

Effects of Individual Placement and Support Supplemented With Cognitive Remediation and Work-Focused Social Skills Training for People With Severe Mental Illness

A Randomized Clinical Trial

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IMPORTANCE Individual placement and support (IPS) seems to be an effective vocational intervention for people with severe mental illness, but its effects have not yet been shown in the Danish welfare model. Also, effects may be enhanced by adding cognitive remediation and work-focused social skills training (IPS with enhancements [IPSE]).

OBJECTIVES To investigate the effects of IPS vs IPSE vs service as usual (SAU) on a population of individuals with severe mental illness in Denmark.

DESIGN, SETTING, AND PARTICIPANTS This was an investigator-initiated, 3-group, parallel, assessor-blinded randomized clinical trial that used early-intervention teams or community mental health services in 3 Danish cities to recruit participants with severe mental illness. Participants were randomly assigned to receive IPS, IPSE, or SAU from November 2012 to February 2016, and follow-up continued until August 2017.

INTERVENTIONS Participants allocated to the IPS intervention received vocational support per the principles of the IPS model. Participants in the IPSE arm received cognitive remediation and social skills training in addition to IPS. The group receiving SAU received vocational rehabilitation at the Danish job centers.

MAIN OUTCOMES AND MEASURES The primary outcome was the number of hours in competitive employment or education during the 18-month follow-up. Secondary outcomes included intergroup differences in employment or education at any point during follow-up; time to employment or education; and cognitive and social functioning, self-esteem, and self-efficacy.

RESULTS Of the 720 included participants (mean [SD] age, 32.8 [9.9] years; 276 [38.3%] women), 243 received IPS, 238 received IPSE, and 239 received SAU. Most participants (551 [76.5%]) were diagnosed with a schizophrenia spectrum disorder. During the 18-month follow-up, the IPSE group worked or studied a mean (SD) of 488.1 (735.6) hours, compared with 340.8 (573.8) hours in the group receiving SAU (success-rate difference [SRD], 0.151 [95% CI, 0.01-0.295]; $P = .016$). The mean (SD) in the IPS group was 411 (656.9) (SRD, 0.127 [95% CI, -0.017 to 0.276]; $P = .004$). There was no difference between IPS and IPSE in any vocational outcomes, and the 3 groups showed no differences in any nonvocational outcomes, except that the IPS and IPSE groups were more satisfied with the services received than the group receiving SAU (IPS vs SAU: SRD, 0.310 [95% CI, 0.167-0.445]); IPSE vs SAU: SRD, 0.341 [95% CI, 0.187-0.478]).

CONCLUSIONS AND RELEVANCE Compared with SAU, IPS and IPSE seem to be viable routes to increase employment and education rates in people with severe mental illness in Denmark, but no additional effects were observed by enhancing IPS.

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Employment and education are central to the recovery process for people with severe mental illness (SMI).¹ Apart from providing financial independence and security, employment contributes to a sense of belonging and identity and can benefit mental well-being.² Nevertheless, unemployment is high among people with SMI,^{3,4} leading to substantial costs for both the individual and society.⁵

In response to these problems, a method of vocational rehabilitation called individual placement and support (IPS) has been developed.⁶ In contrast with traditional approaches to vocational rehabilitation, IPS avoids prolonged prevocational training and provides a rapid, individualized search for competitive employment or education. Participants' preferences regarding jobs are emphasized, and the intervention is integrated within the mental health services. Additionally, job support is ongoing, and benefit counseling is provided.⁶

Although education is the primary goal for many people with SMI, especially young patients with a recent onset of the illness,⁷ most previous IPS trials have mainly focused on supporting participants to obtain competitive employment. This is despite the fact that supported education is described in the updated and expanded IPS manual,⁸ and it has been demonstrated that the IPS principles can be successfully extended to include support for education.^{7,9}

Based on positive findings from numerous randomized clinical trials, IPS seems an effective intervention in obtaining competitive employment compared with other types of vocational rehabilitation programs.¹⁰ However, about 40% of participants do not achieve their vocational goals, and many participants in IPS only work part time or lose their jobs because of poor work performance.¹¹ This may be attributable to cognitive impairments and low social functioning, which are defined as some of the strongest illness-related factors associated with unemployment among people with SMI.^{12,13} In accordance, research suggest that IPS enhanced with either cognitive remediation or work-associated social skills training (IPSE) may improve the positive outcomes of IPS.^{14,15}

The questions are whether the effects of enhancing the intervention can be replicated and whether the same effects of IPS can be achieved when education is included in the primary outcome and when conducted in a highly specialized labor market with a high minimum wage and a relatively generous social-security system. On this background, we conducted a 3-group randomized clinical trial in Denmark with the primary aim of investigating the difference in number of hours in competitive employment or education.

