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**Individual Placement and Support (IPS) versus IPS enhanced with work-focussed CBT: feasibility study for a randomised controlled trial**

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Keywords:	IPS, Employment, Pragmatic Trial
Abstract:	<p><b>Introduction</b> Employment is a key goal for many people with long-term mental health issues. Evidence-based Individual Placement and Support (IPS) is a widely-advocated approach. This study explored whether IPS outcomes could be enhanced with work-related counselling.</p> <p><b>Method</b> The study was designed as a pragmatic RCT comparing the cost-effectiveness, in severe mental illness, of work-focussed intervention (intervention) as an adjunct to IPS compared to IPS alone (control).</p> <p><b>Results</b> The original sample (330) proved impossible to attain so the design was revised to a pilot study from which information on feasibility of a full trial could be drawn. 25 individuals out of 74 found paid work but no difference was found in the mean number of hours in paid employment between the intervention and control groups.</p> <p><b>Conclusion</b> Results demonstrate that delivering work-focussed counselling in tandem with IPS is feasible and acceptable to service users. The study observed that, even during a period of recession (2010-13), individuals with mental health problems succeeded in obtaining paid employment.</p> <p><b>Implications</b> Any additional benefit of counselling over IPS alone could not be ascertained, due mainly to the high drop-out rate from this study. Implications for occupational therapy and for future trials of IPS are discussed.</p>

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For Peer Review

## Introduction

Occupational therapists have always been at the vanguard of innovation and development in promoting employment for people with mental health problems, both in the UK (Rinaldi & Perkins, 2007) and beyond (Waghorn et al., 2009). The approach called Individual Placement and Support (IPS) has a good evidence base (Burns et al., 2007; Marwaha et al., 2007; Kinoshita et al., 2013, Marshall et al., 2014, Drake & Bond, 2014) but its implementation is exacting in many ways. For instance, it requires co-location of employment support staff with community mental health staff, and this can present organisational barriers. Also, IPS employment support workers should have caseloads of about 20, enviably low compared to caseloads of most community mental health team members (Swanson and Becker, 2011, Schneider and Akhtar, 2012). In short, while IPS is increasingly widely-adopted in the UK, it cannot be said to be part of 'standard' mental health services.

## Literature review

There has been a call for a 'more formal evidence base for occupational therapy interventions in the field of supported employment' (Priest and Jones, 2010). Arbesman and Logsdon (2011) reviewed the OT literature on employment support and concluded that IPS had 'strong evidence' in its favour but its outcomes were stronger in combination with cognitive or social skills training. Our earlier review concluded that more evidence was needed concerning the potential to increase the power of IPS by combining it with adjunct interventions (Boycott et al., 2012). There is increasing evidence that on its own IPS results in significant cost offsets by increasing the proportion of clients who work (Bush et al., 2009; Kilian et al., 2011; Perkins et al., 2005; Schneider et al., 2009). In terms of both days worked and whether the individual had worked at least for one day, IPS generated improvements and was cost-saving from the point of view of the health and social care systems (Knapp et al., 2013). However a key question about enhancing IPS is the whether the additional cost of the enhancement is warranted by the benefits.

The present study aimed therefore to test the hypothesis that ***work-focused counselling as an adjunct to IPS will prove more successful in helping people with schizophrenia and***

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3 *related disorders into paid employment than IPS alone.* The design was a two-arm,  
4 parallel, randomised controlled trial of enhanced IPS versus IPS alone, with a cost-  
5 effectiveness arm added because of previous findings cited above. By taking a pragmatic  
6 and exploratory approach we sought also to investigate whether participation might affect  
7 engagement with education, training and volunteering, as well as the implications of the  
8 findings for the wider implementation of IPS. Here, we report on the results of the main  
9 outcome, paid employment in the open labour market, and on the take-up of education,  
10 training and volunteering, together with the results of the costs analysis. The implications  
11 for the wider implementation and evaluation of IPS are also considered in our discussion  
12 below.  
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## 22 **Method**

### 23 **Setting**

24 This context for this study was a Collaborative for Leadership in Applied Health Research  
25 and Care (CLAHRC), focusing on putting evidence into practice (Rowley et al., 2012). The  
26 study was undertaken in one mental health provider, Nottinghamshire Healthcare NHS  
27 Trust. A preliminary phase put in place a fully-operational IPS service through the  
28 appointment of an IPS Development Manager for two years (Schneider and Akhtar, 2012).  
29 Following this period, the present study recruited participants from the caseloads of one  
30 Community Mental Health team ('Rehabilitation and Recovery') and one Early Intervention  
31 in Psychosis (EIP) team based within Nottinghamshire Healthcare NHS Trust (NHCT) in 2010-  
32 2012. A positive ethical opinion was granted by Derbyshire Research Ethics Committee  
33 (ISRCTN18240558).  
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### 45 **Inclusion and Exclusion Criteria**

46 People who consented to participate were eligible if they were aged 18-60 and on the  
47 caseload of the Rehabilitation and Recovery or EIP teams. We excluded anyone who was an  
48 inpatient at the time of the invitation to participate, people currently in work or in  
49 education and those not wishing to work, anyone who was unable to give informed consent,  
50 and anyone who was already receiving cognitive behaviour therapy (CBT). Provision was  
51 made to employ interpreters but none required this support. The initial approach to service  
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3 users was made by their usual care co-ordinators and interested parties responded directly  
4 to the research team or via the care co-ordinator.  
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### 8 **Randomisation**

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10 The researcher, after gaining informed consent, entered participants' details onto a web-  
11 based randomisation system. Group allocation was sent directly via encrypted email to an  
12 administrator, who forwarded details to the psychologist delivering the intervention.  
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15 Details of allocation were kept by the administrator and psychologist in password-protected  
16 files. The psychologist made contact with participants in the intervention arm to inform  
17 them of their allocation. The researcher responsible for assessing participants at baseline  
18 and follow-up was thus 'blind' to allocation until all data collection had been completed.  
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### 24 **Interventions**

#### 25 *Treatment as usual - IPS*

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27 On enrolment to the study participants were assigned to an Employment Specialist (an IPS-  
28 trained worker) who met with them at a mutually-agreed location (often the participant's  
29 home) to produce an action plan for employment. Participants continued to meet with  
30 their Employment Specialist as often as they wished, in keeping with the responsive ethos of  
31 the intervention. The key objectives and methods of working within an IPS model are well  
32 established (Dartmouth IPS Supported Employment Center, 2012). Broadly, this entails  
33 intensive, individualised, employment-focussed advice and practical support without time  
34 limit. The fidelity of the particular IPS service provided for the study was measured in  
35 October, 2010, at the start of recruitment, by an independent team who visited the site,  
36 following the 25-point Fidelity Scale published online as *IPS Resources for Trainers and*  
37 *Fidelity Reviewers* (IPS Dartmouth Supported Employment Center, 2015). The preliminary  
38 score was 63, 'not IPS', because all the community mental health teams had been merged  
39 into one, creating a highly diluted IPS service, and reviewers commented that "...there will  
40 need to be structural changes to the way the service is managed if it is to deliver the  
41 outcomes expected of a high fidelity service". Since changing mental health services  
42 structures was beyond the scope of the study, after recruiting 17 participants, in order to  
43 achieve a more rigorous model of IPS, the focus of recruitment shifted to a team dealing  
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3 with early psychosis, where the remaining 57 participants joined the study by June, 2012.  
4 This team was smaller, working with a younger clientele and more amenable to  
5 implementing IPS fully. The next external fidelity review, in February 2012, scored the  
6 service fidelity as 'good' with 101 points.  
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### 10 11 *Work-Focussed Counselling Intervention*

12 In addition to IPS as described above, participants randomised to the intervention arm of  
13 the trial were offered 3-6 sessions of work-focussed counselling delivered by a psychologist.  
14 This intervention was developed and piloted as part of the present study; informed by  
15 previous studies (Coldham et al., 2002; Rose and Perz, 2005; Boycott et al., 2012) and based  
16 on generic psychological practice, including goal-based motivational procedures and  
17 cognitive behaviour therapy (CBT). This work-focussed counselling intervention was  
18 designed to enhance the impact of IPS by addressing common obstacles to employment  
19 which are not directly due to symptomatology (e.g. hallucinations) and not normally the  
20 concern of the clinical team (e.g. medication adherence). An intervention manual based on  
21 a life goals and a problem solving approach was developed and supplemented by self-help  
22 materials. It was delivered by a trained psychologist (NB) with individual participants. Each  
23 received a booklet ('Working Well!') containing information about six topics (anxiety,  
24 depression, self-esteem, memory/concentration, stigma and getting on with others) and  
25 was asked to choose a maximum of four topics to discuss with the psychologist over up to 6  
26 sessions lasting about an hour, mostly taking place in the participant's home. The  
27 intervention was independently evaluated using a qualitative approach and this is reported  
28 in Boycott, Akhtar and Schneider (2015).  
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### 45 **Outcomes**

#### 46 *Primary*

47 The main outcome was the total number of hours in paid employment (in the open labour  
48 market) 6 months after entering the trial. Whereas many IPS studies use a bivariate  
49 measure of whether or not a person was in work at the primary end point, the fact that  
50 both intervention and control groups were both in receipt of IPS led us to adopt a measure  
51 that would reflect differences in overcoming barriers to sustained employment, such as  
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3 work-focussed counselling was designed to impart. Hence the amount of time in the  
4 workplace was chosen to differentiate the intervention and control groups at six months.

