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Individual Placement and Support in Sweden—A randomized controlled trial

ULRIKA BEJERHOLM, CECILIA AREBERG, CAISA HOFGREN, MIKAEL SANDLUND, MILES RINALDI

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Background: Currently there is no evidence on the effectiveness of Individual Placement and Support (IPS) in Sweden. *Aims:* To determine the effectiveness of IPS on vocational outcomes among people with severe mental illness (SMI) in a Swedish context. A secondary aim was to evaluate a community integration effect. *Methods:* A randomized controlled trial with a parallel design was used. Mental health outpatients with SMI were randomized to IPS or traditional vocational rehabilitation (TVR) services. The allocation status was assessor-blinded. The primary outcome was competitive employment. All vocational outcomes were collected continuously, and socio-demographic and clinical variables at baseline, 6 and 18 months. The trial is registered with ClinicalTrials.gov: NCT00960024. *Results:* One hundred and twenty participants were randomized. Eighty seven per cent were assessed after 6 months, and 73% after 18 months. IPS was more effective than TVR in terms of gaining employment at 18-month follow-up (46% vs. 11%; difference 36%, 95% CI 18–54), along with the amount of working hours and weeks, longer job tenure periods and income. Cox regression analysis showed that IPS participants gained employment five times quicker than those in TVR. Ninety per cent of the IPS participants became involved in work, internships or education, i.e. activities integrated in mainstream community settings, while 24% in the TVR group achieved this. *Conclusions:* IPS is effective in a Swedish context in terms of gaining employment and becoming integrated within the local community. The welfare system presented obstacles for gaining competitive employment directly and it was indicated that internships delayed time to first competitive employment.

• *Community integration, Severe mental illness, Supported employment, Vocational rehabilitation.*

Ulrika Bejerholm, Medical Faculty, Department of Health Sciences/Work and Mental Health, PO Box 157, SE 221 00 Lund, Sweden, E-mail: ulrika.bejerholm@med.lu.se;
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Work plays a vital role in the recovery of people with mental illness (1, 2). The Individual Placement and Support (IPS) approach is an evidence-based practice (EBP) to support people with their working goal according to their preferences (3–5). IPS may also contribute to community integration and forms a vital part in their recovery (6). Community integration refers to that people with severe mental illness (SMI) are being able to lead their own lives and perform desired activities within community mainstream settings (6). Thus, community integration is about supporting people to move out of their patient role and protective environment towards achieving regular life roles in the community, such as the working role (6, 8).

People with SMI are often both stigmatized and marginalized (9), and society has come to accept a non-working lifestyle in this group of persons (10). It is estimated that only between 10% and 20% of people with SMI in Europe work (11). In Sweden, 70% of people with psychiatric disabilities are unemployed (12), and experience social marginalization to a greater extent compared with other disability groups (13, 14). For people with SMI, only 8% have paid employment (15, 16), and 60% have no structured occupations at all (15). More recent figures from a region close to where the present randomized controlled trial (RCT) departs show a similar rate (8.7%), and nine out of 10 participants were relying on sick leave benefits for their income (16).

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It is recognized that social insurance policies lock people with SMI into benefit dependency (17).

In Sweden, traditional vocational rehabilitation (TVR) services for people with SMI do not provide a route to reaching competitive employment directly (18–20). The reasons identified are poor integration of welfare organizations and a predominant caring culture instead of a recovery-focused culture (17). However, the Swedish National Board of Health and Welfare has published National Guidelines of Psychosocial Interventions for Persons with Schizophrenia in which IPS is recommended as the most effective approach to vocational rehabilitation (21). Mental healthcare and municipality services are currently faced with the challenge of implementing IPS into their everyday practice. To date, it is unknown whether IPS is an effective approach compared with TVR for reaching competitive employment in Sweden or within Scandinavia.

