Effect of Individual Placement and Support (IPS) on employment for persons with alcohol and drug addiction in a Swedish context

| Submission date 01/08/2023 | Recruitment status Recruiting | [X] Prospectively registered[X] Protocol | |
|-------------------------------|--------------------------------------|---|--|
| Registration date | Overall study status | Statistical analysis plan | |
| 14/08/2023 | Ongoing | Results | |
| Last Edited 04/04/2025 | Condition category Other | Individual participant data | |
| | | [X] Record updated in last year | |

Plain English summary of protocol

Background and study aims

Employment forms part of society and is a vital source for experiencing meaningfulness, having economic resources, participating in society as well as developing our identities. However, people with experience of abuse and addiction to alcohol and drugs are an underrepresented group in the labour market. Problems that arise are linked to both the addiction and the unemployment itself and are strongly related to poverty, the development of other diseases as well as stress and early death. At the same time, addiction creeps further down the ages and interrupts young adults' development and connection to work.

Furthermore, previous addiction research shows that work plays a part in recovery and staying sober, achieving financial independence, finding social connectedness, and developing new identity and self-confidence. At the same time, a knowledge gap exists in primary studies on return-to-work (RTW). Thus, scientific knowledge on its effectiveness for the target group within the new clinical field in Sweden and in workplaces is entirely lacking.

The Individual Placement and Support (IPS) supported employment intervention holds a promise, is an evidence-based RTW intervention for persons with psychosis and is highlighted but not yet a prioritised intervention in national policy for addiction. IPS is a person-centred RTW intervention that is adjusted in relation to individual needs and preferences, co-created with the employment specialist, the treatment team, professionals within the benefits system, and employers.

The hypothesis of this study is that a significantly larger proportion of IPS+TAU participants will be employed for >1 day at 18-month follow-up, reach employment sooner, work more hours and longer periods of time, and have a higher income as compared to TVR+TAU participants among 330 participants. Another anticipation is that those who benefit from IPS+TAU will use less alcohol and drugs, experience better health, quality of life and well-being, and use less care and support in comparison to TVR+TAU participants, at 18-month follow-up. IPS Fidelity Scale (25-items) review at 6 and 12 months will help to describe delivery and receipt of the IPS as well as contextual hinders and barriers for co-production and implementation. Currently, there is a lack of knowledge about how a trial best can be planned and carried out in co-production with addiction services and persons with lived experience of addiction.

The aim of this study is to add to the development of a scientific basis for IPS for the target

group of persons with alcohol- and drug addiction, with the possibility to influence policy and inform IPS practice in a new field within a Swedish context.

Who can participate?

People aged 18-65 years, willing to work, unemployed, having participated in a IPS-ADAS trial information meeting, diagnosed with addiction disorder (i.e., alcohol and/or drugs) and in treatment at an outpatient addiction centre within the County Council and/or related Municipality, and being financially supported by the welfare system (e.g., the Municipality, Public Employment Service or Social Insurance Agency).

What does the study involve?

After enrolment study participants will be offered to complete an online interview survey to answer questions about their clinical, social, and demographic situation as well as their self-rated health, quality of life and well-being. Once they have completed the survey they will be randomly assigned to either IPS plus addiction services treatment as usual (IPS+TAU) or traditional vocational rehabilitation (TVR) plus TAU (TVR+TAU) in a Swedish context for a period of 12 months (Stockholm, Södertälje, Lund/Malmö). They will in addition complete a survey at 6, 12 and 18 months follow-up.

The addiction service treatment as usual element regards reducing substance use, increasing health and wellbeing, and securing housing.

The IPS is guided by an employment specialist (ES) who is the key professional and provides IPS in coproduction with the participant and the treatment team (TAU), but also the IPS network of family and friends, professionals from the Social Insurance Agency (SIA), Public Employment Service (PES), and keep frequent and quality contacts with employers. The professional role of the ES concerns good-quality emphatic counselling according to eight IPS principles (not to be understood or carried out in any particular order): 1) competitive employment as the primary goal, 2) eligibility based on the participant's choice (zero exclusion), 3) rapid job search, 4) integration of IPS with treatment, 5) job search based on personal preferences, 6) ongoing support and work accommodations as needed, 7) benefit counseling (SIA/PES) in an early stage, and 8) systematic recruitment and quality engagement with local employers. The IPS support process involves an engagement phase of sharing lived experiences and building a mutual relationship, a phase of identifying resources and preferred employment, a job-seeking and jobdevelopment phase, and if employment is gained, a supported employment phase. TVR will be delivered by RTW professionals from different welfare actors of the rehabilitation chain, firstly within Addiction Services, Municipalities but also from professionals from the Public Employment Service (PES) and through the Social Insurance Agency (SIA) throughout the 12month intervention periods. TVR is facilitated through preassessment work ability stages according to the logic of each organisation and its connection to regulations of social, sick-leave and unemployment benefits.

