

Supported employment adapted for people with affective disorders—A randomized controlled trial

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ABSTRACT

Background: While effective vocational methods for gaining employment exist for people with schizophrenia and similar conditions, no evidence exists with regard to people with affective disorders. We aimed to study the effectiveness of a newly developed Individual Enabling and Support (IES) model adapted for the target group and compared to traditional vocational rehabilitation (TVR).

Methods: An assessor-blinded randomized controlled trial (RCT) with a parallel design was performed. Sixty-one participants received IES or TVR. The primary outcome was employment rate at 12-month follow-up. Secondary vocational outcomes, depression severity, and quality of life were also studied. Trial register number is ISRCTN93470551.

Results: IES was more effective for employment compared to TVR (42.4% vs. 4%; difference 38%, 95% CI 0.12–0.55). Significant group differences were present in secondary vocational outcomes (hours and weeks employed, time to employment), and depression severity. The IES-group had significantly lowering in depression scores and increased quality of life scores during the intervention period.

Limitations: This RCT was limited by the small sample size due to restriction of recruitment to middle-sized cities within geographically diverse sites in southern Sweden. Larger trials are needed, also in primary health care and employment services settings.

Conclusions: IES is more effective than TVR for attaining employment and improving depressive symptoms. On a societal level, IES closes the time and service gap between treatment and employment, and thus lowers sick-leave costs.

1. Introduction

Mental health problems such as affective disorders are recognized as the major cause of sick-leave and unemployment (Harvey et al., 2009; OECD, 2013). Having depression affects the entire lifestyle, including work (Adler et al., 2006; Lerner and Henke, 2008). The costs are high for the individual and society (Eaton et al., 2008; Murray et al., 2012; Social Insurance Report, 2015:11; OECD, 2011). Between 1997 and 2005, the costs of depression doubled to 3.5 billion Euros in Sweden. The primary costs are due to sick-leave and early retirement (Sobocki et al., 2007). Sick-leave rates are still increasing for men and women (Social Insurance Report, 2015:11). In Europe, depression is responsible for 7.2% of the total burden of disability adjusted life years (DALY) in women (Wittchen et al., 2011). People with depression have

the longest periods of sick-leave among high risk groups (Swedish Government Official Reports, 2011; OECD, 2011, 2013). Research in this area tends to focus on symptom-reduction in healthcare settings, separate from the work setting and vocational outcomes (Joyce et al., 2016). The need to develop new interventions that address the difficulties persons with depressive symptoms have with gaining and keeping employment are needed (Lauber and Bowen, 2010; Joyce et al., 2016; Martin et al., 2012; Henderson et al., 2011).

Randomized controlled trials (RCT) have shown that the evidence-based place-then-train model of supported employment (SE) is more effective than traditional vocational rehabilitation (TVR) for people with severe mental illness in relation to vocational outcomes, e.g., gaining employment. This is the case for individuals with schizophrenia or other psychoses (Bond et al., 2008, 2012, Burns et al., 2007).

Abbreviations: ASRS, Adult ADHD Self Report Scales; AUDIT, Alcohol Use Disorders Identification Test; IES, Individual Enabling and Support; IPS, Individual Placement and Support; ISRCTN, International Standard Randomized Controlled Trial Number; KEDS, Karolinska Exhaustion Disorder Scale; MADRS-S, Montgomery-Åsberg Depression Self Rating Scale; MANSA, Manchester Short Assessment of Quality of Life; PES, Public Employment Service; SE, Supported Employment; SEFS, Supported Employment Fidelity Scale; SIA, Social Insurance Agency; TVR, Traditional Vocational Rehabilitation.

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Furthermore, a more complex intervention, performed by professionals in various services, i.e., the SE team, services of systematic medication management, behavioral health services, and health insurance services, was also effective for people with schizophrenia, major depression and bipolar disorder as compared to TVR (Drake et al., 2013). TVR refers to services that are performed as a stepwise rehabilitation chain, (the train-then-place model), in which several welfare agencies are involved (Corrigan, 2001; Bejerholm et al., 2011). Treatment is typically seen as a prelude to vocational rehabilitation, and not integrated into vocational rehabilitation. In Sweden, SE according to the Individual Placement and Support model (IPS) was more than three times as effective for attaining employment when compared to TVR (Bejerholm et al., 2015). Participants experience IPS as providing hope, tailored support, decreasing stigma, and increasing feelings of empowerment (Areberg and Bejerholm, 2013). The overwhelming evidence for SE for people with SMI (Bond et al., 2012) is reflected in the National Guidelines of Psychosocial Interventions for Persons with Schizophrenia and Similar Conditions (National Board of Health and Welfare, 2011).

In contrast, no effective intervention with the aims of supporting mental health and employment exists specifically for people with affective disorders (Joyce et al., 2016; Swedish Government Official Reports, 2011; Furlan et al., 2012; Audhoe et al., 2010). Affective disorder is an overarching concept, and includes depression and bipolar disorders. The rationale for including depression and bipolar disorder in this study is our focus on depression severity, and that depressive episodes in bipolar disorder affect work capacity and return-to-work to a greater extent than do manic episodes (Tse et al., 2014; Gilbert and Marwaha, 2013). Recently, SE was adapted to better fit the target group. This is called the Individual Enabling and Support (IES) model. IES is based on high-quality support (Modini et al., 2016), and the idea that special attention should be given to the initial and enabling parts of the intervention (Linder et al., 2009).