RCTs around the world have repeatedly shown that IPS is more effective than TVR at enabling people with SMI to gain competitive employment (22–25). The overall employment rate in the US trials is higher compared with the overall rate in the rest of the world (62% vs. 47%) (25). In Europe, three RCTs with a study period to at least 18 months have been conducted (4, 26, 27). In the UK, the SWAN trial showed IPS not to be effective when compared with TVR (28). However, a related 24-month follow-up study showed that IPS was more effective (22% vs. 11%) (27). In the EQOLISE trial (4), covering six European countries, IPS was more effective than TVR at 18 months (55% vs. 28%). Nevertheless, implementation research on IPS (29–34) and the EQOLISE trial have shown that labour markets and the national context matter. When IPS is translated into practice, there is a risk that the service is adapted or modified to better fit the local context, which in turn has a negative impact of the quality and delivery of the evidence-based service (34). In a recent Swiss RCT, the eligibility criterion was adapted to fit the conditions outlined by the social insurance system and concerned minimum requirements for entering vocational rehabilitation in general. For instance, the participants were pre-assessed to perform $>50\%$ of general work performance capacity, which left several people who wanted to work unable to access support (26). In contrast, an Australian implementation study showed the welfare system had to be bypassed to be able to deliver IPS with good fidelity (33). Although these modifications are made with good intentions, we believe it is important to understand the effectiveness of IPS and implementing this service according to the evidence-based principles without compromising the zero exclusion criterion to fit the existing welfare systems. Therefore, we do not know what impact the Swedish welfare system, e.g. labour market incentives and internships with generous wage subsidies for the employers in particular, has on the effectiveness of IPS with regard to gaining employment (29).

The aim of this study was to determine the effectiveness of IPS on vocational outcomes among people with SMI in Sweden. It was hypothesized that the participants who received IPS would reach competitive employment at a higher rate (primary outcome) and work more hours, increase their income, have longer job tenure and reach a job sooner compared with those receiving TVR after 18 months. The aim was in addition to evaluate the community integration effect of the IPS. It was hypothesized that IPS participants would perform regular activities or life roles in mainstream community settings to a greater extent.

Materials and methods

Trial design

The present RCT began in 2008 and ended in 2011. It was a pragmatic trial and had a parallel group design. The participants were randomly assigned at the individual level to IPS or TVR. The trial partly originated from the idea about adding Sweden to the list of European countries included in the EQOLISE trial (4). Accordingly, the same IPS specialist as in this mentioned trial was employed, who trained the employment specialist (ES) and supervised the IPS delivery and implementation. The trial is registered with ClinicalTrials.gov with the number NCT00960024 and was approved by the Regional Ethical Review Board at Lund University in Sweden, Dnr 202/2008.

Participants

Participants were recruited from all six mental health teams in a southern Swedish city. Malmoe has 300,000 citizens and more than one in four originate from another country. The teams covered all geographical areas in the city and were specializing in meeting the need of people with SMI. In Sweden, people with affective disorder typically see other mental health teams.

Inclusion and exclusion criteria

Participants needed to have an SMI, which refers to having a psychosis diagnosis or a psychiatric diagnosis where the psychiatric disabilities significantly impact on everyday life functioning on a long-term basis (>2 years) (35). The severity of the disability was assessed by the team psychiatrist. Other criteria were to be in receipt of mental health services, aged between 18 and 63, have the ability to understand and read Swedish, and provide written consent, had not worked in the preceding year, and have a desire to work in the near future. Persons with a somatic comorbidity causing reduced

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work ability were excluded in this study. One person was excluded for this reason, with an upper limb physical impairment.

Interventions

IPS

The experimental intervention was the IPS place-train approach, also known as the evidence-based supported employment. IPS supports individuals whose primary goal is to gain competitive employment to support their recovery (36). The eight principles of IPS are administrated by the key person in IPS, the employment specialist, and are adhered to: competitive employment is the goal, eligibility is based on participant choice and zero exclusion, rapid job search, service and job search are based on person's preferences, integration of employment service with the mental healthcare team, ongoing individualized support, personalized counselling on benefits including social insurance, and systematic recruitment of job opportunities and engagement with employers based on person's preferences. Three employment specialists were recruited. Their caseload for working full-time was 20 participants. The employment specialist qualifications concerned being an occupational therapist, a nurse and a social worker, having had work experience in the mental healthcare within the area of vocational rehabilitation and recovery, and having an outgoing personality. The initial IPS training lasted a week and the specialists were supervised every 2 weeks throughout the trial. The IPS service was integrated with the mental healthcare service sharing the same facilities as the teams. The employment specialists, a steering committee, a process leader and a supervisor together formed the IPS organization. Formal working place meetings were held once a month and committee meetings six times during the trial.