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7 *Secondary*

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9 The study was implemented at a time of economic recession in the UK, which seemed likely  
10 to adversely affect the job prospects of participants, so vocational activities such as  
11 education, training and volunteering were also measured. The questionnaires used are  
12 listed in Table 1. They include the Rosenberg Self-Esteem Scale (Rosenberg, 1965), the EQ-  
13 5D (EuroQOL Group, 1990) and the Client Service Receipt Inventory (Beecham and Knapp,  
14 1992) which yield data required for estimating and comparing costs, and the SF-12 which  
15 measures health and wellbeing (Ware et al., 2002). Less widely-used measures were  
16 applied to explore the impact on self-assessed barriers to work (Lerner et al., 2004a, 2004b)  
17 perceived stigma (Schneider et al., 2011), avoidance of social disapproval (Leary, 1983),  
18 social cognition (Burgess et al., 1996) and social problem solving (D’Zurilla et al., 2002).  
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29 *Table 1 about here*

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32 The researcher assessed participants face-to-face at baseline, 6 and 12 months and by  
33 telephone at 9 months. Demographic, work and education history and clinical details were  
34 gathered at baseline. At baseline, 3, 6, 9 and 12 months, the researcher collected data  
35 about working hours, welfare benefits received and services used (excepting the  
36 experimental intervention). Secondary outcome measures shown in Table 1 were  
37 administered at baseline, 6 and 12 months to both groups. At about 9 months, qualitative  
38 interviews were held with an opportunistic sample of 31 individuals, to explore the  
39 participants’ experience of the intervention, their satisfaction with the process and how it  
40 could be improved.  
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50 **Sample size and amendments**

51 The original sample size calculations derived from estimates that 25% of the control group  
52 and 40% of the intervention group would obtain work. While this estimate was informed by  
53 the IPS literature (e.g. Bond et al., 2008), the pragmatic nature of the study led us to adopt  
54 conservative employment rates for both arms of the trial. For an 80% power of  
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3 demonstrating this difference ( $p < 0.05$ ), 165 participants were required in each arm of the  
4 trial. Recruitment during the first 6 months was 17 and it emerged that one Employment  
5 Specialist's caseload capacity was constrained by pre-existing clients, while as noted above  
6 organisational restructuring made IPS fidelity inadequate. Application was therefore made  
7 to the ethics committee for a substantial amendment to enable the study to recruit from an  
8 Early Intervention in Psychosis team, while the target sample size was revised downwards to  
9 a minimum of 28 per arm on the basis of what would be feasible within the constraints of  
10 the funding and remaining time available. The amendment also extended three  
11 psychometric measures (DEX, SPSI-R and BFNE, 20-22), which had initially only been used  
12 with the intervention group, to be used with all participants. This was to assess any  
13 treatment affects, which we expected to be greater in the intervention group. The possible  
14 sample size for the DEX, FNE and SPSI was therefore reduced by 17 because these measures  
15 were only introduced after that number of participants had been recruited.  
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### 28 **Statistical analysis**

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30 The primary analysis was intention-to-treat and included all participants who were  
31 randomly assigned to their respective groups (intervention or control), regardless of  
32 whether they engaged with IPS/enhanced IPS or not. Participants who were lost to follow-  
33 up were assumed to be not working and the number of hours was recoded as zero.  
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### 38 **Costs estimation and analysis**

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40 To estimate costs, we multiplied frequencies obtained by, in most but not all cases, PSSRU  
41 unit costs for 2012 (PSSRU, 2013). Details are in the Appendix. For the purpose of  
42 examining the distributions of the values, we prorated available data to obtain annualized,  
43 and thus comparable, numbers. Having done this, we calculated means by group. We also  
44 used box plots to compare the distributions of paid hours post-baseline for the intervention  
45 and control groups, as well as improvement in paid hours (adjusting for baseline  
46 differences).  
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54 Bootstrapping and multiple imputation were used to both estimate the incremental cost-  
55 effectiveness ratio (ICER), and assess uncertainty in the ICER. We began by obtaining 1000  
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3 sample replicates using bootstrapping. For each sample, we used multiple imputation (with  
4 20 imputed data sets) to calculate a mean cost and mean effect. These were plotted on a  
5 cost-effectiveness plane. From the location of the points on the cost-effectiveness plane, a  
6 cost-effectiveness acceptability curve was derived. This procedure also is used to compute  
7 an ICER and a standard error for the ICER; 'bootstrap' and 'mi' procedures in Stata 13 were  
8 used to calculate this.  
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14 Finally, we examined bivariately whether there appeared to be an association between paid  
15 hours, or improvement in paid hours, on the one hand, and on the other hand, the number  
16 of hours of psychological intervention received. If the psychological intervention increased  
17 paid hours, one would expect to see a dose-response relationship.  
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## 22 **Results**

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25 Seventy four individuals were recruited to the study from August 2010 to June 2012, 37  
26 randomised to each arm. In total, 32 of these individuals (43%) were lost to follow-up (see  
27 Consort diagram). Their destinations up are unknown but in the analysis we assume they  
28 were not working.  
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### 32 *Adverse events*

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35 One participant committed suicide during the trial, but this was judged to be due to a  
36 significant mental health relapse and not related to participation in the study. No other  
37 adverse effects were reported.  
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### 40 *Attrition*

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43 Attrition analyses were conducted in relation to gender, age, clinical history and the  
44 secondary outcome measures. Independent t-tests showed a statistically significant  
45 difference for age; individuals who stayed in the study were older with a mean age of 32.23  
46 (s.d. 9.69) as compared to 27.03 (s.d. 9.32) ( $t = -2.33$ ,  $df = 72$ ,  $p < .05$ ). No other differences  
47 were found for individuals who stayed in the study in comparison to those who were lost to  
48 follow-up at each time-point.  
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54 *Figure 1 (Consort Diagram) about here*  
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### *Demographic and Clinical Characteristics*

Table 2 shows the demographic and clinical characteristics of the entire sample. Independent t-tests and non-parametric Mann Whitney U-tests were conducted to compare the two groups' demographic and clinical characteristics. No significant differences were found, suggesting that the two groups were equally matched at baseline for age, ethnicity, marital status and clinical history.

*Table 2 about here*

### *Primary Outcome*

In relation to the primary outcome, hours per week (hpw) of (paid) employment after six months, the mean hpw worked was 3.22 (s.d. 9.53) for the 37 individuals who were part of the control group, and 3.89 hpw (s.d. 10.60) for the 37 individuals who were part of the intervention group. At 12 months the mean number of hours worked by individuals who were part of the control group (N = 37) was 3.67 (s.d. 7.80) and 7.07 (s.d. 14.09) for individuals who were part of the intervention group (N = 37) (Table 3). Using the Mann-Whitney U test, no statistically significant difference was found between the intervention and control groups in relation to the main outcome; mean number of hours worked per week at 6 months ( $z = 0.57$ ,  $p = 0.56$ ) and this was also true at 12 months ( $z = 0.71$ ,  $p = 0.48$ ). Twenty five out of 74 people entered employment over the course of the study. Of this number, 12 were working full time, defined as 35-45 hours hpw, 3 worked 20-30 hpw, 6 worked 10-16 hpw and 4 less than 10 hpw.

There were no statistically significant differences between the two groups at any time point on the secondary outcome measures.

In terms of voluntary work and education/training, 12 participants started voluntary work and 9 entered education/training during the study. This group comprised 7 individuals from the control group and 5 individuals from the intervention group who were volunteering and 3 individuals from the control group and 6 individuals from the intervention group who were in education/training. There were no statistically significant differences for voluntary work between the two groups ( $\text{Chi}^2 = 0.39$ ,  $df = 1$ ,  $p = 0.53$ ) nor for education/training between the control or intervention group ( $\text{Chi}^2 = 1.14$ ,  $df = 1$ ,  $p = 0.28$ ).

### *Reasons for attrition*

The reasons for attrition are shown in the Consort Diagram (Fig 1). These are similar for both arms of the trial: equal numbers people declined IPS with treatment as usual (control), and the work-focussed counselling with IPS (intervention). Thereafter, the loss to study rates are not remarkably different: three people left the country following baseline assessment, all happened to be in the TAU arm of the trial, while one person from the intervention arm sadly died through suicide. Otherwise people were too unwell or declined the follow-up interviews, despite careful steps taken to engage their co-operation; letters were sent to participants who declined, informing them about the importance of staying in the study and their care coordinators were repeatedly contacted to try and re-engage them back into study. Generally, those who left the study were affected by severe mental illness or felt that they had gained little from participation. The people who obtained work remained in contact with the study, with one exception.

*Figure 1 about here*

### *Secondary Outcomes*

Table 4 shows that mean scores for self-esteem, stigma, physical and mental health and for problem-solving measures did not differ significantly between the two study groups. No difference was found at an individual level for most of the secondary outcomes between baseline and 6 months and baseline and 12 months, with three exceptions. Due to the number of t-tests applied, and given the contradictory interpretations of these findings, they may well be due to chance but they are reported here for future reference:

At an individual level, for the entire study sample, repeated measures t-tests indicated significant change in the mean health state score on the EQ-5D between baseline (65.78) and 6 months (70.63) ( $t = -1.98$ ,  $df = 51$ ,  $p < .05$ ) and this was also true comparing baseline (64.95) to 12 months (71.11) ( $t = -2.28$ ,  $df = 41$ ,  $p < .05$ ). The results suggest that individuals perceived their health status to worsen over time.