Methods

Trial Design

The trial was designed as an investigator-initiated, 3-group, parallel, multisite randomized clinical trial with blinded outcome assessment. The trial protocol was reviewed and approved by the ethics committee in the Capital Region of Denmark and the Danish Data Protection Agency. The only deviations from the trial protocol¹⁶ were inclusion of an additional site (Silkeborg) and the division of the Copenhagen team

Key Points

Question What are the effects of individual placement and support vs individual placement and support enhanced with cognitive remediation and social skills training vs service as usual for people with severe mental illness in Denmark?

Findings In this randomized clinical trial of 720 adults with severe mental illness, the proportion achieving competitive employment or education was 59.9% in individual placement and support, 59.1% in those receiving individual placement and support with enhancements, and 46.5% in those receiving service as usual.

Meaning Individual placement and support and individual placement and support with enhancements are viable routes to increase employment and education among people with severe mental illness in a Danish context, but no additional effect was found by enhancing individual placement and support with cognitive remediation and work-focused social skills training.

into 2 independent teams. Informed consent was obtained from each participant before assessments began.

Eligibility Criteria

Participants were eligible if they had a diagnosis of schizophrenia, schizotypal disorder, delusional disorder (defined by *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision [ICD-10]* codes F20-F29); bipolar disorder (*ICD-10* code F31); or recurrent depression (*ICD-10* code F33). All participants were adults (aged 18-64 years) living in 1 of 3 Danish cities: Copenhagen (including the municipality of Frederiksberg), Odense, or Silkeborg. All were assigned to early-intervention teams or community mental health services. All eligible participants expressed a clear desire in competitive employment or education and spoke and understood Danish sufficiently well to participate without an interpreter.

Recruitment

The participants were recruited by the case managers on the psychiatric outpatient teams or self-selected after encountering advertisements and information available at the psychiatric centers. To ensure participants met the diagnostic criteria, they were assessed by a trained and certified researcher (T.N.C., I.G.W., or a nonauthor) using the diagnostic interview Schedules for Clinical Assessment in Neuropsychiatry.

Randomization and Blinding

Recruited participants were randomized with a 1:1:1 ratio to IPS, IPSE, or service as usual (SAU). The sample was stratified by sex, work history (absence or presence of ≥ 2 months' competitive employment during the previous 5 years), work readiness,¹⁷ and site (Copenhagen/Frederiksberg or Odense/Silkeborg). The Copenhagen Trial Unit conducted a central, computer-generated random allocation sequence with varying block sizes of 6 and 9.¹⁸ The allocation sequence and block sizes were concealed from the investigators. Outcome assessors (T.N.C., I.G.W., or a nonauthor) and all investigators involved in the trial (T.N.C., I.G.W., E.S., A.B.B., C.G., M.N., and

L.F.E.) were blinded to participants' allocation, but participants and employment specialists were not. The randomization code was not broken before all analyses had been performed and conclusions had been drawn.¹⁹

Interventions

All participants in the 3 groups continued to receive their usual psychiatric outpatient treatment, which consisted of at least individual case management based on cognitive therapeutic methods and medical review.²⁰ The content of the 3 vocational intervention groups is briefly outlined but more thoroughly described in the trial protocol (Supplement 1) and in eMethods 1 in Supplement 2.¹⁶ Participants allocated to the IPS group received vocational support per the principles of the IPS model. In addition to IPS, the IPSE group received cognitive computer training using the software program Computerized Interactive Remediation of Cognition—a Training for Schizophrenia (CIRCUITS), Danish version²¹ and training in cognitive coping and compensatory strategies using an adapted version of the *Thinking Skills for Work* manual.¹⁴ The SAU group received the best available vocational rehabilitation provided by the national job centers.

Fidelity With IPS and IPSE

To ensure the quality and adherence to the IPS service, fidelity ratings were conducted by trained and external reviewers, who did not conduct baseline or follow-up interviews, using the Individual Placement and Support Fidelity Scale (IPS-25).²² The evaluation took place 6 months after trial commencement, and subsequently an additional 6 ratings were performed. In addition, a fidelity scale was developed for the enhancement program, aimed at measuring the core elements of the intervention, as described in the manual. For quality improvement purposes, the assessors conducted a fidelity report after each review, summarizing ratings and providing recommendations for improvement.