Efforts were made to facilitate the implementation of IPS. Continuous information and discussion meetings were held 8 months before the start and throughout the study together with six mental healthcare teams, both national and private, the Social Insurance Agency (SIA), the Public Employment Service (PES), and FINSAM, a state-funded organization to facilitate co-ordination across the healthcare system, municipality, SIA and PES. Furthermore, workshops were arranged in relation to the IPS fidelity evaluations (37). The fidelity score at 6 months was 110 (good fidelity), at 12 months 115 (excellent fidelity) and at 18 months 117 points (excellent fidelity).

Traditional vocational rehabilitation

In this RCT, the control intervention (TVR) is referred to as the available train-place vocational services located in the four welfare organizations, the healthcare, municipality, SIA and the PES. Typically, these nationally run services provide prevocational training in sheltered settings in a stepwise manner (31, 36, 38). The allocation of participants was dependent on the individuals' care needs and symptom severity, as estimated by professionals in the mental healthcare team. The services ranged from individual rehabilitation support from a team member in the mental healthcare service, most often occupational therapists, municipality-run sheltered or day centres activities and prevocational training, joint cooperation of vocational service in the SIA/PES, and support from either the PES or the SIA. Some participants also enrolled themselves in Fountainhouse (clubhouse) activities. When assessing IPS fidelity, none of the services was identified as delivering IPS. The average scoring was 38 across the TVR, and it ranged from 36 to 48 (not delivering IPS according to the Supported Employment Fidelity Scale (37)).

Outcomes and measures

The primary and vocational outcome was the competitive employment rate. The numbers of hours and weeks worked, job tenure, income and time to first employment were secondary vocational outcomes. The vocational outcomes were collected regularly in logbooks and additionally validated against data collected at the fixed interviews, at 6 and 18 months follow-up. All competitively employed worked for at least 1 week in employment that paid at least minimum wage, available to any citizen and located in mainstream settings. However, in order to reflect the current context and to be able to compare the outcome of the two interventions more fully, internships, mainstream education and prevocational activities were also registered with regard to what extent these activities were located and performed in mainstream community settings, in contrast to sheltered or prevocational settings.

Measures

In addition to the outcomes presented socio-demographic, health-related and clinical characteristics were used to reflect the sample as a whole, but also to detect group similarities or differences in relation to baseline, follow-up and attrition analyses. The measures were:

(1) An interview-based questionnaire that elicited information on age, gender, diagnosis, hospitalization, ethnicity, living situation, vocational status, work history, education level and income was used. The participants' diagnosis was in addition validated against their medical record and categorized according to the diagnosis system ICD-10.
(2) The Manchester Short Assessment of Quality of Life version 2 (MANSA) (39), which is a brief version of the Lancashire Quality of Life Profile (LQOLP) (40). The self-rating scale had 16 questions scoring 1–7. A lower score indicate a lower quality of life.
(3) The Profile of Occupational Engagement in persons with Severe mental illness (POES), an assessor rated

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time-use measure with nine items on a 4-point scale (41–43). A higher score represented a higher level of daily life engagement and functioning. POES significantly correlates to GAF (0.73).

(4) The Brief Psychiatric Rating Scale (BPRS) (44, 45) is an assessor rated instrument of 18 items on a 7-point scale. A lower score represent fewer symptoms.

(5) The Supported Employment Fidelity Scale (SEFS) (37), which had 25 questions and addressed to what extent the service, organization and delivery of IPS were in accordance with the IPS principles. A data-collection period of 1 month preceded each evaluation. The data were collected by research assistants and an independent IPS specialist moderated the scoring.

Sample size, randomization and blinding

A sample size of 120 participants was calculated. The calculation was originally based on differences in employment rate between the intervention groups in three previous RCT studies from the USA (55 vs. 34; 60.8 vs. 9.2; 27 vs. 7) (46–48). The estimation naturally extended to include the European EQOLISE trial (58 vs. 28) once it was published (4). When assuming a significant level $P = 0.05$ (two-sided) at 80% power, the suggested sample size per group were 87, 12 and 52 in the US trials and 42 in the EQOLISE trial (4). Each randomization group was considered large enough if the sample arrived at 60 participants, allowing for an attrition rate of 30% in agreement with the calculated sample size based on the European trial of 42 participants. Of the 141 persons who provided written consents, 21 did not attend the baseline interview, although three appointments were set.