By contrast, significant difference was found in the vitality scale of the SF-12v2 measure. 'Vitality' measures how much of the time the respondent felt energetic. Vitality scores increased between baseline (2.83) and 12 months (3.19) ( $t = -2.35$ ,  $df = 41$ ,  $p < .05$ ).

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3 Thirdly, change was found in the brief fear of negative evaluation scale scores between  
4 baseline (37.10) and 6 months (34.12) ( $t = 2.37$ ,  $df = 38$ ,  $p < .05$ ), suggesting that individuals'  
5 fear of negative evaluations significantly decreased between baseline and 6 months.  
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#### 8 9 10 11 *Additional Analysis*

12 As an aside from the ITT analysis, if we look post-hoc at the people who took up the  
13 opportunity to engage with the psychotherapeutic input, there is an indication that this  
14 made a difference. Of the 29 people who took up the experimental intervention, 12  
15 obtained employment (41%), compared to 13 of the 45 (29%) who did not receive the  
16 experimental intervention (37 who were randomised to IPS-only group plus 8 who were  
17 randomised to the IPS+ group but did not attend intervention). Although there were no  
18 statistically significant differences between groups ( $\text{Chi}^2 = 0.73$ ,  $p = 0.39$ ), for the people who  
19 received the experimental intervention, the odds ratio of obtaining employment was 1.74  
20 (95% CI = 0.65 – 4.63), suggesting a positive effect of receiving intervention.  
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30 Furthermore, in terms of retention within the trial and in IPS services, fewer of those who  
31 received the work-focussed counselling intervention dropped out than those who had not  
32 received the intervention. Nine of the 29 participants who received intervention dropped  
33 out of the RCT (31%), compared with 23 of the 45 participants who received IPS alone  
34 (51%). Again, this difference was not statistically significant ( $\text{Chi}^2 = 2.14$ ,  $df = 1$ ,  $p = 0.14$ ), but  
35 the odds ratio of 0.43 (95% CI = 0.16 - 1.14) suggests a positive effect of receiving the  
36 intervention.  
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#### 45 **Costs**

46 Table 4 provides means and standard deviations of paid hours, use of services, cost  
47 subtotals and total costs, by group, at baseline and during the subsequent 12-month time  
48 period. The data contained a number of missing values. Some individuals had no data  
49 beyond the baseline assessment. These were dropped from the cost-effectiveness analysis.  
50 Others had at least data for the 3-month period. All cost values, both pre- and post-  
51 baseline, are expressed as over a 3-month period.  
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3 Paid hours appear somewhat higher for the intervention group, both at baseline and during  
4 the 12-month, post-intervention period. Also, total costs are somewhat lower for the  
5 intervention group pre-baseline, and somewhat higher post-baseline, a difference that  
6 arises only partly from the cost of the intervention itself, which averages to £136. More  
7 detailed observation of the distribution of resource use and costs indicated that this  
8 difference was partly due to one participant assigned to the intervention group, who had an  
9 unusually long hospitalization (70 days) towards the end of the one-year post-baseline  
10 period. The participant with the next-highest number of days, who was assigned to the  
11 control group, had 12 days. No other participant was hospitalized. We removed the outlier  
12 from the sample and redid the above calculations as a sensitivity analysis, the results are  
13 shown in Table 4. In order to assess the influence of the multiple imputation procedure on  
14 the results, we also did the calculations, including the individual with a high number of  
15 hospital days, by prorating costs and paid hours rather than by using multiple imputation. It  
16 is important to note that in either case the data in Table 4 show no indication of a possible  
17 cost offset.

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30 *Figures 2a & b about there*

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32 *Figures 3a & b about here*

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36 Figure 2a represents the base case – multiple imputation with complete data. The data  
37 suggest that the intervention is associated with a greater number of paid hours (though the  
38 standard error is greater than the mean – the difference is not statistically significant); it is  
39 also more costly. Costs of the work-focussed intervention were estimated at £136 per  
40 person on average. Only if the decision-maker is willing to pay about £100 per paid hour  
41 does the intervention reach a 50% chance of being cost-effective. If we remove the  
42 individual who had 70 hospital days from the analysis, Figure 2b shows that the difference in  
43 cost between the groups diminishes, without affecting the difference in effectiveness, so  
44 that the apparent cost-effectiveness rises. (Recall that this individual had been assigned to  
45 the intervention group.) The decision-maker needs to be willing to pay about £30, rather  
46 than £100, per paid hour for the intervention to reach a 50% chance of being cost-effective.  
47 Still, even if the decision-maker were willing to pay £100 per paid hour, the probability of  
48 the intervention being cost-effective would only reach about 66%.

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5 Finally, Figures 3a and 3b suggest that, if one abstracts from two unusual individuals with, in  
6 one case, no hours of intervention but a high number of paid hours per week, and in the  
7 other case, 9 hours of psychological intervention but no paid hours, there does seem to be a  
8 possible dose-response relationship between hours of work-focused psychological  
9 intervention and paid hours.  
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### 13 14 15 **Discussion and implications**

16 We found no statistically significant differences between IPS alone and IPS with work-  
17 focussed counselling at any time point on the primary or secondary outcome measures.  
18 While the study does provide some modest encouragement for exploring further the  
19 potential for enhancing IPS with some form of work-focussed counselling, the adjunct  
20 intervention would need to produce a practically significant increase in hours worked to be  
21 considered cost-effective. Waghorn et al. (2009, Table 2) list a range of opportunities for  
22 occupational therapists to enhance employment support for people with mental health  
23 problems, through their professional input as advocates, consultants and practitioners. The  
24 findings reported here may be read in the light of other evidence about 'work-related self-  
25 efficacy', which the same authors define as 'confidence to perform core activities at a  
26 specific task level', and put forward as an area where occupational therapy expertise is  
27 relevant.  
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40 The results also raise a number of learning points which should inform the implementation  
41 of such interventions and the design of future trials of this or similar occupational therapy  
42 interventions. First, the planned sample size was overoptimistic. Despite full co-operation  
43 from senior managers in the service studied and a context amenable to research,  
44 organisational issues – reorganisation, overcrowded offices, and the availability of care co-  
45 ordinators to provide the practical help required to implement the trial, proved  
46 disadvantageous. Second, provision of employment specialists proved more irregular than  
47 intended. Altogether there were 30 months of employment support worker time invested in  
48 the study over a time period of 2 years to treat 74 people. In fact, some people (N = 10)  
49 received only two months of employment specialist support. Studies of IPS (e.g. Perkins,  
50 2005; Rinaldi and Perkins, 2007; Boyce et al., 2008) highlight the importance to service  
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3 users' confidence of the continuity of this contact. Thirdly, the work-focused counselling  
4 intervention was very much a pilot. Six sessions were offered, but participants could stop at  
5 any point. Only six people took up all available sessions and it is unlikely that a low-intensity  
6 intervention would be very powerful. It is also possible that study's intervention was not  
7 sufficiently different from standard IPS in the benefits derived by individual service users.  
8 Both constituted a supportive relationship with a focus on real-world problems; perhaps  
9 that is sufficient to enable a person to pursue his or her work aspirations effectively.  
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17 Two further issues were raised in the implementation of the study. Difficulties were  
18 experienced in completing some of the psychosocial measures, in particular the DEX and  
19 BFNE. More straightforward and user-friendly measures would be preferable if the trial  
20 were to be repeated. Furthermore, the addition of specific anxiety and depression  
21 measures would be helpful considering the popularity of the anxiety and depression topics  
22 among participants. Although receiving CBT was an exclusion criterion for the study, it  
23 emerged that a number of participants (N= 8; 5 intervention and 3 control) did in fact start  
24 seeing clinical psychologists receiving CBT-type therapy after entering the study, either  
25 weekly (3) or fortnightly (5). Given the strong CBT evidence base, future trials should  
26 postpone the start of generic CBT while employment-focused interventions are being  
27 studied.  
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### 38 **Limitations**

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40 The high drop-out rate is the major limitation to this study. Of the 32 who dropped out, 15  
41 were part of the intervention arm and 17 were lost to the control arm. Although no  
42 differences were found in the clinical profile nor the psychometric scores of these two arms,  
43 younger individuals and those who were not actively using the services on offer were more  
44 likely to drop out of the study. Younger individuals present greater likelihood of relapse and  
45 therefore this could have increased the probability of their dropping out (Lysaker and  
46 France, 1999).  
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53 A hostile labour market prevailed throughout the period of the trial with escalating  
54 unemployment figures in the general population. The effects on the trial cannot be  
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3 ascertained, but comparison can be made between the study participants and people across  
4 England and Wales who were unemployed and receiving Job Seeker Allowance during the  
5 same period: The Department of Work and Pensions (DWP) apply an outcome criterion of  
6 13 weeks of continuous paid work, and the national results of the DWP Work Programme  
7 were reported in September 2013 (Centre for Economic and Social Inclusion, 2013). This  
8 found that 11% of the general unemployed population, who were not known to have severe  
9 mental illness, succeeded in attaining employment between July 2012 and June 2013. If we  
10 apply the same 13-week continuous employment measure, 20% of the participants in this  
11 study succeeded retaining work for 13 weeks within 12 months despite the disadvantage of  
12 severe mental health problems.