Outcomes

Data were obtained through multiple sources at baseline and during the 18-month follow-up: researcher-administered semi-structured interviews, self-reported questionnaires, and register-based data. The data were collected over 4.8 years (November 2012 to August 2017) by blinded researchers who were trained and certified in all instruments used. Interrater reliability is described in eMethods 3 in Supplement 2. All outcome measures reported were prespecified and reported in the study protocol.¹⁶

Primary Outcome

The primary outcome was number of hours in competitive employment or education during the 18 months' follow-up.¹⁶ Employment outcomes were extracted from the Danish Register for Evaluation of Marginalization (DREAM) database extended with data from the Danish national income register with 100% response.²³⁻²⁵ The registers cover the entire population and contain data on employment, including salaries. Educational outcomes were reported by the participants at the 18-month follow-up interview to elicit the most detailed infor-

mation on part-time studies and ascertain the exact number of study hours. The study time was measured only if the participant studied actively. All secondary and exploratory outcomes are described in the trial protocol (Supplement 1) and eMethods 2 and eMethods 4 of Supplement 2.

Statistical Analysis

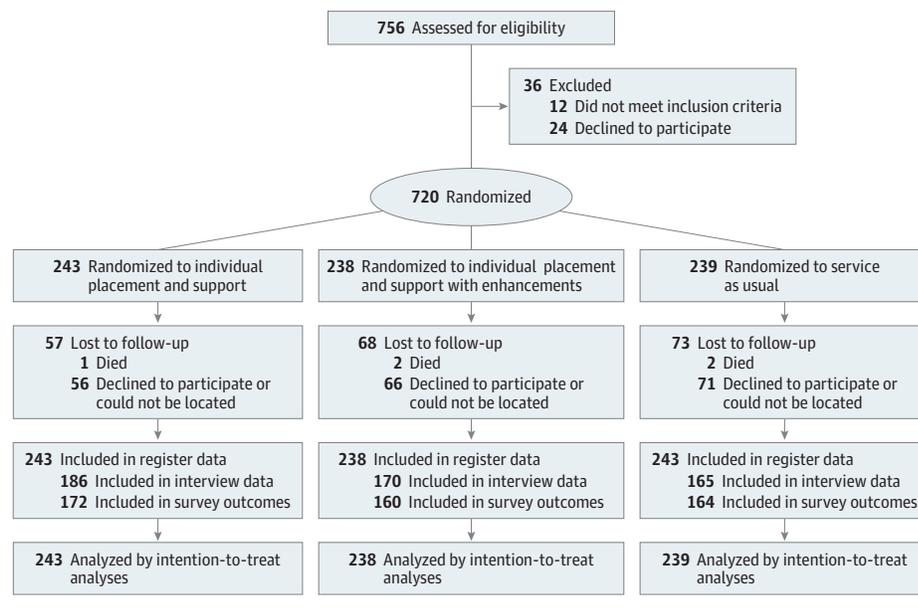
Because we did not fully reach our planned sample size of 750, but rather only 720 participants (96.0%), we used as planned only 3 primary comparisons, with a type I error probability of 1.67%.¹⁶ We hypothesized an effect size of 0.3 standardized mean differences for the primary outcome of hours in competitive employment or education, corresponding to an absolute difference between groups of 150 hours and an SD of 500 hours. This was informed by a previous European trial of IPS.²⁶ Three balanced groups with 236 patients in each group (N = 708) were required to achieve a statistical power of 80%. A priori power analysis was carried out on all secondary outcomes.¹⁶

The outcome analysis was based on the intention-to-treat principles, and to compensate for missing data, we used multiple imputations. Complete baseline data and register-based outcome data were used for the imputation model. Baseline characteristics are reported using means and SDs for numeric variables and numbers with percentages for categorical variables. The primary analyses for differences between groups at follow-up were carried out without adjusting for stratification variables. The reason for this was that the assumptions for including covariates in the analyses may have been violated, which would bias the estimation of the treatment effect sizes.²⁷ Supplementary analyses that reflect the original analysis plan are available in eTable 1 and eTable 2 in Supplement 2. The results are substantially the same regardless of the analytical strategy. Main estimates are presented in the form of success-rate differences (SRDs)²⁸ with bootstrapped inferential statistics. For binary outcomes, the SRD is simply the difference between the proportion of patients who received successful treatment in the 2 groups. For numerical outcomes, the SRD is derived from the Wilcoxon *U* statistic:

$$SRD = \frac{2U}{(N_0 \times N_1) - 1}$$

where *U* is the Wilcoxon *U* statistic and *N*₀ and *N*₁ are the sample sizes for the 2 groups. For numerical outcomes, this amounts to the difference in the probability of a random patient in the intervention group scoring higher (having a better outcome) than a random patient in the comparison group and the probability of a random patient in the comparison group scoring higher than a random patient in the intervention group. Therefore, scores greater than 0 imply a higher numerical value for the intervention group vs the comparison group, while scores less than 0 indicate a higher numerical value in the comparison group. The number of days to employment, education, or noncompetitive employment was analyzed using Cox proportional hazards regression and reported using hazard ratios. Parameter estimates and 95% CIs are based on observed data with no imputations. Data were analyzed from December 2017 to

Figure. Study Flowchart



June 2019 with Stata version 14 (StataCorp) and R version 3.6.0 (R Foundation for Statistical Computing). All *P* values less than .017 (.05 divided by 3, to accommodate the study's 3 comparisons) were considered significant.