The randomization was done centrally at the Swedish Institute of Health Sciences. The software program in use produced a randomization plan covering a block size of eight random group allocation numbers at a time (49). It was not possible to mask the participants' allocation status for the study participants and the professionals involved after the randomization. The researchers had no previous knowledge of the identity of any participants and coded data. The randomization status was not masked during the statistical analyses.

Procedure

Potential participants were invited to attend an IPS research information meeting, or if they preferred, receive information individually. The meetings occurred regularly and explained the IPS and TVR interventions, the study design and the issue of randomization, and ethical issues of approval. Beforehand, the participants had received an information brochure advertising the IPS trial, which was handed out by the case manager or was found in the waiting rooms. The participants could provide written consent to take part in the study any time after attending a meeting. The recruitment ran from May 2008 until August 2009, and the follow-up ended in March 2011. Each participant was enrolled in the trial for 18 months, and was interviewed at baseline, 6 and 18 months.

Statistics

The Student's *t*-test was used for calculations of differences between follow-up groups on continuous variables that were normally distributed. For non-normally distributed continuous and ordinal variables, the Mann–Whitney *U*-test was applied. The Pearson χ^2 test and Fisher's exact test were used for category variable calculations, when estimating differences between the randomization arms on several socio-demographic and clinical characteristic variables at baseline and attrition analysis, as well as for differences of proportions of vocational data. Not all participants provided data for number of weeks, hours worked and job tenure. In order to obtain conservative estimates, missing data was imputed with zero.

Since the vocational outcomes in each follow-up arm was non-normally distributed, we used a bootstrap methods with 10,000 resample. These calculations made it possible for us to calculate the percentage or mean difference between these groups and 95% confidence intervals (CI), which method was employed in a previous RCT (4). The Kaplan–Meier survival analysis helped us analyse the time to event, i.e. number of days to first employment, in the two groups. In addition, the Cox proportional-hazard regression analysis was used to determine the significant difference between these groups with regard to time to event.

The intent-to-treat (ITT) analyses concerned the primary outcome variable of getting competitive employment or not. Since data could not be collected for those who were lost to follow-up, our imputation strategy concerned performing comparative analysis on the best possible scenario (gained work) and the worst scenario (did not gain work) (52). The significance levels were set at 0.05 and 95% CI.

The community integration variables concerned vocational data, which was categorized as 1) competitive employment, 2) internship, 3) mainstream education, 4) prevocational training, 5) work-related activities in day centres or sheltered settings, or 6) individual rehabilitation support by mental healthcare team. The vocational or education activities 1–3 are located in mainstream community setting, labour market interventions possible for anyone and not segregated from the rest of society, while 4–6 were not.

The statistical calculations were performed with IBM SPSS Statistics 21.0. The bootstrap analyses were done using Matlab 7.11.0 (R2010b).

Results

Attrition

Figure 1 presents the trial profile. The total attrition rate arrived at 28% and is in accordance with the power calculations performed in advance and the attrition rate in