Work motivation is inversely related to depression severity among people with mental health problems who enter vocational rehabilitation (Bejerholm and Areberg, 2014; Johanson and Bejerholm, 2016). Work motivation and depressive symptoms predict sick-leave, while motivational strategies enhance engagement in therapy (Zuckoff et al., 2008). Therefore, strengthening motivation begins the enabling part of the IES. The next strategy targets functional cognitive strategies, i.e., thoughts, attitudes and behaviors related to work issues (Rose et al., 2012; Naidu et al., 2016). Cognitive strategies enable useful thinking strategies that diminish depressive thoughts, promote the return-to-work process, and support initial strategies. Sick-leave is not identical with having mental health problems at work. It can also be understood from a work and life-balance perspective, and an unbalanced lifestyle has been identified as related to sick-leave and depression (de Vries et al., 2012; Åkerstedt et al., 2009). The ability to optimize time use in relation to functioning and well-being is central to the understanding of problems related to employment; optimizing time might also be the solution to healthy functioning and well-being at work (Hellerstein et al., 2015; Christiansen, 2005). The IES model integrates motivational, cognitive, and time-use strategies with SE, and delivers them as a comprehensive strategy.

Despite the fact that affective disorder is a major concern, research on this target group tends to evaluate vocational interventions only in relation to mental health outcomes instead of mental health and vocational outcomes. So far, interventions typically do not support mental health, work aspirations, and work performance at the same time (Joyce et al., 2016). While effective SE approaches exist for those with severe conditions, the IES model is developed to integrate motivational, cognitive, and time-use strategies for a better fit for persons with affective disorders.

1.1. Purpose and hypothesis

The overall aim was to determine the effectiveness of IES, as compared to TVR, for persons with affective disorders. The primary outcome was difference in employment rate at 12-month follow-up. Secondary vocational outcomes were hours worked per week, number of weeks worked, total working hours, income, and time to employment, and data on internships, education, and prevocational activities or training were included as well. Depression severity and quality of life were other secondary outcomes. We hypothesized that IES-participants would have a higher employment rate and better vocational outcomes compared with TVR-participants at 12-month follow-up. We also expected to find fewer symptoms and improved quality of life among IES-participants.

2. Methods

2.1. Study design

This was a parallel, randomized, controlled trial (RCT) of two intervention groups (IES and TVR). Participants were recruited from four geographically diverse outpatient settings (Eslöv, Burlöv, Landskrona, Ängelholm) in the County Council of Skåne in southern Sweden. The interventions lasted 12 months, which corresponded to a recent trial (Burns et al., 2015). The trial started in December 2011. Recruitment was estimated to last at least 12 months. The duration of the project was ≤ 2.5 years. The RCT design was based on the CONSORT guidelines for non-pharmacological interventions (Moher et al., 2012), has Trial Number Register ISRCTN93470551, and was approved by the ethics board at Lund University, Lund, Sweden (Dnr 2011-544).

2.2. Participants

Eligibility criteria were having 1) a depressive episode (ICD-10 F32), recurrent depression (F33.0, F33.1), bipolar disorder (F31), or F30 (includes depressive episodes), as diagnosed by the team psychiatrist according to the International Classification of Diseases 10th edition (World Health Organization, 1992), 2) aged 18–63, 3) ability to communicate in Swedish, 4) expressing interest in employment, 5) has not been employed during the past year, 6) receiving mental health services, and 7) attended a research information meeting. Exclusion criteria included 1) severe drug/alcohol abuse, 2) somatic illness or physical disability that impeded work, factors which could potentially interact between the causal factor (IES) and outcome (employment). Potential participants picked-up leaflets in the waiting room, visited a project web-page, or read advertisements in a daily paper. They then attended research information meetings or received information individually. Any time after attending a research meeting, patients could hand in their written consent. The meetings occurred twice a month at each site, and explained the interventions, inclusion criteria, RCT-design, randomization issues, and ethical issues of approval.

2.3. Interventions

2.3.1. Individual Enabling and Support

IES is guided by an employment specialist who works closely with the participant in relation to the outpatient team, family, Social Insurance Agency (SIA), Public Employment Service (PES), and employers (Bejerholm, 2016). The professional role requires high-quality, empathetic counseling corresponding to ten IES principles (which do not need to be carried out in any particular order): 1) handling change and developing motivational and cognitive strategies, 2) having a time-use pattern that supports work-life balance, 3) integration of IES with mental health treatment, 4) competitive employment as a primary goal, 5) eligibility based on client choice,

6) rapid job search, 7) job search based on personal preferences, 8) ongoing support and work accommodations as needed, 9) benefit counseling (SIA/PES) at an early stage, and 10) systematic recruitment and quality engagement with employers. Principles 3–10 correspond to the IPS model. The extent of the counseling is individualized to fit the intervention need of the participant. IES involves phases of 1) enabling mobilization of motivational, cognitive, and lifestyle strategies, 2) completion of a career profile and plan, 3) job-seeking, and 4) supported employment phase during which mobilized strategies are intertwined. Phases 1 and 2 last for 1–2 months. Phase 3 lasts until employment is reached. Phase 4 is the remaining time. The duration and intensity of phases 1, 2, and 3 are approximately one hour per week, while phase 4 requires 20 min per week.

The IES delivery was assessed at six and 12 months using the Supported Employment Fidelity Scale (SEFS) (Becker et al., 2008), and three questions on motivational, cognitive, and time-use support. At six months, 109 points were reached. At 12 months, 106 points were reached. This corresponds to good fidelity (highest sum-score=125). The IES support increased from 12 to 14 points between assessments (highest sum-score=15).

