

As secondary analyses, we will carry out a complier averaged causal effect (CACE) analysis for the primary outcome (29). There are several intercurrent events to consider in respect of this.

Not all of those offered the intervention will have accepted the intervention. In the case that the proportion of those who accept, went on to have had the work preparation session, receive a placement offer, and complete the placement, suffered from heavy attrition, we will secondarily analyse effects at these levels, anticipating being well-powered at least to the level of those receiving an offer (as we cannot control the proportion of those who then accept the placement offer), as per our primary estimand. This will be the principal stratum for use in our CACE analysis ahead of exploring

secondary estimand levels. Intervention take up was lower than anticipated and we aimed to ensured that at least 44 people were offered a placement to ensure power to at least assess down to the second secondary estimand.

Sub-group analyses

We will explore whether the severity of baseline anxiety and depression are moderators of treatment effect' is sufficient for the SAP. [8].

Sensitivity analyses

We will also secondarily model RTW using as little as a single day of work by way of sensitivity analysis to compare to what has become common practice in the literature. Our view is that only a single day of work is not a relevant outcome but running this as a secondary analysis will facilitate cross-trial comparisons. We will also model time-to-RTW using survival analysis approaches (for example, zero-inflated Poisson regression or a negative binomial model, as best fits observed data.)

Missing data

The levels and patterns of non-responders at each follow-up time point will be monitored regularly. The levels and patterns of missingness in the primary outcome will be assessed with the aim of determining the type of missingness (*e.g.* MAR, NMAR). If required, as an additional sensitivity analysis, imputation techniques relevant to the type of missing data mechanism will be used to impute data and estimate the treatment effect to see how it compares to the main ITT analysis.

Harms

The frequency and percentage (%) of serious adverse events (SAE) and adverse events (AE) in the trial will be compared between the two treatments using the chi-squared / Fisher's exact test as appropriate. The results will be expressed as proportions, e.g. point estimates with 95% confidence intervals in both groups. Adjusted analyses will not be performed for any harm data. The event type, severity assessment, expectedness and relatedness to intervention will also be summarised by offer of treatment or cohort only.

Statistical software

Statistical analyses will be conducted using the latest available version of Stata (Statacorp, Texas) and RStudio if necessary (e.g for graphical plots).

References

1. Laerum E, Brage S, Ihlebaek C, Natvig B, Aas E. Et muskel- og skjelettregnskap: forekomst og kostnader knyttet til skader, sykdommer og plager i muskel- og skjelettsystemet: MST-rapport. Oslo: Muskel og Skjelett Tiåret; 2013.
2. Elliott AM, Smith BH, Penny KI, Smith WC, Chambers WA. The epidemiology of chronic pain in the community. Lancet. 1999;354(9186):1248-52.
3. NAV. Fortsatt stabilt sykefravær i Oslo 2019 [Available from: https://www.nav.no/no/lokalt/oslo/pressemeldinger/fortsatt-lavest-sykefravaer-i-oslo.
4. Waddell G, Burton AK. Is work good for your health and well-being? : Department for Work and Pensions; 2006.
5. Skogli E, Theie M.G, Stokke O, L L. Muskel- og skjelettsykdom i Norge: Rammer flest - koster mest. Vurdering av tiltakt for å redusere samfunnskostnadene. Menon Economics 2019.
6. Rustoen T, Wahl AK, Hanestad BR, Lerdal A, Paul S, Miaskowski C. Gender differences in chronic pain--findings from a population-based study of Norwegian adults. Pain Manag Nurs. 2004;5(3):105-17.
7. SSB. Labour force survey. Oslo: Statistics Norway; 2020.
8. NAV. Disability benefit - Quarterly statistics 2020 [cited 2023 June 24]. Available from: https://www.nav.no/no/nav-og-samfunn/statistikk/aap-nedsatt-arbeidsevne-og-uforetrygd-statistikk/uforetrygd.
9. UNECE National Report on Ageing 2016 – NORWAY. Follow-up to the Regional Implementation Strategy of the Madrid International Action Plan on Ageing. Oslo, Norway: Norwegian Ministry of Labour and Social Affairs.; 2016.
10. Linnemørken LTB, Sveinsdottir V, Knutzen T, Rødevand L, Hernæs KH, Reme SE. Protocol for the Individual Placement and Support (IPS) in Pain Trial: A randomized controlled trial investigating the effectiveness of IPS for patients with chronic pain. BMC Musculoskelet Disord. 2018;19(1):47.
11. Sveinsdottir V, Tveito TH, Bond GR, Grasdal AL, Lie SA, Reme SE. Protocol for the SEED-trial: Supported Employment and preventing Early Disability. BMC Public Health. 2016;16:579.
12. Waddell G, Burton AK, Kendall N. Vocational rehabilitation – what works, for whom, and when? : TSO; 2013.
13. Brinchmann B, Widding-Havneraas T, Modini M, Rinaldi M, Moe CF, McDaid D, et al. A meta-regression of the impact of policy on the efficacy of individual placement and support. Acta Psychiatr Scand. 2019.
14. Rodevand L, Ljosaa TM, Granan LP, Knutzen T, Jacobsen HB, Reme SE. A pilot study of the individual placement and support model for patients with chronic pain. BMC Musculoskelet Disord. 2017;18(1):550.
15. Froud R, Grant M, Burton K, Foss J, Ellard DR, Seers K, et al. Development and feasibility of an intervention featuring individual supported work placements to aid return to work for unemployed people living with chronic pain. Pilot Feasibility Stud. 2020;6:49.
16. Linaker C, Fraser S, Price C, Maguire N, Little P, Madan I, et al. Individualised placement and support programme for people unemployed because of chronic pain: a feasibility study and the InSTEP pilot RCT. Health Technol Assess. 2021;25(5):1-72.
17. Sveinsdottir V, Jacobsen HB, Ljosaa TM, Linnemørken LTB, Knutzen T, Ghiasvand R, et al. The Individual Placement and Support (IPS) in Pain Trial: A randomized controlled trial of IPS for patients with chronic pain conditions. Pain Med. 2022.
18. Patel S, Greasley K, Watson PJ. Barriers to rehabilitation and return to work for unemployed chronic pain patients: a qualitative study. Eur J Pain. 2007;11(8):831-40.
19. Waddell G, Burton AK, Kendall N. Vocational rehabilitation – what works, for whom, and when? . Vocational Rehabilitation Task Group; 2013.