### 21 **Conclusion**

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24 The learning points about the study could inform future studies. While the hypothesis that  
25 work-focussed counselling would make a significant improvement to IPS outcomes was not  
26 supported by the trial, the data demonstrate that, even during a recession, people with  
27 severe mental health problems can be helped to attain employment through the IPS  
28 approach. Comparison with the general population suggests that the effects of the  
29 recession were not as detrimental to the participants in our study as to the unemployed  
30 population as a whole. This may arguably be because the IPS approach is more effective  
31 than other employment support approaches available to the general population.

### 38 **Key message**

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41 Occupational therapy can offer promising enhancements to IPS, but evaluating their  
42 marginal benefit would require a robust design that is protected against the vicissitudes of  
43 organisational change in the care environment.

### 47 **What the study has added**

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50 The study has shown that IPS can be successfully delivered despite a negative economic  
51 climate in a UK context, and that it is feasible deliver work-focussed counselling as an  
52 adjunct intervention.

### 57 **Competing interests**

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3 The authors declare that they have no competing interests.  
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7 **Authors' contributions**

8 AA obtained ethical clearance, collected the data and undertook data analysis, NC designed,  
9 delivered and evaluated the psychological intervention, overseen by MM who also  
10 undertook the additional analysis. BG analysed the data and generated the statistical  
11 comparisons. EL oversaw the costs analysis, while ZC performed this. JS conceived, managed  
12 and led the study. All authors contributed to the manuscript and approved the final version.  
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**Table 1 Secondary outcome measures**

Measure	Items
Rosenberg Self-Esteem Scale (Rosenberg, 1989)[22]	10
Work Limitations Questionnaire (Lerner et al, 2004a ; 2004b) [23, 24]	25
Stigma Survey (Schneider et al., 2011) [25]	26
Dysexecutive Questionnaire (DEX; Burgess et al., 1996) [26]	20
Social Problem Solving Inventory – Revised (D’Zurilla et al., 2002) [27]	25
Brief Fear of Negative Evaluation (Leary, 1983) [28]	12
Client Service Receipt Inventory (Beecham and Knapp, 1992) [29]	27
Short Form Health Questionnaire (SF-12v2; Ware et al., 2002) [30]	12
EQ5-D (The Euroqol Group, 1990) [31]	5

Peer Review

Table 2 Baseline demographic and clinical characteristics

Demographics and History	IPS Only (N=37) (Control)	IPS +Psychological Intervention (N= 37) (Experimental)
<b>Gender</b>		
Male	26	26
Female	11	11
<b>Mean Age</b>	29.48	30.48
<b>Ethnicity</b>		
White British	24	26
Other white	2	1
Black British	6	7
Other Ethnic Groups	5	3
<b>Mental Illness Diagnosis</b>		
Psychosis	17	15
Schizophrenia	8	9
Bipolar disorder	7	4
Depression	4	6
Other	1	2
<b>Marital Status</b>		
Not Married	31	26
Married	3	4
Other	3	7
<b>Admission to Psychiatric Hospital</b>		
In the past 2 years	16	20
More than 2 years ago	9	5
Never admitted	12	12
<b>History of Paid Employment</b>		
Yes	34	36
No	3	1
<b>Currently on Medication</b>		
Yes	30	29
No	7	8



**Table 3** Mean and standard deviation for secondary outcomes

Measure	Treatment group	N	Baseline Mean (S.D)	N	6 months Mean (S.D)	N	12 months Mean (S.D)
EQ-5D Index value	IPS only	37	.85 (.11)	26	.88 (.11)	20	.90 (.11)
	Intervention	37	.85 (.12)	26	.88 (.10)	22	.86 (.12)
EQ-5D Health state	IPS only	37	69.32 (20.29)	26	76.19 (15.83)	20	75.10 (15.20)
	Intervention	37	63.51 (23.59)	26	65.08 (19.33)	22	67.50 (17.84)
Stigma	IPS only	37	59.46 (13.32)	26	58.77 (10.60)	20	59.55 (10.91)
	Intervention	37	62.14 (12.13)	26	59.54 (11.60)	22	62.95 (14.36)
Self-esteem	IPS only	37	27.95 (6.24)	26	28.42 (5.71)	20	28.90 (6.86)
	Intervention	37	27.08 (5.90)	26	26.77 (6.64)	22	27.36 (6.28)
SF-12v2 physical functioning	IPS only	37	5.19 (1.05)	26	5.31 (.88)	20	5.50 (.69)
	Intervention	37	5.38 (.95)	26	5.42 (.99)	22	5.59 (.59)
SF-12v2 physical activities	IPS only	37	7.73 (2.12)	26	7.54 (2.19)	20	7.65 (1.87)
	Intervention	37	8.05 (2.03)	26	7.88 (2.10)	22	8.05 (2.17)
SF-12v2 Role Emotional	IPS only	37	7.59 (2.14)	26	7.61 (2.00)	20	7.85 (2.01)
	Intervention	37	6.67 (2.09)	26	6.73 (2.25)	22	6.86 (2.08)
SF-12v2 mental health	IPS only	37	7.02 (1.80)	26	7.31 (1.78)	20	5.50 (.69)
	Intervention	37	6.03 (1.74)	26	6.27 (2.25)	22	6.23 (2.14)
SF-12v2 general health	IPS only	37	2.92 (1.04)	26	3.23 (1.14)	20	3.30 (.86)
	Intervention	37	2.73 (1.04)	26	2.85 (.92)	22	3.09 (1.06)
SF-12v2 bodily pain	IPS only	37	4.16 (1.09)	26	4.15 (1.29)	20	4.25 (.97)
	Intervention	37	4.49 (.96)	26	4.58 (.76)	22	4.45 (.80)
SF-12v2 vitality	IPS only	37	2.76 (.95)	26	3.11 (1.03)	20	3.10 (1.29)
	Intervention	37	2.92 (1.16)	26	2.65 (1.05)	22	2.64 (.95)
DEX	IPS only	30	25.13 (13.68)	20	22 (11.40)	15	27.53 (14.13)
	Intervention	28	25.25 (14.22)	19	24.37 (11.62)	15	21.33 (10.09)
FNE	IPS only	30	35.43 (8.68)	20	34.15 (10.46)	15	34.93 (9.56)
	Intervention	28	36.75 (7.05)	19	34.10 (9.64)	15	36 (9.69)
SPSI	IPS only	30	11.77 (3.67)	19	12.20 (3.57)	12	13.01 (2.72)
	Intervention	28	11.72 (3.26)	18	12.05 (2.90)	15	11.30 (4.25)

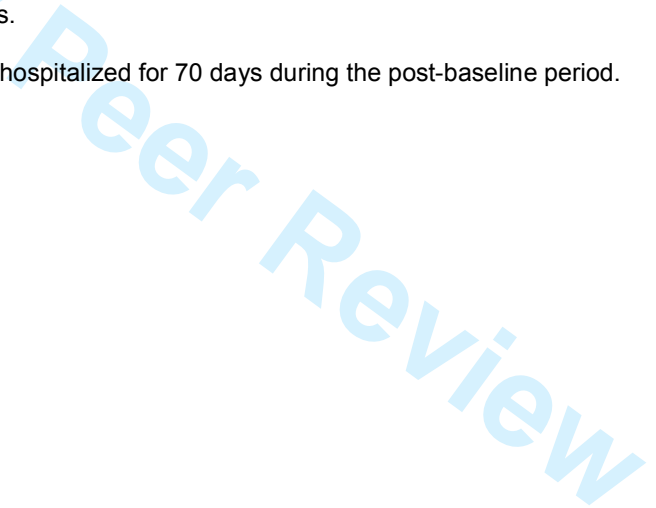
Table 4: Means of costs and work hours by intervention at baseline (3 months before baseline) and over the year post-baseline.‡

Variable	Baseline					0-12M†				
	No intervention (n=37)		Intervention (n¶=36)		P_value#	No intervention (n=29)		Intervention (n=31)		P_value#
	Mean	SD.	Mean	SD.		Mean	Std. Dev.	Mean	SD.	
Paid work (hours/week)	0.3	1.3	1.0	4.8	0.933	2.1	3.8	3.7	7.9	0.681
<b>Cost (£)</b>										
GP	320.0	410.0	195.3	318.0	0.195	181.3	155.8	94.5	102.9	0.0249
Dentist	17.9	29.9	18.4	49.2	0.494	26.0	33.0	24.5	48.9	0.493
Optician	1.2	4.1	0.4	2.5	0.32	1.6	2.6	1.1	2.4	0.365
Chiropodist	0.0	0.0	2.5	15.0	0.311	0.0	0.0	0.7	3.0	0.168
Practice Nurse	37.1	83.1	22.5	69.1	0.279	34.9	51.1	7.4	11.9	0.0066
Other	1.3	8.0	2.7	11.3	0.542	7.9	16.6	4.4	17.7	0.241
Hospital Overnight stay	1,552.0	6,922.0	992.9	4,011.0	0.697	252.6	1,073.0	628.5	2,087.0	0.443
Outpatient Appointment	362.1	520.4	341.2	485.5	0.757	245.7	195.1	298.4	252.2	0.556
A&E Dept	3.5	10.1	2.7	11.8	0.444	2.2	6.4	3.4	7.5	0.538
CCO	442.7	280.7	545.3	338.5	0.154	273.9	260.2	304.6	244.6	0.548
Peer	2.7	12.8	2.1	10.4	0.659	1.0	3.8	1.5	6.2	0.477
Psychiatrist	0.0	0.0	8.9	53.2	0.311	22.0	73.5	7.7	24.0	0.865
Psychologist	0.0	0.0	34.0	163.8	0.149	41.0	138.8	87.7	270.4	0.97
CPN	11.8	71.6	20.5	71.3	0.0953	15.6	57.3	25.1	76.7	0.405
Social worker	54.8	333.4	0.0	0.0	0.324	0.0	0.0	5.0	28.0	0.333
OT	7.3	35.6	3.3	20.0	0.575	5.4	20.3	5.7	24.4	0.477
CMHT or EIP: Other	1.0	6.2	2.1	12.7	0.969	1.0	5.3	0.0	0.0	0.301
SS: Other	42.8	260.4	0.0	0.0	0.324	0.0	0.0	6.4	35.6	0.333
<b>Total cost without IPS</b>	<b>2,858.0</b>	<b>6,909.0</b>	<b>2,195.0</b>	<b>4,015.0</b>	<b>0.834</b>	<b>1,112.2</b>	<b>1,306.0</b>	<b>1,507.0</b>	<b>2,114.0</b>	<b>0.739</b>
<b>Total cost without IPS,</b>	<b>2,858.0</b>	<b>6,909.0</b>	<b>2,236.8</b>	<b>4,065.8</b>		<b>1,112.2</b>	<b>1,306.0</b>	<b>1,199.7</b>	<b>1,264.4</b>	