What are the possible benefits and risks of participating?

Currently, no known risks are studied in connection to participation in IPS, especially since participants benefit from an integrated and person-centered employment support with the aim to empower their own resources, choices and plans. There may be discomfort while participating in the online survey. However, participants will be personally supported if needed in connection to each occasion by the research assistant and/or peer supporter within the study. Notably, an information meeting is obligatory to mitigate possible risks before consent. Furthermore, participation entails ongoing support and outreach activities to maintain contact and assess ambivalence, benefits, and perceived barriers throughout the intervention, even though the employment specialist and participant are not in an active coproduction phase (e.g., adjustment

of medication or a dormant period). Similar outreach activities are performed within the TVR by each organisation. Adverse events will be monitored throughout the study in connection to each site.

Where is the study run from?

- 1. Lund University within the research network of the Centre for Evidence-based Psychosocial Interventions (CEPI) (Sweden)
- 2. Department of Research and Development at Region Skåne (Sweden)

When is the study starting and how long is it expected to run for? September 2022 to June 2026

Who is funding the study?
Swedish Research Council for Health, Working Life and Welfare (FORTE) (Sweden)

Who is the main contact? Ulrika Bejerholm, ulrika.bejerholm@med.lu.se

Contact information

Type(s)

Principal Investigator

Contact name

Prof Ulrika Bejerholm

ORCID ID

http://orcid.org/0000-0001-7505-6955

Contact details

Forum Medicum BMC, Sölvegatan 19 Lund Sweden 223 62 +46 (0)462221958 ulrika.bejerholm@med.lu.se

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2023-00080

Study information

Scientific Title

Individual Placement and Support for persons with alcohol and drug addiction in a Swedish context: the IPS-ADAS trial

Acronym

IPS-ADAS

Study objectives

The hypothesis is that a significantly larger proportion of participants in Individual Placement and Support plus Treatment as Usual (IPS+TAU) will be employed for >1 day at 18-month follow-up (primary outcome), reach employment sooner, work more hours and longer periods of time, have a higher income as compared to participants in Traditional Vocational Rehabilitation (TVR) +TAU in a sample of 330 participants. It is also anticipated that those who benefit from IPS+TAU will use less alcohol and drugs, experience better health, quality of life and well-being, and use less care and support in comparison to TVR+TAU participants at 18-month follow-up.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 03/11/2022, The Swedish Ethical Review Authority (Etikprövningsmyndigheten, Postal Box 2110, Uppsala, 750 02, Sweden; +46 (0)104750800; registrator@etikprovning.se), ref: 2022-05067-01

Study design

Multi-site pragmatic two-arm parallel single-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Built environment/local authority, Community, Workplace, Other

Study type(s)

Other, Quality of life, Efficacy

Participant information sheet

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

Health condition(s) or problem(s) studied

Adults in treatment for alcohol and/or drug addiction who are unemployed and want to work in the near future

Interventions

After completion of baseline assessment participants will be randomly assigned to one of the two intervention arms (ratio 1:1) using randomly varying block sizes of 8 and 4. A randomization schedule is automatically generated in RedCap to assure allocation concealment will be produced. No stratification will be scheduled.

Intervention 1: Individual Placement and Support plus Treatment as Usual (IPS+TAU).

Intervention 2: Traditional Vocational Rehabilitation plus TAU (TVR+TAU)

