

Individual Placement and Support (IPS) for Methadone Maintenance Therapy Patients: A Pilot Randomized Controlled Trial

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Published online: 17 February 2017
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Abstract Individual Placement and Support (IPS) is an evidence-based employment model for people with severe mental illness, but it has not been evaluated for clients enrolled in substance abuse treatment programs. This study evaluated the effectiveness of IPS for people with opioid use disorders enrolled in an opioid treatment program. Within a randomized controlled experiment, 45 patients receiving methadone maintenance therapy were assigned to either IPS or a 6-month waitlist. The waitlist group received IPS after 6 months. The primary outcome assessed over 1 year compared the attainment of a job for the IPS condition to the waitlist comparison group. During the first 6 months after enrollment, 11 (50%) active IPS participants gained competitive employment compared to 1 (5%) waitlist participant ($X^2 = 12.0, p < 0.001$). Over 12 months of enrollment, 11 (50%) IPS participants gained competitive employment compared to 5 (22%) waitlist participants ($X^2 = 3.92, p = 0.07$). We conclude that IPS holds promise as an employment intervention for people with opioid use disorders in methadone maintenance treatment, but larger trials with longer follow-up are needed.

Keywords Supported employment · Methadone · Opioid use disorder

Introduction

Meta-analyses and systematic reviews (Marshall et al. 2014; Modini et al. 2016) suggest that the Individual Placement and Support (IPS) model of supported employment (Becker and Drake 2003) is an established evidence-based treatment for people with severe mental illnesses. IPS incorporates eight principles: eligibility based on consumer choice, focus on competitive employment (i.e. jobs in integrated work settings in the competitive job market at prevailing wages with supervision provided by personnel employed by the business), integration of mental health and employment services, attention to patient preferences, work incentives planning, rapid job search, systematic job development, and individualized job supports (Drake et al. 2012). IPS is a manualized approach, with a validated fidelity scale; employment outcomes with IPS are better when delivered with fidelity (Bond et al. 2012). IPS enables individuals to find jobs, which in turn increases self-esteem and overall satisfaction with life (Luciano et al. 2014). While professionals typically focus on symptom reduction and treatment compliance as primary treatment goals (Deegan and Drake 2006), service recipients often focus on functional outcomes (Ramsay et al. 2011). Working is one such meaningful measure (Eklund et al. 2012).

Recently IPS has been extended to new target populations, including people with developmental disabilities (Noel et al. 2016) and young adults experiencing early psychosis (Bond et al. 2015). The outcomes for these recent extensions of IPS to new populations are encouraging.

For people with opioid use disorder, employment is also meaningful and desirable. The role of vocational services at the treatment site has become increasingly accepted and expected (Center for Substance Abuse Services 2000). Yet, obtaining and maintaining employment for patients with

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opioid use disorder is replete with challenges: many have criminal justice histories, lack stable and safe housing environments, or are educationally disadvantaged. People with substance use disorders may have jeopardized or lost jobs as a consequence of substance use or because of early onset substance use never developed academic or work skills. The research findings of work-focused interventions for methadone patients have been mixed (Magura et al. 2004), and frequently identify challenges and barriers to employment (Richardson et al. 2012; Staines et al. 2005). Further, in practice, many traditional service providers may believe that seeking employment or returning to work could undermine treatment progress. Specifically, the stress associated with a job, or the money that might be obtained, could precipitate premature treatment attrition and relapse. In addition, there are historic concerns that employers would discriminate in hiring people with substance use problems, particularly those with histories of involvement with the criminal justice system. Nonetheless, if patients' needs were met in treatment, outcomes improved (McLellan et al. 1997).

Of three medications approved by the U.S. Food and Drug Administration for the treatment of opioid use disorder (Kampman and Jarvis 2015), methadone is the most common and is an effective medication for reducing opioid use and preventing relapse (Volkow et al. 2014). People receiving methadone must do so in specialized opioid treatment programs. In these federally-regulated clinics, the medication is administered and monitored to ensure compliance and prevent diversion. Patients attend the clinic on a near daily basis, and receive methadone as a maintenance medication. Thus, there are parallels between people with severe and chronic mental illnesses receiving community based mental health services and people with moderate to severe opioid use disorders receiving community-based services in an opioid treatment program, including social stigma and potentially negative attitudes by employers.