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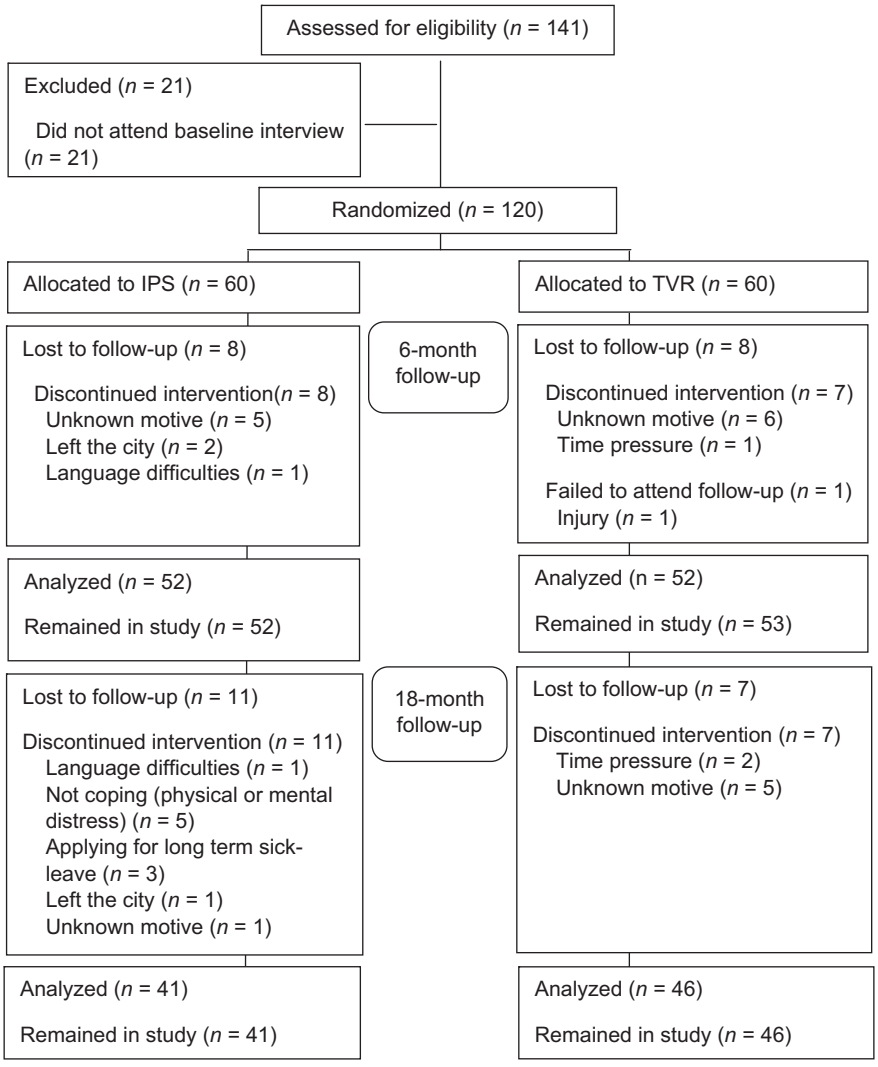

Fig. 1. Trial profile. IPS, Individual Placement and Support; TVR, traditional vocational rehabilitation.

another IPS trial (27). At the 6-month follow-up, no significant differences were found between the participants who stayed ($n = 105$) in the trial and those who left ($n = 15$) with regard to socio-demographic and clinical variables. Within the groups, no differences with regard these variables were detected between the TVR participants who left and those who stayed. However, within the IPS group, we found that non-Swedish born people (immigrants) were more likely to leave the study than those born in Sweden ($P = 0.033$) at 6 months.

At the 18-month follow-up, no differences were found between non-participants and participants for the entire group or within groups.

Socio-demographic and clinical characteristics

Table 1 shows socio-demographic and clinical characteristics at baseline. The statistical comparisons between the IPS and TVR group on these characteristics were equal. Nor did we find significant differences between the two groups at the 18-month follow-up. When calculating for within-group differences between baseline and 18 months for both groups, the TVR participants had increased level of symptoms (BPRS total, $P = 0.003$) and depressive symptoms in particular (BPRS depressive, $P = 0.01$). However, we found no significant change between baseline and 6-month follow-up, which indicates that the symptoms gradually increased over the study period.

Vocational outcomes

At 6 months, no significant differences were found between the groups among the vocational outcomes, although a trend was discerned ($P = 0.066$) concerning competitive employment in favour of the IPS group. Table 2 presents the differences between groups on vocational outcomes at 18 months. IPS was significantly more effective than TVR with regard to gaining competitive

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Table 1. Baseline socio-demographic and clinical characteristics by randomization status* ($n = 120$).