Results

The Figure illustrates the patient flow through the trial and the attrition from it. After exclusion of those not meeting inclusion criteria and those who declined to participate, 720 participants were randomly assigned into the 3 groups: IPS (*n* = 243), IPSE (*n* = 238), and SAU (*n* = 239).

Table 1 shows the baseline sociodemographic and clinical characteristics of the participants. The mean (SD) age was 33.0 (9.9) years, and we included more men (444 [61.6%]) than women. Most participants (551 [76.5%]) were diagnosed with a schizophrenia spectrum disorder, and 279 (38.8%) had a primary or lower secondary education. Further, the participants' global level of cognitive functioning, measured on the Brief Assessment of Cognition in Schizophrenia scale, was a mean (SD) *z* score of 2.70 (1.7) lower than the reference healthy population. The follow-up proportion was 72.5% for the sample as a whole (*n* = 522). However, there was 100% follow-up for all register-based measures, including all employment outcomes.

All IPS teams maintained good or fair levels of IPS fidelity throughout the trial. The scores ranged from 75 to 101 as measured on the IPS-25 scale. All sites demonstrated good fidelity to the IPSE manual, with scores between 21 to 29 points on the 30-point scale. However, 57 of 238 participants (23.9%) in the IPSE group did not attend the sessions with cognitive remediation, and the mean (SD) number of cognitive training sessions attended was 9.6 (9.7) of 30 sessions.

The comparison of IPSE vs SAU groups showed a mean difference of 147.3 (SE, 70.8) hours in competitive employment and education favoring IPSE. The corresponding SRD was 0.151 (95% CI, 0.01-0.295; *P* = .016). The mean difference between IPS vs SAU was 70.0 (SE, 66.4) hours, with an SRD of 0.127 (95% CI, -0.017 to 0.276; *P* = .004).

In an explorative analysis, we combined IPS and IPSE vs SAU. The SRD for working or studying more hours in the 2 IPS groups, compared with SAU, was 0.138 (95% CI, 0.009-0.263; *P* = .002). There was no significant difference between the outcomes of the IPS and IPSE groups in any of the vocational outcomes (Tables 2, 3, and 4).

All secondary and exploratory outcomes are shown in Tables 2, 3, and 4. Because of multiple testing and occasional lack of power, these analyses should be interpreted with caution. Over the 18-month follow-up period, participants in the IPS group were more likely than those in the SAU group to work competitively or be enrolled in education (112 [59.9%] vs 79 [46.5%]; SRD, 0.134 [95% CI, 0.009-0.257]; *P* = .002). The difference between IPSE and SAU was 101 (59.1%) vs 79 (46.5%) (SRD, 0.126 [95% CI, 0.003-0.256]; *P* = .03). When the IPS and IPSE groups were combined and compared with SAU, the SRD was 0.130 (95% CI, 0.025-0.239; *P* = .002).

The participants in the IPS and IPSE groups also obtained employment or education more rapidly than did the SAU group. It took the IPS group 286 (SE, 72.6) days and the IPSE group 346 (SE, 85.8) days vs the SAU group's 548 (SE, 61.7) days before 46.5% of each group's participants were employed or actively attending educational programs. Cox regression found a significant difference between IPS vs SAU (hazard ratio, 1.57 [95% CI, 1.14-2.18]; *P* = .006) and between IPSE vs SAU (hazard ratio, 1.54 [95% CI, 1.10-2.16]; *P* = .01) (Table 4). Kaplan-Meier curves are shown in eFigure in Supplement 2.