IPS may be of potential clinical utility for people with opioid use disorders in methadone maintenance therapy because of the benefits from employment in enhanced self-esteem and higher quality of life (Luciano et al. 2014). Retention in treatment is essential for individuals with opioid use disorder, as the risk of relapse to use of non-prescribed drugs and mortality due to overdose is high with discontinuation of maintenance therapy (Schuckit 2016). These are possible concerns of introducing employment within traditional addiction treatment organizations.

Our study examined whether patients enrolled in methadone treatment would benefit from IPS services. In a small randomized controlled trial, we randomly assigned opioid treatment program patients to IPS plus treatment-as-usual or to IPS waitlist plus treatment-as-usual (6 month waitlist for IPS). We hypothesized that IPS participants would have

better competitive employment outcomes than the waitlist participants at 6 months.

Methods

Design

In a 12-month pilot randomized clinical trial (RCT), we randomized participants to active IPS plus treatment-as-usual ($n=22$) or to a Waitlist for deferred IPS in 6 months plus treatment-as-usual ($n=23$). All participants received standard opioid treatment program care including daily methadone dosing, weekly random urine drug-screen testing, at least 1 weekly group session, and monthly individual counseling sessions.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional review boards and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Study Population

We recruited study participants with moderate to severe opioid use disorder from a large, nonprofit, opioid treatment program serving the greater Portland, OR area. As methadone comprised the majority of medication-assisted treatment at this agency (91%), we restricted selection to methadone patients. Eligibility criteria required that participants be aged 18 years or older, meet DSM-V (American Psychiatric Association 2013) criteria for moderate to severe opioid use disorder, receive methadone treatment for at least 14 days at this agency prior to informed consent, never received supported employment services from the agency, be currently unemployed, have a desire to work, lack pending incarceration or housing which disallowed external work, and provide informed consent. Prior to enrollment, all potential participants were also required to attend an information session held weekly at the treatment site describing both the supported employment model and the research study.

Sampling

We enrolled eligible participants between December 4, 2014 and June 26, 2015. Individuals interested in participating were pre-screened; if eligible, they received informed consent and signed the document. Baseline data were collected prior to randomization. After participants completed baseline assessments, a research associate

opened a sealed envelope provided by the lead team which determined status—active IPS or Waitlist.

Given the nature of the design, clinical staff were not blind to group assignment. Trained research assistants from the agency’s research department conducted all in person and phone interviews.

Data Collection Procedures

We collected data at 3-month intervals. Data and survey instrument collection varied by the visit month. Baseline and months 6 and 12 data visits lasted approximately 30 min. Months 3 and 9 averaged 10 min. When possible, interviews were conducted in person in the research wing of the building. However, phone interviews were conducted for shorter visits, if participants were no longer enrolled at the treatment site, or if participants had moved away. Once randomized, we attempted to contact all individuals regardless of whether they remained in treatment.

All participants received a \$20 gift card to a local retail supermarket chain for completed baseline, month 6, and month 12 visits. For shorter interviews at months 3 and 9, participants received \$10 gift cards.

Intervention

Researchers notified the IPS specialist when new participants were assigned to IPS or as waitlist participants became eligible for intervention at month 6. While the IPS intervention was conducted in the treatment site’s clinic, the IPS specialist should spend 60% of their time outside of the clinic setting. The IPS specialist was supervised by an outside trainer. The same specialist provided all IPS participant services throughout the trial. An IPS fidelity review was completed by outside trained reviewers at approximately the mid-point of the trial and the program had a “Fair Fidelity” score of 85 out of a possible 125. (Oregon Supported Employment Center for Excellence 2011).

Outcome Measures

Demographics, risk behavior history, and substance use history were abstracted from medical records. Employment history and income status were collected at each visit using the Dartmouth Employment and Income Review (Drake et al. 1996). We did a complete employment history at baseline and updated employment status, salary, benefits status, and efforts towards employment at every visit.