Characteristic	IPS	TVR	Statistical test	p
Age	38 (8)	38 (8)	$t(118) = 0.011$	0.991
Sex			$\chi^2(1) = 3.379$	0.066
Male	28 (47)	39 (65)		
Marital status ($n = 119$)			$\chi^2(1) = 0.192$	0.661
Married/partnership	12 (20)	9 (15)		
Single	48 (80)	50 (85)		
Ethnicity			$\chi^2(1) = 0.580$	0.446
Native	36 (60)	41 (68)		
Immigrant	24 (40)	19 (32)		
Diagnosis ICD-10 ($n = 119$)			$\chi^2(1) = 0.015^{\dagger}$	0.901
Schizophrenia and other psychosis, F20-29	39 (66)	38 (63)		
Bipolar, F31	4 (7)	5 (8)		
Other diagnoses, F32, F40, F60	16 (27)	17 (28)		
Symptoms (BPRS) (range 1–7)				
Positive symptoms	1.34 (0.40)	1.31 (0.38)	$Z = -0.455$	0.649
Negative symptoms	1.34 (0.58)	1.41 (0.69)	$Z = -0.795$	0.427
Depressive symptoms	2.43 (1.06)	2.41 (1.02)	$Z = -0.005$	0.996
General symptoms	1.69 (0.53)	1.54 (0.57)	$Z = -1.788$	0.074
BPRS total	1.44 (0.37)	1.49 (0.34)	$Z = -0.295$	0.768
Years of illness ($n = 117$)	12.6 (9.63)	10.5 (7.37)	$t(115) = 1.344$	0.181
Hospital admissions ($n = 111$)	3.12 (3.7)	4.09 (7.1)	$t(109) = -0.917$	0.361
Income				
Net income (€)	872 (378)	863 (335)	$t(116) = 0.140$	0.889
Work history ($n = 91$)				
Working the last 5 years	26 (56)	25 (56)	$\chi^2(1) = 0.000$	1.000

IPS, Individual Placement and Support; TVR, traditional vocational rehabilitation; BPRS, Brief Psychiatric Rating Scale.
Data in columns are mean (standard deviation) or number of participants (%) if not explained in any other way.
*No statistical differences between groups were found (5% significant level).
†Compared participants with schizophrenia and other psychoses to participants with bipolar and other diagnoses in IPS and TVR.

Table 2. Differences in vocational outcomes between groups at 18-month follow-up ($n = 87$).

	IPS ($n = 41$)	TVR ($n = 46$)	Difference (95% CI)*	Sign.
Competitive employment				
Rate	19 (46)	5 (11)	36 (18–54)	0.000
Weeks	9.3 (17.5)	2.2 (9.2)	7.1 (1.6–13.3)	0.007
Workings hours	196 (384)	19 (82)	176 (66–302)	0.003
Job tenure (weeks)	9.9 (19.3)	2.6 (11.1)	7.3 (0.9–14.0)	0.004
Competitive employment and Internship				
Rate	33 (80)	9 (20)	61 (44–77)	0.000
Weeks	22.4 (20.7)	5.6 (14.8)	16.9 (9.2–24.4)	0.000
Workings hours	443 (453)	74 (211)	369 (223–522)	0.000
Job tenure (weeks)	18.8 (20.58)	4.87 (12.99)	14.1 (7.0–21.5)	0.000
	IPS ($n = 60$)	TVR ($n = 60$)	Difference (95% CI)*	Sign.
Competitive employment				
ITT best	38 (63)	19 (32)	32 (15–48)	0.001
ITT worst	19 (32)	5 (8)	23 (10–37)	0.002

IPS, Individual Placement and Support; TVR, traditional vocational rehabilitation; ITT, intent-to-treat.
Data in columns are mean (standard deviation) or number of participants (%) if not explained in any other way.
*Bootstrapped estimates of percentage or mean difference between groups and 95% CI.

employment, length of job tenure, hours and weeks worked. To reflect the effectiveness of the IPS in a Swedish context, internships were incorporated in the calculations of differences in vocational outcomes between the two arms. The ITT analyses, assuming that the participants who were lost to follow-up either became

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employed (best), or not (worst), showed significant group differences.

The estimated mean for number of days to first employment was lower in the IPS group compared with the TVR group (462.5, 95% CI 406.30–518.78 vs. 541.2, 95% CI 515.57–566.83). According to the Cox regression test, the speed to first employment was five times quicker in the IPS group (5.0, 95% CI 1.8–13.4), and the difference between the two arms was significant ($P = 0.002$). When combining the employment and internship outcomes, the mean for number of days decreased in the IPS group and increased in TVR group (326, 95% CI 266–387 vs. 529, 95% CI 500–559), with a significant group difference ($P = 0.000$). For the IPS group it was more than eight times quicker to reach employment or internship (8.6, 95% CI 4.0–18.9; difference, $P = 0.000$).

At 18-month follow-up, the net income reported in the IPS group ($n = 34$, mean ± standard deviation = €1294 ± 545) and TVR group ($n = 44$, mean = €1004) differed significantly ($P = 0.01$, 95% CI 82–475).