To meet the estimated effect size (60 per group), recruitment of three full-time employment specialists was undertaken, since the recommended case-load is 20 participants. Only two positions were filled (from among 46 applicants) because of the recruitment pace and numbers. The employment specialists were experienced in vocational rehabilitation, working with the target group, and familiarity with IES support strategies.

The employment specialists received training in motivational interviewing from a certified motivational interviewer, cognitive strategies from a cognitive behavioral therapy psychologist, time-for-work strategies from an occupational therapist, and supported employment from supported employment specialists. Initially, training was delivered through a three-week educational program, and then continuously through face-to-face supervision.

2.3.2. Traditional Vocational Rehabilitation

TVR was delivered by various professionals in several settings and organizations, e.g., healthcare, municipality, SIA and PES. TVR is regulated by the social benefit and unemployment security system. The service is individualized to a lesser extent; to a larger extent it is facilitated in several assessment stages that are regulated by the organizations. The first step involves reducing symptoms and increasing work ability at a mental health service (1 h per week). Step 2 involves assessment of 50% work capacity and is performed by the SIA and PES (10–20 h per week). If work capacity is not met, the participant is encouraged to enter Step 3 with pre-vocational activities at the municipality. Step 3 is regulated by law at 5–20 h per week. The last step is vocational training during internship placements (20–40 h per week), and these can lead to employment positions through the PES.

For process evaluation, TVR was assessed by SEFS at six and 12 months as well. Since a TVR fidelity scale is not available, this allowed for comparison between intervention groups (Becker et al., 2008). The mean scores were 35 and 40 respectively which correspond to not delivering SE (highest sum-score=125).

2.4. Outcomes

Vocational outcomes were assessed at three measurement points (0, 6, and 12 months). Sociodemographic characteristics were assessed at baseline, in order to reflect the sample as whole, detect differences between intervention groups, and detect differences between participants who were analyzed or lost to follow-up. In addition, participants were screened for the comorbidities of attention deficit hyperactivity disorder, exhaustion disorder, and misuse of alcohol. Depressive severity was assessed at each measurement point. Quality of life was

assessed at baseline and 12 months. Two research assistants were recruited. They had extensive experience in instrument usage and assessment, and interaction with persons with affective disorders. Creation of a safe environment for data collection was essential. The research assistants underwent a 3-day training in instrument coverage and usage to assure standardization.

2.4.1. Vocational outcomes

The primary outcome (employment rate) and secondary vocational outcomes were recorded in a vocational log on a weekly basis. The logs were handed in every three months, and validated against the interview data collected by research assistants at the same time intervals. Both internship and education provide means toward gaining employment in the desired work area. Internship forms part of the employer culture in Sweden (employers receive subsidies from PES). Internship, rather than direct employment, is recommended to any Swedish citizen in vocational rehabilitation (Bejerholm et al., 2015).

2.5. Baseline characteristics, depression and quality of life outcomes

A questionnaire was used to gather data on sociodemographic and clinical characteristics. Diagnoses were validated by the team psychiatrist using ICD-10.

The Adult ADHD Self Report Scales (ASRS) (Kessler et al., 2005) screened for symptoms of attention and hyperactivity. ASRS has 18 items that score frequency of symptoms on a five-point rating scale (0–4). Symptoms of inattention are reflected in nine items, and the remaining items address hyperactivity. The highest possible sum-score is 72. A sum >24 on either subscale indicates a high probability of ADHD (Konstenius et al., 2015).

The Karolinska Exhaustion Disorder Scale (KEDS) screens for exhaustion disorder symptoms (Besér et al., 2014). KEDS has nine items on concentration, memory, physical stamina, mental stamina, recovery, sleep, hypersensitivity to sensory impression, experiences of demands, and irritation/anger. Difficulties are rated on a seven-point scale (0–6), and the highest sum-score is 54. The cut-off score of 19 discriminates between the presence or absence of exhaustion disorder (Besér et al., 2014).

The Alcohol Use Disorders Identification Test (AUDIT) was administered as a measure of risk or misuse of alcohol (Cruce et al., 2007). Ten questions are graded on a five-point rating scale (0–4), and the sum-score ranges from 0 to 40. Hazardous use cut off scores were set at >6 for women and >8 for men. Test-retest and internal reliability for AUDIT are satisfactory (Bergman and Källmén, 2002).

The Montgomery-Åsberg Depression Self Rating Scale (MADRS-S), addressed depression severity (Montgomery and Åsberg, 1979). MADRS-S consists of nine items, (mood, feelings of unease, sleep, appetite, ability to concentrate, initiative, motivational involvement, pessimism, and zest for life), on a seven-point scale (0–6). Sum-scores range from 0 to 54 (0–12=no or hardly any depression, 13–19=less severe depression, 20–34=moderate depression, ≥35=severe depression).

Quality of life was measured by the Manchester Short Assessment of Quality of Life (MANSA), which was developed for people with mental illness (Priebe et al., 1999). MANSA has 12 items on satisfaction with: life as a whole, finances, work situations, friends, family relations, leisure, living conditions, safety, fellow residents, sexual life, physical, and mental health. Satisfaction is rated on a seven-point scale (1–7), with sum-score ranges from 12 to 84. MANSA has good psychometric properties (Björkman and Svensson, 2005; Priebe et al., 1999).