Data Management

Data were managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at the

treatment site. REDCap is a secure, web-based application designed to support data capture for research studies, providing: (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources (Harris et al. 2009).

Statistical Analysis

We restricted the current analyses to the first 12 months of follow-up. Data were imported into SPSS, (IBM Corp 2015) and STATA 12 (StataCorp 2011). Descriptive statistics were computed for all study variables. Crude differences between active IPS and waitlist groups were assessed using *t* tests for continuous measures; and Mann–Whitney *U* tests, Kruskal–Wallis tests, or Fisher’s Exact tests when data were categorical or nonparametric. Rate ratios were calculated to compare the probability of events occurring in the IPS and Waitlist groups. Baseline health status measures were also compared between each group. Because of the small sample size and attrition, analyses were restricted to basic statistics.

Results

Participant Characteristics

Baseline demographic, clinical, and employment characteristics were similar between the two groups and representative of agency’s patient population (Tables 1, 2). Both groups had high proportions of individuals with histories of homelessness, substance use, and incarceration, as well as self-reported negative consequences of drinking and drug use.

Table 3 presents employment for the two groups by study assessment time points. Baseline time point is not included, as by definition, all participants were unemployed and all desired employment.

Primary Outcome

Table 3 shows that participants in the active IPS group were 11.0 (95% CI 1.6–77.0) times more likely to have a job within the first 6 months of participation and by 12 months were 2.6 (95% CI 1.1–5.9) times more likely to have gained employment. The jobs obtained in the IPS group ($n = 11$) were sustained through month 12. After the waitlist group became eligible for IPS intervention at month 6, the number employed increased from one at month 6 to 5 at month 12. Of the 16 jobs gained over the 12 months, the majority

Table 1 Demographics: IPS study and agency population

| Characteristic ^b | IPS (<i>n</i> = 22) | Waitlist (<i>n</i> = 23) | Agency MAT ^a patient population 2015 (<i>n</i> = 427) |
|-----------------------------|----------------------|---------------------------|---|
| Age (years) | | | |
| Mean | 34 | 40 | 37 |
| SD | 8 | 12 | 12 |
| Gender | | | |
| Male | 7 (32) | 13 (57) | 240 (56) |
| Female | 15 (68) | 10 (43) | 187 (44) |
| Hispanic | | | |
| Yes | 2 (9) | 0 | 14 (4) |
| Race | | | |
| White | 21 (96) | 20 (87) | 328 (91) |
| Black | 0 | 2 (9) | 18 (5) |
| Other | 1 (4) | 1 (4) | 15 (4) |
| Marital status | | | |
| Single/never married | 12 (55) | 13 (57) | 209 (58) |
| Married/living married | 2 (9) | 5 (22) | 57 (16) |
| Separated/divorced/widowed | 8 (36) | 5 (22) | 94 (26) |
| Housing status | | | |
| Own/rent/sublet | 10 (45) | 9 (39) | 128 (58) |
| Living with family | 2 (9) | 5 (22) | 67 (11) |
| Living with non-family | 3 (14) | 4 (17) | Not collected |
| Couch surf/shelter/homeless | 7 (32) | 5 (22) | 131 (4) |
| Education (years) | | | |
| <12 | 2 (9) | 5 (22) | 79 (24) |
| 12 | 8 (36) | 8 (35) | 156 (46) |
| >12 | 12 (55) | 10 (43) | 102 (30) |

^aMedication-assisted treatment (methadone for opioid use disorder)

^b*p* > 0.05 for all comparisons

was for minimum wage, and only four included healthcare benefits (Table 4).

Ten participants were lost to follow-up (six in IPS group and four in Waitlist group) by month 12. Two participants were incarcerated; one withdrew consent, and the status of the remaining seven was unknown.

Discussion

The study's primary hypothesis was supported: the IPS intervention facilitated the employment of methadone patients by month 6. After the Waitlist group became eligible to receive IPS services at month 6, the IPS group remained more likely to be employed relative to the Waitlist group.