Community integration

Figure 2 illustrates the proportion in vocational status in the two groups at 18 months. Besides reaching competitive employment the IPS group became more involved in activities integrated in mainstream community settings. In the IPS group, 90% ($n = 37$) worked, had an internship or studied in comparison with 24% ($n = 12$) of the TVR group. The majority of the TVR participants remained in prevocational and segregated settings (difference 66%, 95% CI 50–80, $P = 0.000$).

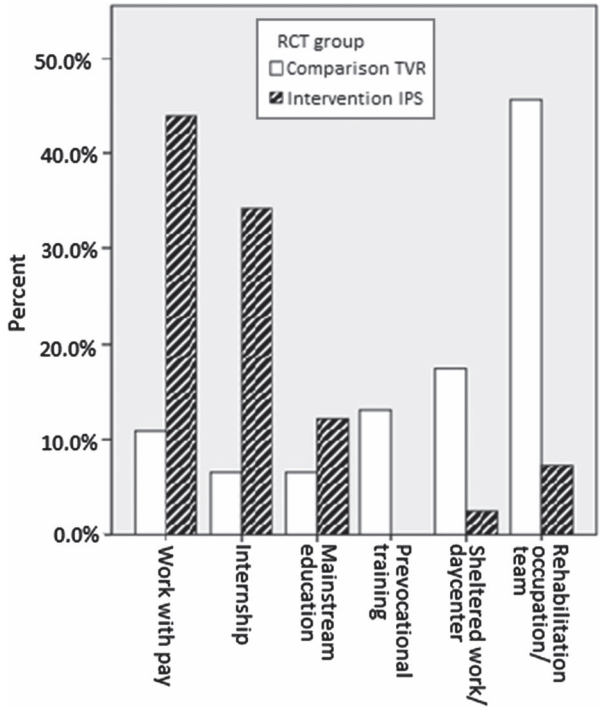

Fig. 2. The distribution of participants' vocational status at 18-month follow-up. RCT, randomized controlled trial; IPS, Individual Placement and Support; TVR, traditional vocational rehabilitation.

Conclusions

The present study was the first RCT in Sweden and within Scandinavia that aimed to determine the effectiveness of IPS compared with traditional vocational services (TVR). IPS was more effective in terms of gaining competitive employment (46% vs. 11%), amount of working hours and weeks, length of job tenure, income and rapidity to gaining competitive employment. The difference between the groups regarding competitive employment was 36%. This proportion is larger than that in the EQOLISE trial (26.9%) (4). The results, however, reflect difficulties for the IPS participants of achieving competitive employment due to a strict internship culture promoted by the Swedish welfare system. Thus, although the employment rate of the IPS group showed to be high at the end, the job tenure average was 9.9 weeks, which is not equivalent to that of other RCT trials (24.2 weeks) (24, 26). However, when internships were incorporated in the calculations, as being an alternative to working in Sweden, job tenure increased to 18.8 weeks on average, compared with 4.8 weeks in the TVR group. The same trend in results was shown with regard to time to first employment versus time to first employment/internship. These context-related findings could in part be explained by the result in an implementation study, which was performed alongside the present RCT (29). That study showed that welfare benefits could be withdrawn if the IPS participants did not pass through the obligatory route in the welfare system, where they had to submit to work capacity evaluations of being able to work ≥ 20 h a week and assessed against the entire working market and not in relation to the work actualized through IPS. Moreover, as competitive work was not the first goal in this aforementioned mandatory route, but internship was, many participants had to adapt to these regulations. However, although internships are very much a secondary issue in relation to our primary outcome, the data has helped to explain that the Swedish welfare context challenges the IPS principles of 'competitive employment is the goal' and 'rapid and direct job search'. As a consequence, time was added to IPS and the job seeking process. From an IPS perspective, we believe that internships is more of a barrier when it comes to securing employment for people with SMI. Nevertheless, we found that IPS was more effective than TVR in Sweden, in any of the variables set out, despite the Swedish welfare context and the economic recession that occurred during the study, with five successive quarters of negative economic growth, between

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2008 and 2010 (51). In fact, the competitive employment rate in our trial (46%) was equivalent to the overall rate in trials in non-US countries (47%), as shown in a recent review (25).