Table 1. Baseline Characteristics of 720 Participants in the Trial Randomized to Individual Placement and Support vs Individual Placement and Support Enhanced With Cognitive Remediation and Work-Focused Social Skills Training and Service as Usual

Characteristic	Participants, No. (%)		
	Individual Placement and Support (n = 243)	Individual Placement and Support With Enhancements ^a (n = 238)	Service as Usual (n = 239)
Sex			
Female	94 (38.7)	87 (36.6)	95 (39.8)
Male	149 (61.3)	151 (63.5)	144 (60.3)
Age, mean (SD), y	33.3 (10.3)	33.0 (9.5)	32.8 (9.9)
Previous work history^b			
No	125 (51.4)	117 (49.2)	123 (51.5)
Yes	118 (48.6)	121 (50.8)	116 (48.5)
Education			
Master or equivalent	13 (5.4)	14 (5.9)	21 (8.8)
Bachelor or equivalent	28 (11.5)	22 (9.2)	28 (11.7)
Short-term tertiary education	43 (17.7)	53 (22.3)	44 (18.4)
Upper secondary education	61 (25.1)	57 (24.0)	57 (23.9)
Primary secondary education or lower (9 y of school or less)	98 (40.3)	92 (38.7)	89 (37.2)
Married or cohabiting			
No	197 (81.1)	194 (81.5)	187 (78.2)
Yes	46 (18.9)	44 (18.5)	52 (21.8)
Site			
Copenhagen, Frederiksberg	174 (71.6)	165 (69.3)	169 (70.7)
Odense, Silkeborg	69 (28.4)	73 (30.7)	70 (29.3)
Diagnoses			
Schizophrenia spectrum disorders ^c	184 (75.7)	181 (76.1)	186 (77.8)
Bipolar disorder ^d	32 (13.2)	30 (12.6)	25 (10.5)
Recurrent depression ^e	27 (11.1)	27 (11.3)	28 (11.7)
Match group^f			
2	191 (78.6)	186 (78.2)	190 (79.5)
3	52 (21.4)	52 (21.9)	49 (20.5)
Psychiatric scale scores, mean (SD)			
Personal and Social Performance Scale score	47.3 (10.8)	47.2 (10.8)	47.0 (10.0)
Psychotic symptoms per SAPS	1.2 (1.3)	1.2 (1.3)	1.2 (1.3)
Negative symptoms per SANS	1.9 (0.8)	1.9 (0.8)	2.0 (0.8)
Disorganized symptoms per SAPS or SANS	0.3 (0.5)	0.3 (0.5)	0.3 (0.5)
Brief Assessment of Cognition in Schizophrenia Global	-2.6 (1.61)	-2.8 (1.9)	-2.7 (1.8)
Hamilton score	6.0 (4.2)	6.4 (4.2)	6.8 (4.1)
Self-efficacy	14.1 (6.3)	14.3 (6.1)	13.1 (6.4)
Rosenberg Self-esteem Scale score	15.6 (6.1)	15.6 (5.7)	16.0 (5.9)
SF-12 Total score	83.4 (7.9)	82.0 (7.9)	81.5 (7.8)

Abbreviations: SANS, Scale for the Assessment of Negative Symptoms; SAPS, Scale for the Assessment of Positive Symptoms; SF-12, 12-Item Short-Form Health Survey.

^a Individual placement and support enhanced with cognitive remediation and work-focused social skills training.

^b Previous work history was defined as 2 or more months of paid work in the last 5 years.

^c Defined by *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10)* codes F20 through F29.

^d Defined by *ICD-10* codes F31.0 through F31.9.

^e Defined by *ICD-10* codes F33.0 through F33.9.

^f Danish legislation operates with 3 different match groups; match group 2 was assessed as being ready to participate in a vocational rehabilitation program but not able to be self-sufficient within 3 months and match group 3 was assessed as having severe, long-term problems and being unable to work or participate in prevocational training.

Consistent with most published trials, the association of IPS with outcomes on nonvocational measures appeared to be negligible (Tables 2 and 3), which also indicates that there were no adverse effects of the intervention. Nevertheless, we found significantly higher satisfaction with the vocational rehabilitation in the 2 experimental groups compared with SAU (IPS vs SAU: SRD, 0.310 [95% CI, 0.167-0.445]; $P < .001$ and IPSE vs SAU: SRD, 0.341 [95% CI, 0.187-0.478]; $P < .001$).