Intervention 1

The IPS intervention (IPS+TAU) is a coproduced and person-centered intervention in which IPS becomes an integrated part of the Addiction Services Treatment as Usual (TAU). The TAU element regards reducing substance use, increasing health and well-being, and securing housing (1-10 hours a week). IPS is guided by an employment specialist (ES) who is the key professional and provides IPS to a caseload of <20 participants for 12 months, with the possibility to abate the support. The time frame is referenced to previous IPS research. The ES works in coproduction with the participant and the treatment team (TAU), but also the IPS network of family and friends, professionals from the Social Insurance Agency (SIA), Public Employment Service (PES), and keep frequent and quality contacts with employers. The professional role of the ES concerns good-quality emphatic counseling according to eight IPS principles (not to be understood or carried out in any particular order): 1) competitive employment as the primary goal, 2) eligibility based on the participant's choice (zero exclusion), 3) rapid job search, 4) integration of IPS with treatment, 5) job search based on personal preferences, 6) on-going support and work accommodations as needed, 7) benefit counseling (SIA/PES) in an early stage, and 8) systematic recruitment and quality engagement with local employers. The dose of delivery is individualized to fit the support need of the users. IPS involves 1) an engagement phase of sharing lived experiences and building a mutual relationship (ES+participant), 2) a phase of coproducing and completing a career profile and plan based on user interest and preferences, 3) a job-seeking and -development phase, and if employment is gained. 4) a supported employment phase in which mobilized support strategies of IPS are intertwined. Phase 1) and 2) last for about 1 months, phase 3) until employment is reached, and phase 4) the remaining time. Against the backdrop of previous IPS research, the dosage of phases 1), 2), and 3) is approximately 1 hour a week, while phase 4) requires 20 minutes per week. In the Swedish National guidelines for care and support in cases of substance abuse and addiction, IPS is prioritised as 3 on a 10-point scale, where 1 represents the highest priority.

Intervention 2

The comparative intervention (TVR+TAU) is considered the best choice since it entails the standard stepwise work support towards employment provided by the Swedish welfare system and is performed in parallel or as the next phase to the Addiction Services Treatment as Usual (TAU). It will be delivered by return-to-work (RTW) professionals within the stepwise rehabilitation chain of Addiction Service, Municipality (e.g., social worker, occupational therapist, physiotherapist), Public Employment Service (PES) and Social Insurance Agency (SIA) (e.g., handling officers) throughout the 12-months intervention period. Each step is facilitated or hindered by the outcome of the prevocational work ability assessment and the regulation around the financial situation of the participant (e.g., social, sick-leave and unemployment benefits). In case of sobriety, the first phase of TVR 1) involves prevocational rehabilitation, including Supported Employment strategies, within labour market units at Municipality (1-5 hours week). If the work ability across the entire labour market is met, participants may move on the phase 4). If work ability is not met, users may enter 2) prevocational training in day centres for meaningful activities, regulated by law to 5-20 hours a week. Phase 3) vocational training in internship placements (20-40 hours a week) through the PES/SIA or Municipality, and the last phase 4) application for employment positions through the PES.

Intervention Type

Behavioural

Primary outcome measure

Proportion of participants in competitive employment (yes/no, 1 day) retrieved from LISA register (Swedish Longitudinal Integrated Database for Health Insurance and Labour Market Studies) retrospectively at 18 months

Secondary outcome measures

- 1. Vocational outcomes:
- 1.1 Time to event (employment) retrieved from LISA register retrospectively at 18 months.
- 1.2 Total time (days) in employment retrieved from LISA register retrospectively at 18 months.
- 1.3 Job tenure (continuous time period) retrieved from LISA register retrospectively at 18 months
- 1.4 Total employments retrieved from LISA register retrospectively at 18 months
- 1.5 Proportion of full-time work (% of 40 h/week) retrieved from LISA register retrospectively at 18 months
- 1.6 Income (monthly) retrieved from LISA register retrospectively at 18 months

Data will be collected by Statistics Sweden from the LISA register and be delivered to the researcher coded. Register data will be validated against users' own registration of employment status in the Addiction Severity Index (ASI) for Clinical Trials and e-use, and logbooks of employment specialists, by an independent researcher. Self-employment data will also be collected.

Clinical, social, and demographic characteristics and outcomes

2. 2. Clinical, social, and demographic characteristics and outcomes (i.e., age, gender/gender identity, ethnicity, civil status, diagnosis, substance use, housing situation, income, benefit type, sick-leave status, education and employment history/status, treatment, care, and support) will be measured using the Addiction Severity Index (ASI) for Clinical Trial and e-use questionnaire at baseline, 6, 12 and 18 months.

Health, quality of life, and well-being outcomes:

- 3.1. Health in terms of empowerment measured using the questionnaire Empowerment Scale questionnaire with 28 statements reflecting five subscales of self-esteem/self-efficacy, power/powerlessness, community activism and autonomy, optimism and control over the future, and righteous anger, at baseline, 6, 12, and 18 months
- 3.2. Health in terms of engagement level in daily activity and community life measured using the Profiles of Occupational Engagement Scale questionnaire at baseline, 6, 12, and 18 months
- 3.3. Health in terms of anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS) questionnaire at baseline, 6, 12, and 18 months
- 3.4. Quality of life measured using the EuroQol 5 Dimension (EQ-5D) questionnaire to study 5 health-related quality of life dimensions at baseline, 6, 12, and 18 months
- 3.5. Quality-adjusted life-years (QALYs) assessed with an economic evaluation using the EuroQol 5 Dimension (EQ-5D) questionnaire at baseline, 6, 12, and 18 months
- 3.6. Quality of life measured using the Manchester Short Assessment of Quality of Life (MANSA) instrument 12 items at baseline, 6, 12 and 18 months
- 3.7. Wellbeing over the last 2 weeks measured using the WHO-5 Well-being index (WHO-5) at baseline, 6, 12 and 18 months