Community integration was not the primary outcome in this study. The results, however, showed that 76% of the TVR participants, whose intervention was aligned with the Swedish welfare system, stayed in prevocational, sheltered or segregated settings. This result indicates that persons with SMI in Sweden are unnecessarily segregated from the rest of society, and IPS participation as a whole can provide a means for gaining competitive employment along with becoming integrated in the community and promoting recovery, in line with previous research (6, 52). However, the construct of community integration is complex and multidimensional (53). In the present study, community integration was estimated in an objective manner, whether the participants performed a worker or a student role in community mainstream settings or not, and not in relation to the participants' experiences. In a related RCT that was performed with the same sample, it was shown that the IPS participants increased their engagement in meaningful social activities and time spent in various mainstream community settings, while the TVR participants did not (52).

Study limitations and strengths

When discussing the issue of external validity, the results showed that the Swedish context and welfare system impacted on the effectiveness of IPS in terms of gaining competitive employment, which was also shown in other European countries (4). The wide inclusion criteria can help to explain the fairly high attrition rate at 28%, which in turn may have impacted to trial quality. However, the proportion was expected and in line with the initial sample size calculation and in accordance with the estimated rate of 30% in the SWAN trial (27, 28), which can be considered a strength. Furthermore, the trial was powerful enough to detect differences between the intervention groups.

The only statistical significant difference between those who left and those who remained at 6 months was a higher proportion of non-Swedish born people left the IPS group. It is possible that persons with a non-native ethnic background experience stigma on three levels: with regard to having language difficulties; cultural/religious/ethnic background; and having a mental health condition. It is thus important that the employment specialists are sensitive to these needs and support the participants accordingly.

Although efforts were made to keep attrition to a minimum, such as having research assistants reminding the participants about follow-up interviews and minimizing time between randomization and intervention start, it was not possible to collect valid outcome data of those who were lost to follow-up, which may have limited the experimental validity of the study. The ITT analyses of the worst and best scenario made it possible to consider the possible effects on the results of those who withdrew, in addition to the quantitative attrition analysis. Nevertheless, descriptive analysis showed, for example, that three participants left the IPS group because they risked losing their welfare benefits if they continued with IPS and did not agree to terms set up by the SIA. Such circumstances were not reported among the TVR participants whose rehabilitation was aligned with the welfare system. Thus, for future implementation of IPS in Sweden, it is of great importance on a national level and local level to consider the welfare services regulations that will restrict effectiveness of IPS (29).

In contrast to the IPS intervention provided, it was not possible to achieve full transparency of the control intervention. The control interventions concerned different steps of prevocational and traditional rehabilitation and the actual service delivery may have varied, with regard to both the extent and the quality. However, it was possible to perform IPS fidelity assessment and none of these services was delivering IPS. To note, however, the occupational therapists performing the rehabilitation support at the mental healthcare team were assessed as having the highest fidelity score in the control intervention, since their focus in rehabilitation was individualized.

Adverse events were not registered in a systematic way during the trial, which is a limitation. However, no changes in hospitalization, medication or type of contact with mental health professionals were recorded in the questionnaire on socio-demographic characteristics at the baseline interview in comparison to follow-ups.

To conclude, this Swedish RCT showed that IPS was far more effective in terms of gaining competitive employment more rapidly, working more hours and weeks, having longer job tenure and in increasing income compared with TVR. The IPS participants became involved in activities integrated in community and mainstream settings (90%) compared with the TVR participants (24%) who performed activities in prevocational and sheltered settings (66% difference). The TVR, which is aligned with the welfare and benefit system, presented obstacles for gaining competitive employment and being integrated in the community. In light of the Swedish welfare context, the present results may not generalize to all Scandinavian countries with different welfare system and national labour market regulations. Moreover, the study was limited by size and attrition and should be replicated in further RCTs.

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Ulrika Bejerholm, Ph.D., Associate Professor, Department of Health Sciences/Work and Mental Health, Medical Faculty, Lund University, Sweden.
Cecilia Areberg, Ph.D., Department of Health Sciences/Work and Mental Health, Medical Faculty, Lund University, Sweden.
Caisa Hofgren, Ph.D., Department of Neuroscience and Physiology, Gothenburg University, Gothenburg, Sweden.
Mikael Sandlund, Ph.D., Professor, Department of Clinical Science/Psychiatry, Umeå University, Umeå, Sweden.
Rinaldi, Miles, South West London and St George's Mental Health NHS, London, UK.

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