2.6. Sample size

The estimated sample size of 120 participants was based on the employment rate in similar RCTs for people with schizophrenia or

psychosis in the US (Cook et al., 2005; Drake et al., 1999; Lehman et al., 2002), and Europe (Burns et al., 2007). With a two-sided alpha set at 0.05 and power of 0.80, the suggested sample size ranged from 11 to 42 per group. Each randomization group was considered large enough if there were 60 per group, as this allowed for a 30% attrition rate. However, recruitment was restricted to four geographically diverse middle-sized cities and four outpatient teams in southern Sweden, rather than one larger catchment area as originally intended. This decision was made by the division head of the Mental Health Services and REHSAM (Rehabilitation and Coordination Program) steering committee because of other ongoing projects. Additional sites could not be included because of logistics for the employment specialists. Risk-analysis of recruitment highlighted the importance of frequent contact with teams and presumptive participants, and these guidelines were followed.

2.7. Randomization and blinding

The participants were randomized to an IES-group or a TVR-group. Central randomization was done by an independent researcher at Lund University who was not involved in recruitment or the intervention. A software program produced a randomization plan with a block size of eight random group allocation numbers at a time (Dallal, 2015). The sequence was concealed until interventions were assigned. The participants received a letter of confirmation. The trial is single-blind and assessor blind, i.e., researchers had no prior knowledge of the identity or allocation of participants, and data were coded. Participant allocation status could not be blinded for those delivering the interventions.

No adverse events were recorded.

2.8. Statistical methods

Hypotheses for the primary and secondary outcomes were tested on the whole group. Statistical testing used Student's independent *t*-tests to compare means, Mann-Whitney *U* test to compare medians, and Pearson χ^2 -test/Fisher's Exact tests to compare proportions. Within group differences were calculated for ordinal variables and with Wilcoxon Sign Rank tests and for categorical variables with McNemar tests. Calculations of confidence intervals (95%) for two binomial proportions with a small sample size, e.g., having employment or not, were computed by an exact confidence interval test (Chan and Zhang, 1999). SAS® statistical package (version 9.2) was used. Confidence intervals (95%) around the mean differences were bootstrapped with 1000 resamples due to the small sample size and skewed distribution (Burns et al., 2007). For proportions, Cramer's Phi was used (small=0.10, medium=0.30, large=0.50). Cohen's D was used for calculations of effect sizes of means (small=0.20, medium=0.50, large=0.80) (Cohen, 1988; Kotrlik et al., 2011). Conservative estimates of continuous vocational outcomes were used. All participants were included in the analyses. When no outcome (e.g., weeks, hours) was applicable, data were imputed with zero. Sensitivity analyses allowed calculations on the principle of intention-to-treat for employment rate. Data of those who were lost to follow-up were imputed by applying the “best” (employed) and “worst” case scenario (not employed). Logistic regression models were constructed to control for potential confounders of employment rate at 12 months. Age, sex, diagnosis (depression

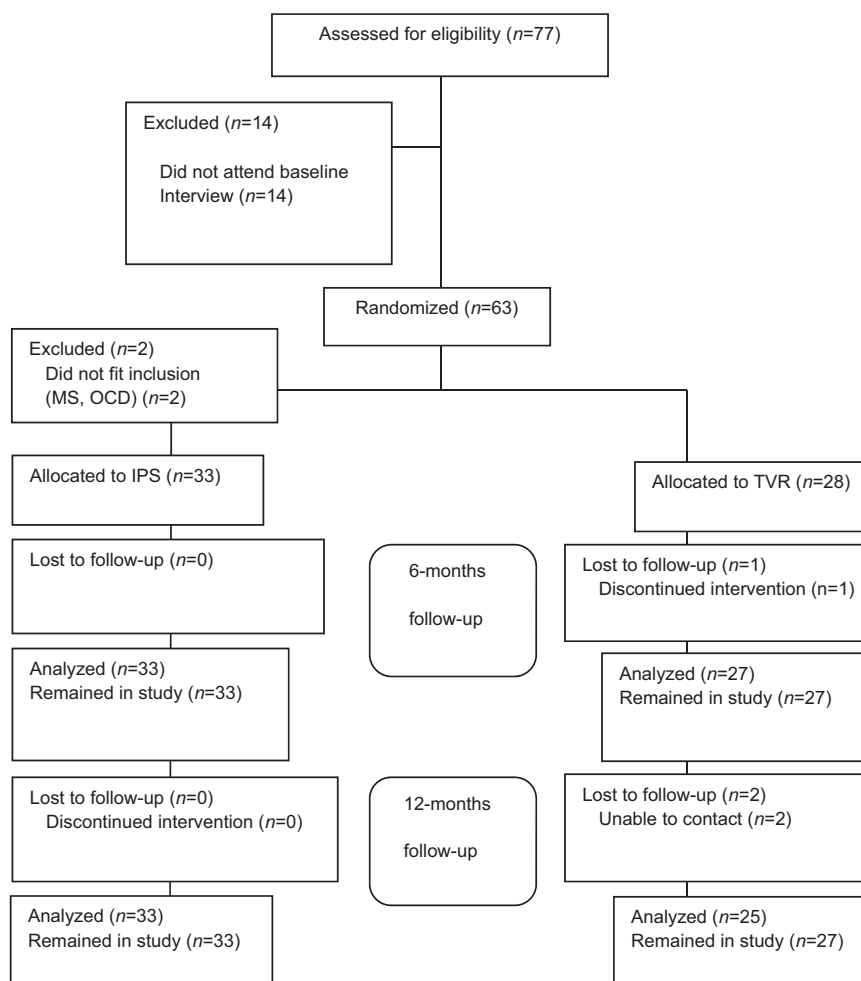


Fig. 1. Trial profile.

and bipolar/unipolar and bipolar depression), work history, age at first contact with psychiatry, and alcohol use (differed significantly between groups at baseline) were included in the model. Kaplan-Meier survival analysis helped analyze time-to-employment. Cox proportional-hazard regression analysis determined the significant difference between groups with regard to time-to-event. These statistical calculations were performed with IBM SPSS for Windows (version 22.0) and the significance level was set at 0.05.