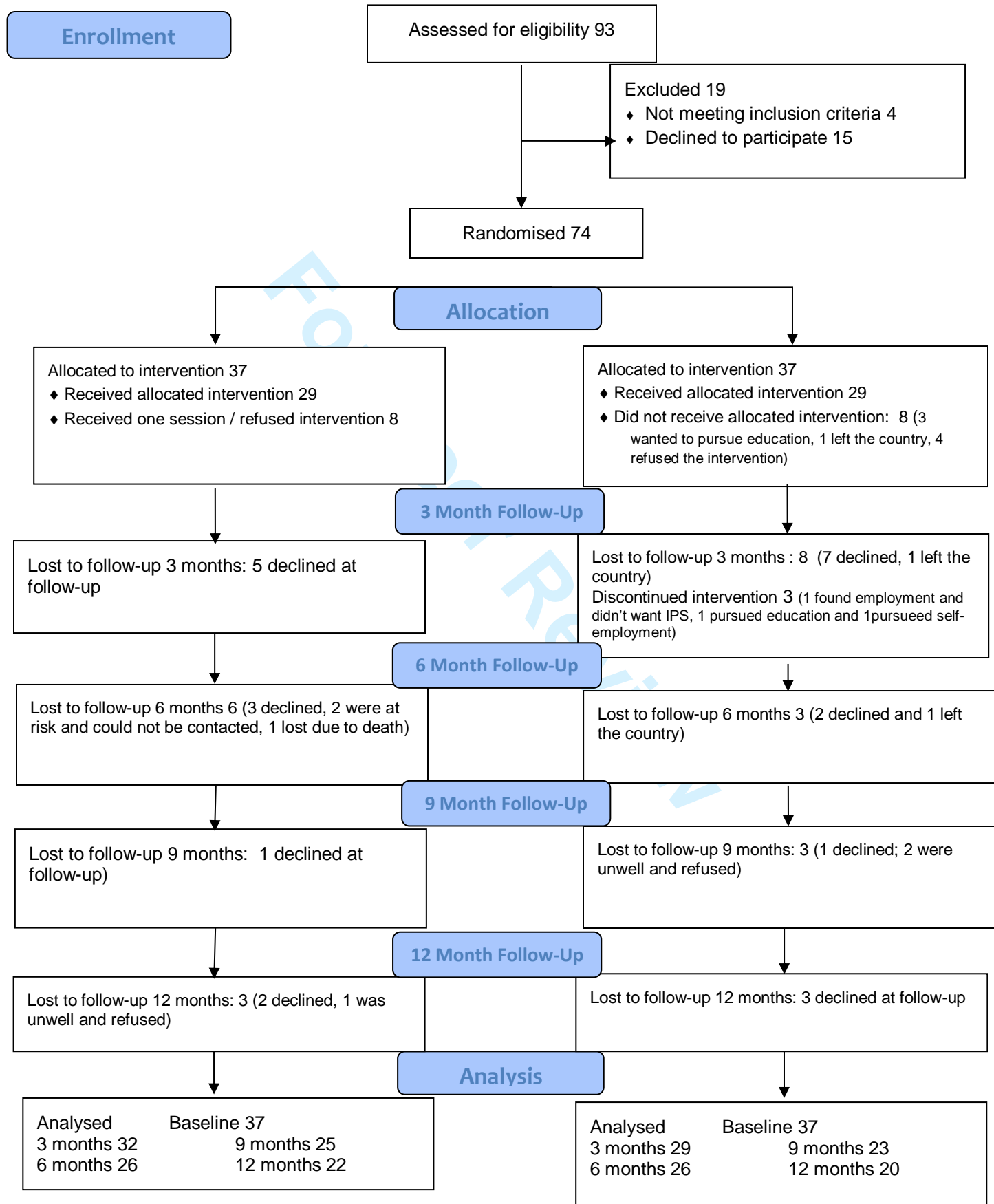
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<b>excluding participant 1034§</b>					0.915					0.904
Employment_Specialist	119.1	508.9	83.8	400.5	0.438	768.3	757.7	741.2	733.6	0.882
<b>Total cost with IPS</b>	<b>2,978.0</b>	<b>6,884.0</b>	<b>2,279.0</b>	<b>3,998.0</b>	<b>0.808</b>	<b>1,880.0</b>	<b>1,387.0</b>	<b>2,248.0</b>	<b>2,030.0</b>	<b>0.559</b>
Intervention						0.0	0.0	136.0*	87.2	----
<b>Total cost with intervention</b>						<b>1,880.0</b>	<b>1,387.0</b>	<b>2,397.0</b>	<b>2,032.0</b>	<b>0.290</b>

‡ Observed means for baseline, and prorated means over the period 0-12 months. All values represent average costs over a 3-month period.  
† N=60. 0 to 12 month cost calculations excluded those who had only baseline data but without any follow-ups.  
¶ One participant (1004) was excluded who had 40 hours/week paid work throughout the observation period, including pre-baseline.  
\* N=36, but 5 participants (1070, 1009, 1060, 1066, 1071) did not have any follow-ups. Two of these got intervention sessions (1060:2, 1071:6). Those 5 participants are excluded from the total cost calculations.  
# From Mann-Whitney Test  
§ This outlier participant from the intervention group was hospitalized for 70 days during the post-baseline period.



IPS Study Consort Diagram



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**Figure 2: Box plots of average paid hours per week in 0-12 month period, and average improvement in paid hours per week from baseline to 0-12 month, by intervention group (N=60)**



Figure 3a: Average paid hours per week during the 0 – 12 month period vs. number of work-focused psychological intervention sessions received (Intervention group only, N=31)

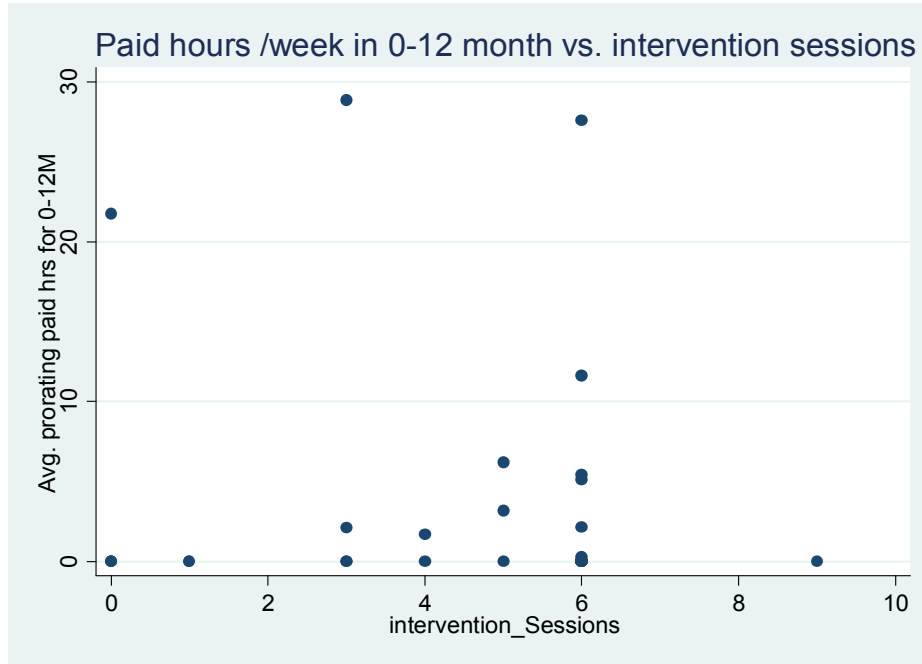
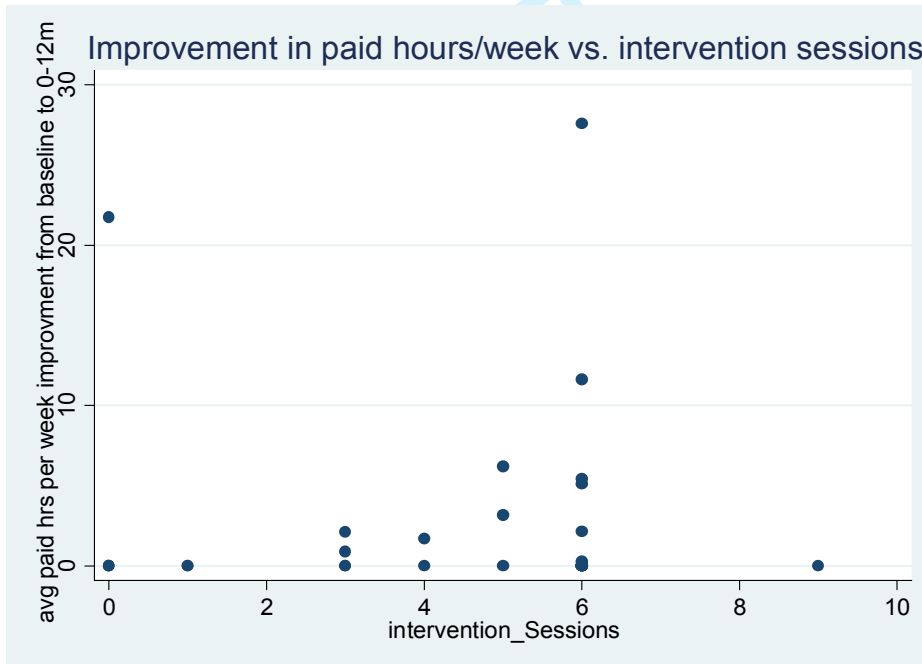