Discussion

Individuals with severe mental illness who participated in IPS or IPSE obtained higher employment and study rates or had more hours in employment and education than did participants in a conventional Danish vocational rehabilitation program (SAU). The participants in the IPS and IPSE groups also obtained employment or education faster and were more sat-

Table 2. Comparison of Effect on Primary and Secondary Outcomes After 18 Months' Follow-up for 720 Patients With Severe Mental Illness Randomized to the 3 Study Groups^a

Primary and Secondary Outcomes	Mean (SD)			Success-Rate Difference (95% CI)		
	Individual Placement and Support	Individual Placement and Support With Enhancements ^b	Service as Usual	Individual Placement and Support vs Service as Usual	Individual Placement and Support With Enhancements vs Service as Usual	Individual Placement and Support With Enhancements
Time spent in employment and education, h	411.0 (656.9)	488.1 (735.6)	340.8 (573.8)	0.127 (-0.017 to 0.276)	0.151 (0.01-0.295)	-0.034 (-0.178 to 0.109)
Number needed to treat, No.	NA	NA	NA	7.9	6.6	-29.4
P value, unadjusted/adjusted with multiple imputations ^c	NA	NA	NA	.03/.004	.01/.016	.57/.35
Employment or education at some point, No. (%)	112 (59.9)	101 (59.1)	79 (46.5)	0.134 (0.009-0.257)	0.126 (0.003-0.256)	0.008 (-0.119 to 0.131)
Brief Assessment of Cognition in Schizophrenia score	-2.2 (1.8)	-2.2 (1.7)	-2.1 (1.9)	-0.044 (-0.195 to 0.102)	-0.028 (-0.175 to 0.124)	-0.015 (-0.165 to 0.127)
Personal and Social Performance Scale score	49.8 (14.1)	52.1 (14.5)	49.9 (12.9)	-0.005 (-0.152 to 0.141)	0.085 (-0.059 to 0.234)	-0.085 (-0.225 to 0.059)
General Self-efficacy Scale score	16.4 (6.1)	16.3 (6.3)	15.9 (6.7)	0.031 (-0.118 to 0.177)	0.009 (-0.144 to 0.161)	0.018 (-0.131 to 0.175)
Rosenberg Self-esteem Scale score	14.1 (5.8)	13.5 (5.8)	14.5 (6.0)	-0.022 (-0.163 to 0.131)	-0.082 (-0.233 to 0.063)	0.061 (-0.085 to 0.208)

Abbreviation: NA, not applicable.

^a All analyses are unadjusted. Analyses adjusted for stratification variables are presented in eTable 1 in Supplement 2.

^b Individual placement and support enhanced with cognitive remediation and work-focused social skills training.

^c Multiple-imputations P values are derived from multiple imputation using 250 imputations and 5 iterations per imputation.

ified with the support they received compared with those receiving SAU, but there was no significant difference between IPS and IPSE in any of the vocational outcomes.

With regard to the primary outcome (the number of hours in competitive employment or education), we hypothesized a clinically relevant mean difference of 150 hours between the groups when conducting the sample-size calculation. This was achieved in the comparison between IPSE and SAU, but this was not the case between IPS and SAU, between which a difference of 70 hours was detected. Nonetheless, when we also consider the 13% difference in study and employment rates, the difference in days to employment and education and the difference in satisfaction with the intervention between the IPS and IPSE groups and those receiving SAU, these effects are assessed as both substantial and clinically relevant. Since the SAU group also received a costly and substantial amount of vocational rehabilitation, we believe that these results are relevant to warrant its extra cost and time as well.

The control (SAU) group performed better than expected, including better than most previous IPS trials from countries with a comparable labor market and labor policy. In a Swedish randomized trial on IPS, 46% of participants in the IPS group obtained employment, compared with 11% in the SAU group.²⁹ In the present trial, 38% in the IPS group and 28% in the SAU group obtained competitive employment. When education was included, the figures were 60% vs 47%. Thus, the vocational outcomes in the SAU group in the present trial almost reached benchmarks established for high-fidelity IPS programs. However, it is worth noting that the control group was significantly less satisfied with the support they received than the 2 experimental groups. We believe that the strong focus on the individual's own preferences for work or education is an es-

sential factor behind this difference, which has also been suggested by previous research.^{1,30}

This trial differed from most previous IPS trials in focusing on both employment and education, making it difficult to make comparisons with previous international IPS trials. However, a recent meta-analysis demonstrated a pooled risk ratio of 2.40 (95% CI, 1.99-2.90) for competitive employment when IPS was compared with traditional vocational rehabilitation.¹⁰ In the present trial, we also demonstrated a difference between IPS and SAU in the measure of employment or education at some point, but when we analyzed employment alone, the significant effect disappeared. The main reason for this could be a statistical power issue, because approximately half of the participants had education, rather than employment, as their goal at baseline.