3. Results

3.1. Trial profile

Seventy-seven participants were assessed for eligibility (Fig. 1). Fourteen were lost before baseline assessment because they changed their minds and were ambivalent about wanting to enter the research project with employment as goal. Another two were excluded by the inclusion/exclusion criteria; one had multiple sclerosis, one had obsessive compulsive disorder. The participant with multiple sclerosis did not declare his or her somatic illness or physical disability at the information meeting or baseline interview, but was recognized as being a wheelchair user on a regular basis at the start of the intervention. The other participant did not grasp the depression criterion of having a diagnosis but he or she referred to it as feeling depressed. Thirty-three participants were allocated to the IES intervention and 28 to the TVR intervention. The uneven distribution is explained by the block-sized randomization plan that originally estimated 120 participants. One TVR participant was lost to follow-up at six months and two more were lost at 12 months. No significant differences between intervention groups were found in baseline characteristics (Table 1) except for age ($p=0.04$) and alcohol use ($p=0.03$). No differences were found on any of the baseline characteristics between participants who were analyzed and those lost to follow-up.

3.2. Baseline characteristics

The majority of participants were women (72%), two-thirds had children, and nearly all had previously worked and originated from Sweden (Table 1). Half of the participants had completed upper secondary school and were co-habiting with a partner or family (parents or sibling). A third were married. Income consisted of welfare benefits: 33% were on sick-leave, 13% were on long-term sick-leave, 13% had activity support, and 10% had social benefits. Thirty-one percent of participants reported no income source. The majority (60%) had no vocational rehabilitation, and a third had contact with SIA and PES.

In terms of clinical characteristics, two-thirds of the participants had depression and one-third had bipolar disorder. The mean age for first contact with mental healthcare was 28 yr (SD 12). Forty-one percent of participants had been admitted to the hospital once or twice. The average number of depressive episodes was six. The most frequently reported somatic comorbidity was long-term pain. Each participant had contact with an outpatient team (Table 1). Treatments consisted of medication ($n=57/51$, 90%), nurse counseling ($n=61/46$, 79%) or cognitive behavioral therapy ($n=55/21$, 38%), psychodynamic therapy ($n=51/6$, 12%), and physiotherapy or occupational therapy ($n=55/22$, 37%). Among 55 participants, 25% received primary healthcare. When controlling for differences in treatments between groups at baseline and 12 months, a significant difference on counseling was evident at 12 months ($n=56$, $\chi^2=7.08$, $df=1$, $p=0.008$). The IES-participants ($n=31$, yes/no=10/21) needed less nurse counseling as compared to those in TVR ($n=25$, yes/no=17/8).

The group as a whole ($m=26$) suffered risk of exhaustion (> 19 risk) (KEDS). They also exhibited a small increased risk of having attention deficits (ADHD) by ASRS 1 ($m=18.6$, risk = < 17). There was no risk for alcohol misuse present. The average score of depression severity was

equivalent to having moderate depression. Table 2.

3.3. Primary vocational outcome

At 12-month follow-up, 42.4% of IES-participants were competitively employed, while 4% of TVR-participants reached their working goal (38% difference; $p=0.001$; Cramer's Phi effect size=0.44) (Table 3). None of the variables fitted the regression model and predicted employment rate at 12 months after controlling for age, sex, diagnosis, work history, age at first contact with psychiatry, and the characteristics found to significantly differ between groups at baseline. The p -value ranged from 0.564 (age) to 1.0 (diagnosis),

The intention to treat analyses revealed significant group differences when the assumption was that lost to follow-up participants were unemployed (worst: $p=0.001$, $\chi^2=10.95$, $df=1$, effect size=0.45) or employed (best: $p=0.024$, $\chi^2=5.77$, $df=1$, effect size=0.31).

3.4. Secondary vocational outcomes

The 6-month employment rate did not differ between intervention groups (Table 3). A non-significant trend was present for differences in internship rate ($p=0.06$, $\chi^2=3.53$, $df=1$, effect size=0.24). Twelve IES and four TVR-participants had internships. A large effect size was found in rates of pre-vocational training or activities ($p=0.000$, $\chi^2=15$, $df=1$, effect size=0.50).

At 12-month follow-up, no significant group differences were

Table 1
Baseline sociodemographic and clinical characteristics of participants ($n=61$) by randomization group.

Characteristic	Total		IES		TVR	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Age (mean)	41	11	38	10	44	11
Sex						
Men/Women	17/44	28/72	11/22	33/67	6/22	21/79
Civil Status						
Married/Divorced	20/30	33/18	9/6	27/18	11/5	39/18
Living situation						
Cohabiting with partner or other	35	58	18	55	17	63
Number of Children						
0/ 1–2 / 3–5	24/ 28/ 9	39/ 46/15	15/14/4	46/ 42/12	9/14/5	32/ 50/18
Ethnicity						
Native	56	92	31	94	25	89
Immigrant	5	8	2	6	3	11
Diagnosis (ICD-10)						
Depression F32-33	42	69	21	64	20	72
Bipolar F30-31	19	31	12	36	7	25
Illness episodes ($n=47$)	6	9	5.4	9.7	7.2	8.7
Hospital admission ($n=59$)	1.8	5.3	2.4	7.0	1.2	1.3
Income						
Net income (€) ($n=50$)	1055	463	1098	522	1005	389
Source of income						
Welfare benefit	41	70	24	69	18	64
Other	19	30	9	27	10	36
Educational level						
University	19	31	11	33	8	29
Upper secondary school	33	54	16	48	17	61
Primary school	9	15	6	18	3	11
Work history						
Work experience	58	95.0	31	94.0	27	96.4
Years since last employment	4.4	3.1	4.5	2.8	4.4	3.4
Vocational rehabilitation						
Yes	15	25.9	5	15.6	10	38.5
No	35	60.3	25	78.1	10	38.5

Table 2

Baseline comorbidity and health-related variables of participants (n=61).