Figure 3b : Improvement in average paid hours per week vs. number of work-focused psychological intervention sessions received (Intervention group only, N=31).



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1 **Table A.1. Unit costs and their sources**<sup>1</sup>

Variables	Unit cost	Notes
GP	£ 185.00	"10.8b General Practitioner - unit costs" Hour/minute of patient contact: average clinic visit time 17.2 minutes Includes direct care staff costs (practice nurses) Excludes qualification costs.
Dentist	£ 66.38	Average of lowest (£33) and highest quartile (£72) costs "per attendance" of Community Dental Services (source PSSRU 2005). Adjusted for 2012 inflation (average 3.4% per year, online Bank of England calculator)
Optician	£ 14.90	Average NHS voucher expenditure on sight tests. From "General Ophthalmic Services: Activity Statistics for England, year ending 31 March 2012". (99.8% of NHS sight tests performed by optometrists, not ophthalmologists)
Chiropodist	£ 30.00	
PracticeNurse	£ 45.00	"10.6 Nurse (GP practice)" Per hour of face to face contact Excludes qualification costs Duration of contacts: 15.5 min (per surgery consultation)
Other	£ 48.5	This type of "Other" response was Average of unit cost for a CPN and for an OT.
Hospital_Overnightstay	£ 586.00	"7.1 NHS reference costs for hospital services - Non-elective inpatient stays (short stays)":
Outpatient_App	£ 319.00	15.7 Consultant: Psychiatrist Per face to face contact Excludes qualification costs
AandE_Dept	£ 32.00	7.1 NHS reference costs for hospital services - Walk in services leading to admitted
CCO	£ 67.00	10.2 Nurse (Mental Health) Per hour of face to face contact Excludes qualification costs
Peer	£ 6.19	2012 UK minimum wage
Psychiatrist	£ 319.00	15.7 Consultant: Psychiatrist Per face to face contact Excludes qualification costs
Psychologist	£ 136.00	9.5 Clinical Psychologist Per hour of client contact
CPN	£ 67.00	10.2 Nurse (Mental Health) Per hour of face to face contact Excludes qualification costs
Social worker	£ 156.00	11.2 Social worker (adult services) Per hour of face to face contact Excludes qualification costs
OT	£ 30.00	9.2 NHS Community Occupational Therapist Includes qualification costs
CMHTorEIP_Other	£ 38.00	12.2 Community mental health team for adults with mental health problems Per hour per team member

Employment Specialist	£ 232.00	We estimated £ 61,039 as the annual wage of an employment specialist, with oncosts and overhead included. In total, 8.6 full-time equivalent employment specialists provided 2,270 contacts, for a cost per contact of $8.6 \times \text{£ } 61,039 = \text{£ } 524,935 / 2,270 = \text{£ } 232$ .
SS_CCO	£ 67.00	10.2 Nurse (Mental Health) Per hour of face to face contact Excludes qualification costs
Homecare	£ 23.00	11.5 Home care worker. Based on the price multipliers for the independent sector provided for social services : Face to face per hour (weekday)
SS_Other	£ 156.00	Unit cost for a social worker visit
Intervention Psychologist	£ 136.00	9.5 Clinical Psychologist Per hour of client contact

## Notes:

<sup>1</sup> Based on the most recently available PSSRU unit costs (2012).

<sup>2</sup> This is an approximate number that may be revised for the final report.



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Responses to comments IPS paper September 25 2015		
	Comments to the Author	
1	In terms of its relevance to occupational therapy, there is an important point missing from the key message about occupational therapists' role in the effective delivery of IPS as well as in the enhancement to IPS.	See new opening sentence and paragraph added to the discussion. Unfortunately, it is difficult to go into this in depth but we think that by referencing Arbesman & Logsdon (2011) and Waghorn (2009) we have indicated the additional body of literature relevant to OTs.
2	The referencing to the IPS literature is not up to date and in parts of the manuscript is actually incorrect or confusing	Newer citations added: Kinoshita et al., 2013, Marshall et al., 2014. Drake & Bond, 2014. Again, lack of space means these are indicative of a wider body of work.
3	The fidelity of implementation to IPS needs reporting, so that its contribution to the outcomes obtained can be better understood and discussed	The following has been inserted: <i>"The fidelity of the IPS service input for the study was measured in October, 2010, at the start of recruitment, by an independent team who visited the site, following the 25-point Fidelity Scale published online as IPS Resources for Trainers and Fidelity Reviewers (IPS Dartmouth Supported Employment Centre, 2015). The preliminary score was 63 'not IPS' because all the community mental health teams had been merged into one, creating a highly diluted IPS service, reviewers commented that "...there will need to be structural changes to the way the service is managed if it is to deliver the outcomes expected of a high fidelity service". To achieve a more rigorous model of IPS, after recruiting 17 participants, the focus of the study shifted to a team dealing with early psychosis, where the remaining 57 participants were recruited up to June, 2012. This team was smaller, working with a younger clientele and more amenable to implementing IPS fully. The next external fidelity review, in February 2012, scored the service fidelity as 'good' with 101 points."</i>
4	The primary outcome is not clear, and a definition of paid employment is needed.	We have added the phrase 'in the open labour market' to our definition of the primary outcome. See 13 below for clarification of primary outcome.
5	Throughout the document difference phrases are used to	Standardised as 'work-focussed counselling' throughout.

	describe the intervention.	
6	Following these changes, I recommend the abstract and conclusions are revised accordingly.	Done
	Introduction	
7	More up to date references can be used for the opening statement about the evidence base for IPS –	See 2 above
	Methods	
8	The authors should report here how the CONSORT methods for conducting RCTs were followed.	Consort diagram was inadvertently omitted from the submission and has been reintegrated.
9	Interventions: Treatment as usual A more accurate citation than to the Dartmouth website list of principles as the authors are trying to convey not just the principles but the method of implementation as well.	A more recent edition has been cited: Swanson, S & Becker, D (2011) <i>Supported employment: A practical guide for practitioners and supervisor</i> . 2nd edition. Hazelden Publishing & Educational Services, Center City, Minnesota.
10	Fidelity measurement – the reference used is Bond et al, 1997 – this is the IPS-15 scale. Was this scale used, or was the IPS-25 used? Please clarify, and also outline - how fidelity was measured (internal review, research team review or an independent review and the process used	The paragraph now reads: <i>“The key objectives and methods of working within an IPS model are well established (Dartmouth IPS Supported Employment Center, 2012). Broadly, this entails intensive, individualised, employment-focussed advice and practical support without time limit. The fidelity of the particular IPS service provided for the study was measured in October, 2010, at the start of</i>

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	<p>(telephone interviews, on-site for 2 days?),</p> <p>what the scores were and which individual items the program did not score a 4 or 5 on.</p>	<p><i>recruitment, by an independent team who visited the site, following the 25-point Fidelity Scale published online as IPS Resources for Trainers and Fidelity Reviewers (IPS Dartmouth Supported Employment Center, 2015). The preliminary score was 63, 'not IPS', because all the community mental health teams had been merged into one, creating a highly diluted IPS service, and reviewers commented that "...there will need to be structural changes to the way the service is managed if it is to deliver the outcomes expected of a high fidelity service". Since changing mental health services structures was beyond the scope of the study, after recruiting 17 participants, in order to achieve a more rigorous model of IPS, the focus of recruitment shifted to a team dealing with early psychosis, where the remaining 57 participants joined the study by June, 2012. This team was smaller, working with a younger clientele and more amenable to implementing IPS fully. The next external fidelity review, in February 2012, scored the service fidelity as 'good' with 101 points. "</i></p> <p>In our view giving the detail requested on individual items would not improve the paper because the ratings were not done by the researchers. While the global scores serve to describe the IPS available to our participants, sub-scores would add little information to this paper without a great deal of contextual detail. It's our considered view that this detail is not relevant to the paper as an account of a pragmatic trial; the total scores give sufficient information. Moreover, the sub-scores are data for which the research team cannot vouch.</p>
	Work-focussed intervention	
11	It is hard to understand if Working Well! is what the work-focused intervention etc.	Please see response to comment 5.
12	Finally how was the quality of the psychological intervention measured?	<i>Added: The intervention was independently evaluated using a qualitative approach and this is reported in Boycott, Akhtar and Schneider (2015).</i>