To conclude implementation fidelity to the IPS intervention the Supported Employment Fidelity Scale (SEFS) will be used at 6 and 12 months. Several data sources, e.g., interviews with IPS participants, unit managers, processors, IPS employment specialists and managers, IPS documentation and statistics, will form the basis for the review. Data is collected by the process leader (each site) and a research administrator the preceding month according to 25 items related to staffing, organisation, and services. Higher scores indicate greater fidelity. The review will be carried out by an external IPS expert and be based on the gathered data and dialogue with the process leader of each site. Adherence to IPS at 6 months will be shared in project- and operational work groups as well as with integrated actors in which context strategies will be developed to target improvements. The TVR intervention will be reviewed in relation to the SEFS scale as well since no available TVR fidelity scale exists. This allows for comparisons between groups regarding similarities and diverse features.

Overall study start date

01/09/2022

Completion date

26/06/2026

Eligibility

Key inclusion criteria

- 1. Aged 18-67 years
- 2. Willing to work in the near future
- 3. Unemployed
- 4. Participate in an IPS-ADAS trial information meeting (in group or individually)
- 5. Diagnosed with addiction disorder (i.e., alcohol and/or drugs) as primary diagnosis
- 6. In treatment at outpatient addiction service within the healthcare Region and/or Municipality
- 7. Financially supported by welfare system (e.g., decision on financial aid/benefit from the Municipality, Public Employment Service or Social Insurance)

Note: Eligibility criteria for the study centres will concern being an addiction healthcare provider within the publicly financed healthcare of Region Stockholm and Region Skåne and/or City of Stockholm, Municipality of Södertälje, and Municipality of Lund/Malmö. Addiction services in Sweden are typically divided between Regions and Municipalities and new governmental directives for coproduction and person-centeredness of services is currently presented.

Participant type(s)

Patient, Service user

Age group

Adult

Lower age limit

18 Years

Upper age limit

67 Years

Sex

Target number of participants

330

Key exclusion criteria

- 1. Lack of interest to become employed or to participate in a research trial
- 2. In acute abstinence treatment
- 3. Disability caused by another main condition (e.g., serious mental or somatic illness)
- 4. Acute homelessness
- 5. Engagement in lengthy legal process
- 6. Occupied with suicide plans or having had recent attempts (<3 months)

Date of first enrolment

01/09/2023

Date of final enrolment

31/12/2026

Locations

Countries of recruitment

Sweden

Study participating centre City of Stockholm, Unit of Disability and Mental Health

Heliosgatan 26 Stockholm Sweden 120 78

Study participating centre

County Council of Region Skåne/Municipality Lund/Malmö

Baravägen 1 Lund Sweden 21121

Sponsor information

Organisation

Lund University

Sponsor details

Forum Medicum BMC, Sölvegatan 19 Lund Sweden 22362 +46 (0)462221972 agneta.malmgren_fange@med.lu.se

Sponsor type

University/education

Website

http://www.lunduniversity.lu.se/

ROR

https://ror.org/012a77v79

Funder(s)

Funder type

Research council

Funder Name

Forskningsrådet om Hälsa, Arbetsliv och Välfärd

Alternative Name(s)

Swedish Research Council for Health, Working Life and Welfare, FORTE

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Results and Publications

Publication and dissemination plan

For transparency, the plan is to publish the study protocol in Trials journal in autumn 2023. Further publications will be published in peer-reviewed journals, including one paper on primary

and secondary outcomes, one on health-economy (QUALY), and one that regards the process of implementation and co-production efforts. An interview study on the experience of participating in IPS is also planned.

Intention to publish date

30/06/2027

Individual participant data (IPD) sharing plan

Datasets will not be shared with anyone outside the trial context in accordance with the ethical review and plan.

IPD sharing plan summary

Not expected to be made available

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------|---------|--------------|------------|----------------|-----------------|
| Protocol article | | 27/03/2024 | 28/03/2024 | Yes | No |