Characteristic	Total		IES		TVR	
<i>Comorbidity assessments</i>	Median (min-max)	Mean(SD)	Median (min-max)	Mean(SD)	Median (min-max)	Mean(SD)
KEDS	26 (9–49)	26.3 (8.3)	27 (15–43)	26.3 (7.4)	25 (10–39)	26.4 (7.7)
ASRS1	20 (1–31)	18.6 (6.6)	20 (7–31)	19.7 (6.2)	19 (1–30)	17.3 (6.9)
ASRS2	15 (2–29)	14.3 (6.5)	16 (3–28)	14.6 (6.5)	13.5 (2–29)	14 (6.6)
Audit	2 (0–10)	2.7 (2.5)	3 (0–10)	3.4 (2.7)	1 (0–6)	1.8 (1.8)
<i>Depression and quality of life</i>						
MADRS-S	23 (3–42)	22.7 (7.8)	22 (11–39)	21.4(6.8)	23.3 (3–42)	24.12(8.8)
MANSA	47(22–63)	46.1(9.2)	47(22–62)	46.39(8.6)	46(27–63)	42.25(7.6)

Note: SD=Standard Deviation; ASRS=Adult ADHD Self-Report Scale; Audit=Alcohol Use Disorders Identification Test; KEDS= Karolinska Exhaustion Disorder Scale; MADRS-S= Montgomery-Åsberg Depression Self Rating Scale; MANSA=Manchester Short Assessment of Quality of Life.

Table 3

Intervention group differences in vocational outcome rates at six- and 12-month follow-up (n=61).

6-month	Group (n)	Rate (n)	95% CI	Difference	95% CI	Sign (χ^2/df)	Effect size ^a	95% CI
Employment	IES (33) TVR (27)	12.1(4) 14.8(4)	3.0–24.2 0–24	–0.03	(–0.23–0.16)	0.76 (0.93/1)	0.002	–0.256–0.249
Internship	IES (33) TVR (27)	36.4(12) 16(4)	21.2–54.5 4–32	0.21	–0.02–0.43	0.086(3.53/1)	0.226	0.086–0.138
Education	IES (33) TVR (27)	3(9.1) n.a.	0–21.2 n.a.	0.09	–0.05–0.25	0.122(2.58/1)	0.203	0.104–0.323
Pre-vocational activity/training	IES (33) TVR (27)	3(1) 44(11)	0–9.1 24–64	–0.41	–0.61–0.19	0.000(15/1)	–0.501	–685 to –0.290
12-month	Group (n)	Rate (n)	95% CI	Difference	95% CI	Sign (χ^2/df)	Effect size^a	95% CI
Employment ^b	IES (33) TVR (25)	42.4 (14) 4(1)	24.2–57.6 0–12	0.38	0.12–0.55	0.001(10.95/1)	0.435	0.228–0.601
Internship	IES (33) TVR (25)	39.4(13) 20(5)	24.2–57.6 4–36	0.19	–0.07 to 0.42	0.114(2.5/1)	0.208	–0.042–0.440
Education	IES (33) TVR (25)	15.2(5) 4(1)	3–27.3 0–12	0.19	–0.07 to 0.42	0.167(1.91/1)	0.181	–0.061–0.360
Pre-vocational activity/training	IES (33) TVR (25)	3(1) 40(10)	0–9.1 20–60	–0.36	–0.58 to 0.15	0.000(12.65/1)	–0.467	–0.653–0.253

Note: CI=Confidence Interval; IES=Individual Enabling and Support; TVR=Traditional Vocational Rehabilitation; χ^2 =Pearson Chi-Square test Coefficient; df=degree of freedom.

^a Effect size: small = 0.10, medium = 0.30, large = 0.50.

^b Primary outcome; χ^2 =Pearson Chi-Square test coefficient; df=degree of freedom.

present in rate of internship or education, although the IES-participants were twice as many. The prevocational outcome rates differed significantly ($p=0.000$, $\chi^2=12.65$, $df=1$, -0.47).

Within group differences, using exact McNemar's test, of having or not having employment were found for the IES-group between baseline and 12 months ($n=33$, $p=0.000$), and between six and 12 months ($n=33$, $p=0.004$). No such changes were found in the TVR-group.

Continuous vocational outcomes, (i.e., number of weeks, working hours per week, and total working hours), did not differ between groups at six months. At 12 months, the IES-participants worked significantly more hours than TVR-participants, in both employment and internships (Table 4). The direction on prevocational activities was the opposite. Time spent in employment, internship, education, or prevocational activities were calculated for the whole group. The working hours per week for those who worked were greater at six months (IES group: $n=4$, $m=38(4)$ vs. TVR group: $n=4$, $m=20(4)$), and 12 months (IES group: $n=14$, $m=35.78(7.10)$ vs. TVR group: $n=1$, m =not applicable).