Previous research has suggested that generous welfare systems, such as the Danish system, lead to lack of financial incentives, resulting in a low level of motivation for employment among the participants.²⁶ Nevertheless, even though many participants had a relatively small financial gain from working, we succeeded with the recruitment. In a qualitative study, the participants underlined that the key motivation for participating in the trial was to be able to contribute to and have a role in society.¹

Consistent with earlier IPS research findings, we found no difference between the groups on nonvocational outcomes. However, a difference between groups in cognitive functioning was expected. A small improvement was found in all groups from baseline to the 18-month follow-up, but unexpectedly, no differences were found between the IPSE group and the IPS group or the SAU group at follow-up. Previous research¹⁴ has found a higher overall composite cognitive score after interventions and follow-up assessment

Table 3. Comparison of Effect on Exploratory Outcomes After 18 Months' Follow-up for 720 Patients With Severe Mental Illness Randomized to the 3 Study Groups

Exploratory Outcomes	Mean (SD)			Success-Rate Difference (95% CI)		
	Individual Placement and Support	Individual Placement and Support With Enhancements ^a	Service as Usual	Individual Placement and Support vs Service as Usual	Individual Placement and Support With Enhancements vs Service as Usual	Individual Placement and Support vs Individual Placement and Support With Enhancements
Labor-force engagement, mean (SD), h						
Employment	189.8 (450.9)	170.0 (400.6)	142.7 (360.6)	0.097 (-0.004 to 0.2)	0.06 (-0.035 to 0.159)	0.035 (-0.08 to 0.139)
Education	221.3 (481.3)	286.3 (538.4)	181.6 (476.2)	0.093 (-0.03 to 0.208)	0.132 (0.007-0.25)	-0.047 (-0.164 to 0.079)
Noncompetitive employment	134.0 (255.7)	97.8 (203.9)	178.2 (334.6)	-0.063 (-0.201 to 0.073)	-0.148 (-0.28 to -0.009)	0.083 (-0.053 to 0.219)
Total earnings, mean (SD), Danish kroner [\$]	29 230 (71 075) [4388.13 (10 670.07)]	25 283 (61 809) [3795.59 (9279.02)]	24 694 (65 527) [3707.17 (9837.18)]	0.093 (-0.011 to 0.195)	0.057 (-0.048 to 0.16)	0.035 (-0.074 to 0.14)
Labor force engagement at any point, No. (%)						
Employment	92 (37.9)	80 (33.6)	66 (27.6)	0.102 (-0.003 to 0.205)	0.06 (-0.037 to 0.161)	0.042 (-0.066 to 0.147)
Education	58 (31.0)	58 (33.9)	40 (23.5)	0.075 (-0.036 to 0.186)	0.104 (-0.013 to 0.221)	-0.029 (-0.14 to 0.088)
Noncompetitive employment	72 (38.5)	54 (31.6)	72 (42.4)	-0.039 (-0.157 to 0.084)	-0.108 (-0.231 to 0.011)	0.069 (-0.046 to 0.187)
Survey and scale scores, mean (SD)						
Satisfaction with treatment	24.3 (5.0)	24.6 (5.1)	20.9 (6.2)	0.310 (0.167-0.445)	0.341 (0.187-0.478)	-0.038 (-0.187 to 0.108)
Brief Assessment of Cognition in Schizophrenia scores						
Memory domain	-1.3 (1.7)	-1.2 (1.4)	-1.3 (1.7)	-0.040 (-0.192 to 0.105)	0.025 (-0.126 to 0.175)	-0.073 (-0.223 to 0.079)
Speed domain	-2.2 (1.5)	-2.2 (1.6)	-2.1 (1.7)	-0.037 (-0.183 to 0.119)	-0.015 (-0.163 to 0.141)	-0.025 (-0.176 to 0.125)
Problem domain	-1.0 (2.3)	-1.1 (2.0)	-0.8 (1.9)	-0.044 (-0.199 to 0.104)	-0.117 (-0.277 to 0.046)	0.070 (-0.081 to 0.212)
Negative symptoms per SANS	1.6 (0.8)	1.5 (0.9)	1.5 (0.8)	0.049 (-0.101 to 0.189)	-0.016 (-0.163 to 0.137)	0.062 (-0.084 to 0.195)
Psychotic symptoms per SAPS	1.1 (1.3)	0.9 (1.2)	1.0 (1.3)	0.025 (-0.116 to 0.159)	-0.037 (-0.174 to 0.102)	0.058 (-0.07 to 0.193)
Disorganized symptoms per SANS or SAPS	0.3 (0.5)	0.3 (0.5)	0.3 (0.5)	-0.027 (-0.157 to 0.104)	-0.102 (-0.22 to 0.018)	0.074 (-0.049 to 0.197)
Medical care, mean (SD)						
Outpatient courses	1.6 (1.8)	1.5 (1.8)	1.7 (2.1)	0.006 (-0.12 to 0.13)	-0.014 (-0.135 to 0.104)	0.020 (-0.1 to 0.138)
Outpatient visits	29.2 (27.2)	28.9 (31.0)	33.8 (30.7)	-0.097 (-0.225 to 0.02)	-0.129 (-0.253 to -0.005)	0.035 (-0.094 to 0.159)
Hospitalizations	0.7 (1.6)	0.6 (1.6)	0.8 (1.8)	-0.040 (-0.135 to 0.056)	-0.040 (-0.131 to 0.06)	-0.002 (-0.099 to 0.093)

Abbreviations: SANS, Scale for the Assessment of Negative Symptoms; SAPS, Scale for the Assessment of Positive Symptoms.