These data warrant more rigorous and sufficiently powered research: a full randomized trial, a multicenter trial with adequate sample size, staffing including more than one IPS specialist, and a proper process analysis.

Strengths of the current project were the randomized design, comprehensive training and technical assistance in implementing IPS, and the prospective nature of data collection. We tracked participants engaged in treatment at the agency as well as participants no longer seeking treatment from this site. The support of the treatment agency, the long-term relationship between the treatment agency and the study research team, and the availability of experienced onsite research staff at the agency provided an opportunity to test the feasibility of conducting a randomized trial testing the efficacy of IPS for methadone patients.

Limitations were typical of small pilot studies. The study included only one treatment agency and one IPS specialist. Neither the participants nor the research staff were blind to the group assignment. The findings may not be representative of other patients receiving methadone for opioid use disorder. The small sample size precluded statistical power for secondary analyses.

Table 2 Baseline sample characteristics

| Characteristic ^a | IPS (n=22) | Waitlist (n=23) |
|-------------------------------------|------------|-----------------|
| Ever held a legal job | | |
| Yes | 20 (91) | 20 (83) |
| Had a legal job in the last 5 years | 16 (73) | 11 (48) |
| Ever worked 12 consecutive months | 19 (85) | 18 (78) |
| Ever homeless | | |
| Yes | 19 (86) | 18 (78) |
| Ever arrested | | |
| Yes | 18 (82) | 22 (97) |
| Mean number of arrests | 7.2 | 9.4 |
| Range | 0–35 | 0–30 |
| Ever incarcerated | | |
| Yes | 17 (77) | 16 (70) |
| Mean number of incarcerations | 6.9 | 5.3 |
| Range | 0–30 | 0–20 |
| Alcohol use | | |
| Age of first use (years) | 15 | 16 |
| SD | 3.3 | 3.7 |
| Never drank | 1 | 2 |
| Heroin use | | |
| Age of first use (years) | 22 | 26 |
| SD | 8.7 | 9.9 |
| Never used heroin | 3 | 1 |
| Baseline perception of health | | |
| Excellent/very good | 9 (41) | 7 (30) |
| Good | 7 (32) | 11 (48) |
| Fair/poor | 6 (27) | 5 (22) |
| Current smoker | 19 (86) | 16 (70) |
| Duration in MAT ^b | | |
| <6 months | 15 (68) | 10 (43) |
| ≥6 months | 7 (32) | 13 (57) |
| Average methadone dose (mg) | | |
| Mean | 79 | 89 |
| Range | 40–150 | 30–145 |

^a $p > 0.05$ for all comparisons

^bMedication-assisted treatment (methadone for opioid use disorder)

Table 3 Employment by randomization group

| Group | Month 6 ^a | | Month 12 ^b | |
|-----------------|----------------------|--------------|-----------------------|--------------|
| | Employed | Not employed | Employed | Not employed |
| IPS (n=22) | 11 (50%) | 11 (50%) | 11 (50%) | 11 (50%) |
| Waitlist (n=23) | 1 (4%) | 22 (96%) | 5 (22%) | 18 (78%) |

^a $\chi^2 = 12; p < 0.001$

^b $\chi^2 = 3.92; p = 0.07$

Table 4 Number of days worked and salary for employed participants at 12 months by randomization group

| Characteristic | IPS (n=11) | Waitlist (n=5) |
|------------------------------|----------------|----------------|
| Days worked | | |
| Average | 177 | 156 |
| Range | 11–318 | 7–300 |
| Hourly salary | | |
| Average | \$12.84 | \$13.25 |
| Range | \$9.15–\$25.00 | \$9.15–\$16.00 |
| Received healthcare benefits | | |
| Yes | 3 | 1 |

Despite the limitations, our study provides an encouraging signal for IPS as an option for patients receiving medication-assisted treatment for opioid use disorder.

Acknowledgements For this unfunded pilot project, we gratefully acknowledge the in-kind support from the CODA, Inc. administration. We thank the CODA Research Department for their implementation and conduct of the trial. A special thanks to the patients and study participants.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

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