Net income (Euro) did not differ between intervention groups at baseline ($n=54$, mean difference 26.70, 95%CI 216–269, $t=0.22$, $df=50$, $p=0.83$), but was higher in the IES-group at six months ($n=58$, mean difference 353, 95%CI =111–594, $t=2.92$, $df=56$,

$p=0.005$), and 12 months ($n=54$, mean difference 517, 95%CI=251–783, $t=3.90$, $df=50$, $p=0.000$). Income also increased between measurement points in the IES-group ($m=1081$;1385;1565, 0–12 months: $t=-4.09$, $df=26$, $p=0.000$). This was not the case in the TVR-group ($m=1054$;1032;1048, 0–12 months: $t=-0.14$, $df=20$, $p=0.89$).

A significant difference in Kaplan-Meier survival probability estimates for days to employment at 12 months (log rank test: $\chi^2=4.45$, $df=1$, $p=0.03$) between the IES (316 days) and TVR-groups (344 days).

3.5. Secondary outcomes of depression and quality of life

No significant difference was found in depression severity between intervention groups at baseline ($n=61$, $Z=-1.50$, $p=0.13$), or 6-month follow-up ($n=60$, $Z=-1.83$, $p=0.067$). At 12 months, however, scores on depression significantly differed between groups ($n=56$, $Z=-2.14$, $p=0.03$).

Within group changes showed that IES-participants had significantly improved depression severity from moderate to mild depression (0–6 months: $n=33$, $mdn=22$ vs $n=33$, $mdn=17$, $Z=-2.54$, $p=0.010$; 0–12 months: $n=33$, $mdn=22$ vs $n=31$, $mdn=15$, $Z=-2.90$, $p=0.001$). No such changes occurred within the TVR-group (0–6 months: $n=28$, $mdn=23.5$ vs $n=27$, $mdn=22$, $Z=-1.08$, $p=0.32$; 0–12 months: $n=28$,

Table 4Differences in vocational outcomes (hours and weeks) at 12-month follow-up between intervention groups ($n=61$).

	IES $n=33$		TVR $n=25$		Difference means (CI) ^a	Sign	t -value	Effect size ^b
	Mean	SD	Mean	SD				
Employment								
Hours/week	10.97	17.28	0.32	1.60	10.65 (5.08–16.64)	0.003	3.25	0.82
Weeks	7.73	13.41	0.64	2.50	7.09 (2.30–11.45)	0.005	2.97	0.73
Hours	210.39	432.84	3.84	19.20	206.55 (75.33–368.21)	0.010	2.74	0.67
Internship								
Hours/week	10.24	14.57	3.72	7.01	6.52 (0.89–12.25)	0.029	2.25	0.57
Weeks	8.52	12.16	3.36	6.84	5.16 (0.22–10.00)	0.046	2.04	0.52
Hours	172.21	265.40	32.92	78.93	139.30 (48.63–237.63)	0.007	2.85	0.71
Education								
Hours/week	5.61	12.73	1.60	8.00	4.01 (–1.16 to 9.40)	0.149	1.46	0.38
Weeks	3.67	10.37	0.76	3.80	2.91 (–0.48 to 7.04)	0.145	1.48	0.50
Hours	117.52	322.82	30.40	152.00	87.11(–25.33 to 219.95)	0.179	1.36	0.34
Pre-vocational activity/training								
Hours/week	1.21	6.96	5.92	9.18	–4.71(–9.05 to –0.44)	0.038	2.14	–0.55
Weeks	0.73	4.18	12.80	18.96	–12.07 (–20.17 to –4.91)	0.004	3.13	–0.88
Hours	30.39	174.08	203.40	390.28	–173.10(–345.63 to –21.82)	0.047	2.07	–0.57

Note: IES=Individual Enabling and Support; TVR=Traditional Vocational Rehabilitation; CI=Confidence Interval; t -value= t -test coefficient of differences between means. Missing data (applicable for participants *not* working, in internship, education and prevocational training) were imputed with zero for conservative estimates.

^a Bootstrapped estimates.

^b Effect size: small=0.20, medium=0.50, large=0.80.

$mdn=23.5$ vs $n=25$, $mdn=20$, $Z=-1.18$, $p=0.24$). IES-participant scores on quality of life between baseline and 12 months increased ($n=31$, $Z=-3.19$, $p=0.001$), while the TVR-participants scores did not ($n=25$, $Z=-1.05$, $p=0.293$).

4. Discussion

This RCT investigated the 12-month effectiveness of a newly developed IES-supported employment approach adapted for people with affective disorders compared to TVR after 12 months. Our main hypothesis of a higher employment rate among IES-participants was confirmed (42.4% vs. 4%; mean difference 38%, 95%CI 0.12–0.55, $p=0.001$, Cramer's Phi effect size=0.44). This result is consistent with trials on IPS at 18-month follow-up for individuals with psychosis in Sweden (46% IES vs 11% TVR) and in other non-US countries (Bejerholm et al., 2015; Bond et al., 2012). More than twice as many IES-participants reached internship and educational goals. The IES-participants changed their employment status over time (became employed) while those in TVR did not. The TVR-participants also did not improve their depression or quality of life scores, while those in IES did. The majority of the IES-participants were engaged in work, internship, or education at 12-month follow-up, while the majority of TVR-participants were kept in the prevocational loop of treatment and rehabilitation. We conclude that TVR does not provide integrated support in an overall intervention strategy that is needed for improved mood and employment. A few TVR-participants were employed at six months, but this achievement did not last. Many people with mental health problems are left behind in less effective prevocational efforts that are not integrated (Eriksson et al., 2008). Our target group is marginalized, and has little support for their return-to-work process (Burstrom et al., 2011; Johanson and Bejerholm, 2016).