	Outcomes	
13	Primary outcome - It would be good if the authors could outline their rationale for choosing 'total number of hours completed in paid employment within 6 months' which is a different primary outcome from the majority of other IPS RCTs. i.e. commenced a competitive job for one day during the study period.	We have added." <i>Whereas many IPS studies use a bivariate measure of whether or not a person was in work at the primary end point, the fact that both intervention and control groups were both in receipt of IPS led us to adopt a measure that would reflect differences in overcoming barriers to sustained employment, such as work-focussed counselling was designed to impart. Hence the amount of time in the workplace was chosen to differentiate the intervention and control groups at six months."</i>
14	However, it is worth noting that this differs from the information on page 8, when reporting results under 'the primary outcome', job starts are actually reported as well as the hours. It would therefore be good for the authors to clarify the primary outcome(s) Could the authors also please include the definition of paid employment used and highlight any differences in their definition to the definition of competitive employment as defined by the majority of RCTs.	Both points addressed at 4 above.
	Sample size and amendments	
15	It is not clear why the authors estimated that only 25% of their control group (IPS) would obtain work and cite Bond et al., 2008, when the control sites in this systematic review were not delivering IPS – would the authors not have expected their control to obtain 60% outcomes as these are the average outcomes achieved in the Bond et al, 2008 systematic review by the IPS sites? If not, why not?	This was a cautious estimate and proved prescient since the implementation of IPS was sub-optimal. The text now reads: <i>"The original sample size calculations derived from estimates that 25% of the control group and 40% of the intervention group would obtain work. While this estimate was informed by the IPS literature (e.g. Bond et al., 2008), the pragmatic nature of the study led us to adopt conservative employment rates for both arms of the trial."</i>

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	Limitations	
16	In the discussion on the influence of labour market it would be worth citing Catty et al, 2007 (from the EQOLISE trial) where the specific effect of the local unemployment rate on employment outcomes were documented. I am not sure the DWP comparisons are that helpful, after all a 7% increase in outcomes is small given the intensive employment program offered in this trial. If the Work Programme data is kept in, then it will be important to explain briefly what 'the Work Programme offers' and how this compares to IPS.	The same study has been cited as Knapp et al. in terms of its cost-effectiveness. The EQOLISE trial was a cross-national comparison, with widely varying labour markets and social security systems. We consider that UK-specific data are a more relevant comparator in the context of our small, local study. This is our justification for the DWP comparison.
	Conclusion	
17	The hypothesis stated here is different from that outlined at the start of the study. The term CBT is used, whereas in the introduction 'work-focused intervention' is used.	Corrected
	What the study has added - Again the term CBT is used.	Corrected
	Reviewer: 2	
	Comments to the Author	
18	1. The intervention has to be defined and better described. Authors suggest to consult the following paper for obtaining more information on the intervention: Boycott N, Schneider J, McMurrin M (2012) Interventions to Enhance the Effectiveness of Individual Placement and Support: A Rapid Evidence Assessment, Rehabilitation	This now reads: <i>"This intervention was developed and piloted as part of the present study; informed by previous studies (Coldham et al., 2002; Rose and Perz, 2005; Boycott et al., 2012) and based on generic psychological practice, including goal-based motivational procedures and cognitive behaviour therapy (CBT). This work-focussed counselling intervention was designed to enhance the impact of IPS by addressing common obstacles to employment which are not directly due to</i>

	<p>Research and Practice Article ID 382420, 8 pages, doi:10.1155/2012/382420. However, this paper presents different types of interventions (e.g., skills training, cognitive remediation) and consequently, the reader does not know which intervention has been retained for the present manuscript. Has the content been developed from these interventions? On reading, the content appears related to psycho-education and not CBT per se. Please give more details on this intervention.</p>	<p><i>symptomatology (e.g. hallucinations) and not normally the concern of the clinical team (e.g. medication adherence). An intervention manual based on a life goals and a problem solving approach was developed and supplemented by self-help materials. It was delivered by a trained psychologist (NB) with individual participants. Each received a booklet ('Working Well!') containing information about six topics (anxiety, depression, self-esteem, memory/concentration, stigma and getting on with others) and was asked to choose a maximum of four topics to discuss with the psychologist over up to 6 sessions lasting about an hour, mostly taking place in the participant's home. The intervention was independently evaluated using a qualitative approach and this is reported in Boycott, Akhtar and Schneider (2015)."</i></p>
19	<p>2. In link with the previous point, results from the pilot project are non-significant and I am wondering if it is due to the content of the intervention or the sample size. Two suggestions: to better define the intervention (i.e. components and goals) as mentioned above and comment on potential gaps, or recruit more participants for the study or both suggestions.</p>	<p>This is discussed in the paper on p12ff</p>
20	<p>3. The consort diagram is not included in the manuscript, and the table 1 needs more details (ex. alphas, sub-scales). With respect to table 3, the information could be only included into the text.</p>	<p>Consort diagram has been added. Table 1 applies to the methods rather than the results and describes the numerous scales uses. Table 3 has been deleted since the details are in the text and replaced with a table of results from the secondary outcome measures.</p>
21	<p>4. I am not convinced when authors mentioned (in the section entitled: what the study has added) that CBT is broadly acceptable and feasible as an adjunct intervention to IPS. Please give more arguments.</p>	<p>Corrected</p>
22	<p>The cost evaluation requires to be evaluated by an expert on this domain.</p>	<p>This is a comment for the editor.</p>

## Introduction

Occupational therapists have always been at the vanguard of innovation and development in promoting employment for people with mental health problems, both in the UK (Rinaldi & Perkins, 2007) and beyond (Waghorn et al., 2009). The approach called Individual Placement and Support (IPS) has a good evidence base (Burns et al., 2007; Marwaha et al., 2007; Kinoshita et al., 2013, Marshall et al., 2014, Drake & Bond, 2014) but its implementation is exacting in many ways. For instance, it requires co-location of employment support staff with community mental health staff, and this can present organisational barriers. Also, IPS employment support workers should have caseloads of about 20, enviably low compared to caseloads of most community mental health team members (Swanson and Becker, 2011, Schneider and Akhtar, 2012). In short, while IPS is increasingly widely-adopted in the UK, it cannot be said to be part of 'standard' mental health services.

## Literature review

There has been a call for a 'more formal evidence base for occupational therapy interventions in the field of supported employment' (Priest and Jones, 2010). Arbesman and Logsdon (2011) reviewed the OT literature on employment support and concluded that IPS had 'strong evidence' in its favour but its outcomes were stronger in combination with cognitive or social skills training. Our earlier review concluded that more evidence was needed concerning the potential to increase the power of IPS by combining it with adjunct interventions (Boycott et al., 2012). There is increasing evidence that on its own IPS results in significant cost offsets by increasing the proportion of clients who work (Bush et al., 2009; Kilian et al., 2011; Perkins et al., 2005; Schneider et al., 2009). In terms of both days worked and whether the individual had worked at least for one day, IPS generated improvements and was cost-saving from the point of view of the health and social care systems (Knapp et al., 2013). However a key question about enhancing IPS is the whether the additional cost of the enhancement is warranted by the benefits.

The present study aimed therefore to test the hypothesis that ***work-focused counselling as an adjunct to IPS will prove more successful in helping people with schizophrenia and***

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3 *related disorders into paid employment than IPS alone.* The design was a two-arm,  
4 parallel, randomised controlled trial of enhanced IPS versus IPS alone, with a cost-  
5 effectiveness arm added because of previous findings cited above. By taking a pragmatic  
6 and exploratory approach we sought also to investigate whether participation might affect  
7 engagement with education, training and volunteering, as well as the implications of the  
8 findings for the wider implementation of IPS. Here, we report on the results of the main  
9 outcome, paid employment in the open labour market, and on the take-up of education,  
10 training and volunteering, together with the results of the costs analysis. The implications  
11 for the wider implementation and evaluation of IPS are also considered in our discussion  
12 below.  
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## 22 **Method**

### 23 **Setting**

24 This context for this study was a Collaborative for Leadership in Applied Health Research  
25 and Care (CLAHRC), focusing on putting evidence into practice (Rowley et al., 2012). The  
26 study was undertaken in one mental health provider, Nottinghamshire Healthcare NHS  
27 Trust. A preliminary phase put in place a fully-operational IPS service through the  
28 appointment of an IPS Development Manager for two years (Schneider and Akhtar, 2012).  
29 Following this period, the present study recruited participants from the caseloads of one  
30 Community Mental Health team ('Rehabilitation and Recovery') and one Early Intervention  
31 in Psychosis (EIP) team based within Nottinghamshire Healthcare NHS Trust (NHCT) in 2010-  
32 2012. A positive ethical opinion was granted by Derbyshire Research Ethics Committee  
33 (ISRCTN18240558).  
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### 45 **Inclusion and Exclusion Criteria**