20. Bejerholm U, Areberg C, Hofgren C, Sandlund M, Rinaldi M. Individual placement and support in Sweden - a randomized controlled trial. Nord J Psychiatry. 2015;69(1):57-66.
21. Jensen C, Jensen OK, Nielsen CV. Sustainability of return to work in sick-listed employees with low-back pain. Two-year follow-up in a randomized clinical trial comparing multidisciplinary and brief intervention. BMC Musculoskelet Disord. 2012;13:156.
22. Altman DG, Bland JM. Treatment allocation by minimisation. BMJ. 2005;330(7495):843-.
23. Saghaei M. An overview of randomization and minimization programs for randomized clinical trials. J Med Signals Sens. 2011;1(1):55-61.
24. Saghaei M, Saghaei, S. Implementation of an open-source customizable minimization program for allocation of patients to parallel groups in clinical trials. Journal of Biomedical Science and Engineering. 2011(4):734-9.
25. Altman D. Avoiding bias in trials in which allocation ratio is varied. JLL Bulletin [Internet]. 2017. Available from: https://www.jameslindlibrary.org/articles/avoiding-bias-trials-allocation-ratio-varied/.
26. Amundsen PA, Underwood M, Burton K, Grotle M, Malmberg-Heimonen I, Kisa A, et al. Individual supported work placements (ReISE) for improving sustained return to work in unemployed people with persistent pain: study protocol for a cohort randomised controlled trial with embedded economic and process evaluations. Trials. 2023;24(1):179.
27. Eldridge SM, Ashby D, Kerry S. Sample size for cluster randomized trials: effect of coefficient of variation of cluster size and analysis method. Int J Epidemiol. 2006;35(5):1292-300.
28. Amundsen PA, Underwood M, Burton K, Grotle M, Engedahl MS, Malmberg-Heimonen I, et al. Individual supported work placements (ReISE) for improving sustained return to work in unemployed people with persistent pain: an internal pilot study of a cohort randomised controlled approach. Pilot and Feasibility Studies. 2024;10(1):110.
29. Hewitt C, Torgerson D, Miles J. Is there another way to take account of noncompliance in randomized controlled trials? CMAJ. 2006;175(4):347-8.
30. Tennant R, Hiller L, Fishwick R, Platt S, Joseph S, Weich S, et al. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. Health and Quality of Life Outcomes. 2007;5(1):63.
31. Cella D, Choi SW, Condon DM, Schalet B, Hays RD, Rothrock NE, et al. PROMIS(®) Adult Health Profiles: Efficient Short-Form Measures of Seven Health Domains. Value Health. 2019;22(5):537-44.
32. Abma FI, Bültmann U, Amick Iii BC, Arends I, Dorland HF, Flach PA, et al. The Work Role Functioning Questionnaire v2.0 Showed Consistent Factor Structure Across Six Working Samples. Journal of Occupational Rehabilitation. 2018;28(3):465-74.
33. NICE. NICE guide to the methods of technology appraisal. National Institute for Health & Clinical Excellence (NICE); 2008.
34. Dolan P. Modeling valuations for EuroQol health states. Med Care. 1997;35(11):1095-108.
35. Brazier JE, Roberts J. The estimation of a preference-based measure of health from the SF-12. Med Care. 2004;42(9):851-9.