^a Individual placement and support enhanced with cognitive remediation and work-focused social skills training.

when IPS was enhanced with the *Thinking Skills for Work* program and compared with IPS alone. The reasons for not finding the same effect in the present trial could be because of participants' lack of motivation to participate in a highly complex and group-based cognitive program or because participants who started working prioritized this over the cognitive and social training. This was also reflected in the relative high dropout rate from the intervention compared with previous studies, which is likely to explain the missing effect. Since there was no significant difference between the IPS and IPSE groups in any of the vocational outcomes and

because cognitive remediation and work-focused social skills training increase both time to employment or education and costs of the intervention, it is not recommended to implement this supplement to IPS in the form used in this trial. If potential benefits of enhancing IPS with work-focused social skills training and cognitive remediation should be investigated in future research, specific factors associated with benefits to this enhancement should be identified, and it should be ensured that the intervention is appealing to the participants and they demonstrate need at baseline.

Table 4. Days to Employment, Education, or Noncompetitive Employment for 720 Patients With Severe Mental Illness Randomized to 3 Study Groups

Outcome	Time to Outcome, d, Mean (SD)			Hazard Ratio (95% CI)		
	Individual Placement and Support	Individual Placement and Support With Enhancements ^a	Service as Usual	Individual Placement and Support vs Service as Usual	Individual Placement and Support With Enhancements vs Service as Usual	Individual Placement and Support vs Individual Placement and Support With Enhancements
Employment or education	351.01 (197.18)	371.51 (194.92)	406.20 (188.17)	1.57 (1.14-2.18)	1.54 (1.10-2.16)	1.06 (0.78-1.43)
Employment	430.68 (180.32)	460.50 (165.32)	462.10 (169.00)	1.62 (1.11-2.35)	1.25 (0.84-1.85)	1.29 (0.91-1.83)
Education	456.76 (167.78)	455.13 (166.49)	486.48 (142.83)	1.39 (0.91-2.13)	1.74 (1.14-2.66)	0.85 (0.58-1.24)
Noncompetitive employment	415.52 (199.03)	478.47 (142.11)	415.26 (193.60)	0.83 (0.59-1.16)	0.60 (0.41-0.87)	1.39 (0.96-2.02)

^a Individual placement and support enhanced with cognitive remediation and work-focused social skills training.

Strengths

We aimed at increasing the quality of the trial by avoiding a range of biases. First, sample-size and power calculations for the primary and all secondary outcomes were calculated prior the trial, to avoid substantial type I and II errors. Second, the trial had central randomization stratifications for important predictive factors; all outcome assessors and researchers, including statisticians, were blinded to allocation; and blinding was concealed until conclusions were drawn. Third, we used register data with 100% follow-up to measure employment outcomes and thereby avoided recall bias. Lastly, we performed fidelity ratings throughout the entire trial period to ensure adherence to the model.

Limitations

There are also limitations that should be mentioned. Owing to the nature of the intervention, it was not possible to blind the participants, employment specialists, psychiatric team members, and cognitive specialists to the allocations. Moreover, we

cannot be sure that all eligible participants were recruited, because this depended on the mental health staff and participants' reactions to the advertisement, which could have led to selection bias.

Conclusions

We demonstrate that IPS and IPSE can be implemented effectively in a Scandinavian welfare model with relatively generous social benefits, a high minimum wage, and complex employment legislation. The participants were highly satisfied with the support, and based on these results and the consistent IPS literature, we suggest that these approaches are viable routes to increase employment and educational rates among people with severe mental illness in a Danish context. However, no additional significant effect was found by enhancing IPS with cognitive remediation and social skills training.

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Correction: This article was corrected on October 16, 2019, to remove the phrase "(2012; Spika Ltd)" from the Methods section. This mention of a software company was included in error. The article has been corrected online.

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Concept and design: Christensen, Wallstrøm, Stenager, Nordentoft, Eplöv.

Acquisition, analysis, or interpretation of data: Christensen, Wallstrøm, Bojesen, Gluud, Nordentoft, Eplöv.

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