The idea of integrating motivational, cognitive, and time-use strategies with SE, and delivering IES as an overall support strategy through a person-centered approach that takes place while the patient is still in treatment, is in contrast to most interventions. Usually, recovery from symptoms is the first step. As highlighted in a meta-review by Joyce et al. (2016) on interventions that improve work outcomes (Joyce et al., 2016) and in two RCTs on work support integrated with mental health service (Schene et al., 2007; Hees et al.,

2013), symptoms and function should be managed at the same time, and be connected to the return-to-work process or work support. The meta-review promotes the idea that improved case management (employment specialists in our trial), and integration between health and vocational services (outpatient team and IES) could improve patient outcomes. This is consistent with the IES model, and in contrast to the TVR model, which is governed by different stakeholders in the rehabilitation chain. The service-user needs to meet a large number of professionals during the TVR route to employment. With no one (in TVR) taking the lead, the situation can lead to a loss of empowerment (Hillborg et al., 2010). We strongly recommend that the service-user have one person to rely on (i.e., an employment specialist), as suggested by qualitative research from a service user perspective (Areberg et al., 2013). Furthermore, the authors of the meta-review (Joyce et al., 2016) propose that multiple interventions should be coordinated into one overall strategy, with a balanced mix of primary, secondary and tertiary interventions. They stress that no evidence exists for how single interventions are best combined. Perhaps the IES model can inform us about how such a combination could be achieved. The communication style of motivational strategies was applicable to the person-centered approach used to elicit the participant's motivation for change. The importance of this is emphasized in a review by Hetteema et al. (2005). Lagerveld et al. (2010) also discuss how motivational strategies are applicable to the anticipated low self-efficacy that people with affective disorders on sick leave experience toward future work achievements. Time-to-work strategies functioned as a primary preventive intervention to avoid the risk of having a lifestyle that was too demanding and interfered with work capacity. Cognitive strategies functioned as secondary and tertiary preventions since they were used both before and at work. In a Norwegian trial, the combination of CBT-sessions and SE was also shown to be successful for attaining employment for those on long term sick-leave who had depression and anxiety (Reme et al., 2015). That trial is encouraging for the IES methodology, and together with the present trial, stresses the urgency of national and international incentives for implementing well-designed vocational interventions that close the gap between healthcare, employment services, and employers.

In addition, RCT results from the Netherlands also confirm the value of supporting people with major depression to resume work

although depression symptoms are still present, and of integrating specific work support with mental health services (Schene et al., 2007; Hees et al., 2013). These trials presented positive outcomes, the intervention group returned to work earlier (Schene et al., 2007), and their mental health sustained over time (Hees et al., 2013), compared to the control groups. The results are important from an intervention point of view. However, the study participants were employed and where not on sick-leave full time at enrollment, as distinct from participants in the present trial.

Cost-effectiveness was not reported in the present study. A brief evaluation has been performed on cost-effectiveness in relation to IES vocational and quality of life outcomes and is in favor of IES (Saha et al., submitted for publication). However, it is also important to compare the actual cost of IES to TVR, and to focus on the entire treatment and rehabilitation chain, not only treatment costs in the healthcare context.

Despite the limitations of this study, our trial supports the effectiveness of IES on vocational, depression, and quality of life outcomes. However, it will also be important to understand the impact of a complex, long-lasting intervention at the individual level (Campbell et al., 2007). To understand *what matters* to the service users is critical (Thornicroft and Slade, 2014). Thus, future research needs to address the experience of participating in IES or TVR, and whether participation benefits personal recovery, needs, and empowerment (Bejerholm and Björkman, 2011; Slade et al., 2005). Larger trials are warranted, which are integrated into primary healthcare and PES settings, and well as an overall strategy of primary, secondary, and tertiary interventions for people with affective disorders.

4.1. Methodological considerations

This study did not recruit as many participants as intended. Final group sizes of 30 participants were just right for a pilot RCT (Lancaster et al., 2004). Based on power calculations from a recent IPS trial in Sweden (Bejerholm et al., 2015), 30 is a large enough number to detect a significant difference between our groups. Furthermore, if the primary outcome is dichotomous, (as in our trial), general calculations of a 0.40 effect size suggests 21 participants are needed in each group (Chan, 2003). Larger group samples would have provided a less skewed distribution of vocational data, and the conservative method of imputing missing data with zero, and using bootstrapping, would have been unnecessary.

Ethnic diversity and gender equality were not achieved, although they were considered as prerequisites for inclusion. This can be viewed as a limitation. However, the inclusion criteria were broad, and being able to communicate in Swedish is consistent with the obligatory Swedish education provided to everyone. The low rates of ethnic diversity may largely be explained by immigrant or ethnicity group help-seeking behaviors. Having a mental disorder is not accepted among all cultures, and mental health literacy may be low (Bhugra and Mastrogianni, 2003).

Key strengths of this trial were that no group differences were found at baseline, and no baseline characteristics predicted employment status. The results as a whole point in the same direction and confirm the quality of the trial and IES intervention.

5. Conclusions

The IES model was more effective than traditional vocational rehabilitation for achieving employment at 12 months among people with affective disorder. IES helps them find and keep employment, earn a higher income, and feel less depressed. This trial demonstrates how multiple interventions can be coordinated by an IES employment specialist into one overall strategy, with a mix of primary, secondary, and tertiary preventive interventions. The IES strategy decreases the time and service gap between treatment and employment for those

with affective disorders. Further trials of IES on affective disorders in primary health care are needed.

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