46 People who consented to participate were eligible if they were aged 18-60 and on the  
47 caseload of the Rehabilitation and Recovery or EIP teams. We excluded anyone who was an  
48 inpatient at the time of the invitation to participate, people currently in work or in  
49 education and those not wishing to work, anyone who was unable to give informed consent,  
50 and anyone who was already receiving cognitive behaviour therapy (CBT). Provision was  
51 made to employ interpreters but none required this support. The initial approach to service  
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3 users was made by their usual care co-ordinators and interested parties responded directly  
4 to the research team or via the care co-ordinator.  
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### 8 **Randomisation**

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10 The researcher, after gaining informed consent, entered participants' details onto a web-  
11 based randomisation system. Group allocation was sent directly via encrypted email to an  
12 administrator, who forwarded details to the psychologist delivering the intervention.  
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15 Details of allocation were kept by the administrator and psychologist in password-protected  
16 files. The psychologist made contact with participants in the intervention arm to inform  
17 them of their allocation. The researcher responsible for assessing participants at baseline  
18 and follow-up was thus 'blind' to allocation until all data collection had been completed.  
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### 24 **Interventions**

#### 25 *Treatment as usual - IPS*

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27 On enrolment to the study participants were assigned to an Employment Specialist (an IPS-  
28 trained worker) who met with them at a mutually-agreed location (often the participant's  
29 home) to produce an action plan for employment. Participants continued to meet with  
30 their Employment Specialist as often as they wished, in keeping with the responsive ethos of  
31 the intervention. The key objectives and methods of working within an IPS model are well  
32 established (Dartmouth IPS Supported Employment Center, 2012). Broadly, this entails  
33 intensive, individualised, employment-focussed advice and practical support without time  
34 limit. The fidelity of the particular IPS service provided for the study was measured in  
35 October, 2010, at the start of recruitment, by an independent team who visited the site,  
36 following the 25-point Fidelity Scale published online as *IPS Resources for Trainers and*  
37 *Fidelity Reviewers* (IPS Dartmouth Supported Employment Center, 2015). The preliminary  
38 score was 63, 'not IPS', because all the community mental health teams had been merged  
39 into one, creating a highly diluted IPS service, and reviewers commented that "...there will  
40 need to be structural changes to the way the service is managed if it is to deliver the  
41 outcomes expected of a high fidelity service". Since changing mental health services  
42 structures was beyond the scope of the study, after recruiting 17 participants, in order to  
43 achieve a more rigorous model of IPS, the focus of recruitment shifted to a team dealing  
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3 with early psychosis, where the remaining 57 participants joined the study by June, 2012.  
4 This team was smaller, working with a younger clientele and more amenable to  
5 implementing IPS fully. The next external fidelity review, in February 2012, scored the  
6 service fidelity as 'good' with 101 points.  
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### 10 11 *Work-Focussed Counselling Intervention*

12 In addition to IPS as described above, participants randomised to the intervention arm of  
13 the trial were offered 3-6 sessions of work-focussed counselling delivered by a psychologist.  
14 This intervention was developed and piloted as part of the present study; informed by  
15 previous studies (Coldham et al., 2002; Rose and Perz, 2005; Boycott et al., 2012) and based  
16 on generic psychological practice, including goal-based motivational procedures and  
17 cognitive behaviour therapy (CBT). This work-focussed counselling intervention was  
18 designed to enhance the impact of IPS by addressing common obstacles to employment  
19 which are not directly due to symptomatology (e.g. hallucinations) and not normally the  
20 concern of the clinical team (e.g. medication adherence). An intervention manual based on  
21 a life goals and a problem solving approach was developed and supplemented by self-help  
22 materials. It was delivered by a trained psychologist (NB) with individual participants. Each  
23 received a booklet ('Working Well!') containing information about six topics (anxiety,  
24 depression, self-esteem, memory/concentration, stigma and getting on with others) and  
25 was asked to choose a maximum of four topics to discuss with the psychologist over up to 6  
26 sessions lasting about an hour, mostly taking place in the participant's home. The  
27 intervention was independently evaluated using a qualitative approach and this is reported  
28 in Boycott, Akhtar and Schneider (2015).  
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### 45 **Outcomes**

#### 46 *Primary*

47 The main outcome was the total number of hours in paid employment (in the open labour  
48 market) 6 months after entering the trial. Whereas many IPS studies use a bivariate  
49 measure of whether or not a person was in work at the primary end point, the fact that  
50 both intervention and control groups were both in receipt of IPS led us to adopt a measure  
51 that would reflect differences in overcoming barriers to sustained employment, such as  
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work-focussed counselling was designed to impart. Hence the amount of time in the workplace was chosen to differentiate the intervention and control groups at six months.

### *Secondary*

The study was implemented at a time of economic recession in the UK, which seemed likely to adversely affect the job prospects of participants, so vocational activities such as education, training and volunteering were also measured. The questionnaires used are listed in Table 1. They include the Rosenberg Self-Esteem Scale (Rosenberg, 1965), the EQ-5D (EuroQOL Group, 1990) and the Client Service Receipt Inventory (Beecham and Knapp, 1992) which yield data required for estimating and comparing costs, and the SF-12 which measures health and wellbeing (Ware et al., 2002). Less widely-used measures were applied to explore the impact on self-assessed barriers to work (Lerner et al., 2004a, 2004b) perceived stigma (Schneider et al., 2011), avoidance of social disapproval (Leary, 1983), social cognition (Burgess et al., 1996) and social problem solving (D’Zurilla et al., 2002).

### *Table 1 about here*

The researcher assessed participants face-to-face at baseline, 6 and 12 months and by telephone at 9 months. Demographic, work and education history and clinical details were gathered at baseline. At baseline, 3, 6, 9 and 12 months, the researcher collected data about working hours, welfare benefits received and services used (excepting the experimental intervention). Secondary outcome measures shown in Table 1 were administered at baseline, 6 and 12 months to both groups. At about 9 months, qualitative interviews were held with an opportunistic sample of 31 individuals, to explore the participants’ experience of the intervention, their satisfaction with the process and how it could be improved.

### **Sample size and amendments**

The original sample size calculations derived from estimates that 25% of the control group and 40% of the intervention group would obtain work. While this estimate was informed by the IPS literature (e.g. Bond et al., 2008), the pragmatic nature of the study led us to adopt conservative employment rates for both arms of the trial. For an 80% power of

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3 demonstrating this difference ( $p < 0.05$ ), 165 participants were required in each arm of the  
4 trial. Recruitment during the first 6 months was 17 and it emerged that one Employment  
5 Specialist's caseload capacity was constrained by pre-existing clients, while as noted above  
6 organisational restructuring made IPS fidelity inadequate. Application was therefore made  
7 to the ethics committee for a substantial amendment to enable the study to recruit from an  
8 Early Intervention in Psychosis team, while the target sample size was revised downwards to  
9 a minimum of 28 per arm on the basis of what would be feasible within the constraints of  
10 the funding and remaining time available. The amendment also extended three  
11 psychometric measures (DEX, SPSI-R and BFNE, 20-22), which had initially only been used  
12 with the intervention group, to be used with all participants. This was to assess any  
13 treatment affects, which we expected to be greater in the intervention group. The possible  
14 sample size for the DEX, FNE and SPSI was therefore reduced by 17 because these measures  
15 were only introduced after that number of participants had been recruited.  
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### 28 **Statistical analysis**

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30 The primary analysis was intention-to-treat and included all participants who were  
31 randomly assigned to their respective groups (intervention or control), regardless of  
32 whether they engaged with IPS/enhanced IPS or not. Participants who were lost to follow-  
33 up were assumed to be not working and the number of hours was recoded as zero.  
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### 38 **Costs estimation and analysis**

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40 To estimate costs, we multiplied frequencies obtained by, in most but not all cases, PSSRU  
41 unit costs for 2012 (PSSRU, 2013). Details are in the Appendix. For the purpose of  
42 examining the distributions of the values, we prorated available data to obtain annualized,  
43 and thus comparable, numbers. Having done this, we calculated means by group. We also  
44 used box plots to compare the distributions of paid hours post-baseline for the intervention  
45 and control groups, as well as improvement in paid hours (adjusting for baseline  
46 differences).  
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54 Bootstrapping and multiple imputation were used to both estimate the incremental cost-  
55 effectiveness ratio (ICER), and assess uncertainty in the ICER. We began by obtaining 1000  
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sample replicates using bootstrapping. For each sample, we used multiple imputation (with 20 imputed data sets) to calculate a mean cost and mean effect. These were plotted on a cost-effectiveness plane. From the location of the points on the cost-effectiveness plane, a cost-effectiveness acceptability curve was derived. This procedure also is used to compute an ICER and a standard error for the ICER; 'bootstrap' and 'mi' procedures in Stata 13 were used to calculate this.

Finally, we examined bivariately whether there appeared to be an association between paid hours, or improvement in paid hours, on the one hand, and on the other hand, the number of hours of psychological intervention received. If the psychological intervention increased paid hours, one would expect to see a dose-response relationship.

## Results

Seventy four individuals were recruited to the study from August 2010 to June 2012, 37 randomised to each arm. In total, 32 of these individuals (43%) were lost to follow-up (see Consort diagram). Their destinations up are unknown but in the analysis we assume they were not working.

### *Adverse events*

One participant committed suicide during the trial, but this was judged to be due to a significant mental health relapse and not related to participation in the study. No other adverse effects were reported.

### *Attrition*

Attrition analyses were conducted in relation to gender, age, clinical history and the secondary outcome measures. Independent t-tests showed a statistically significant difference for age; individuals who stayed in the study were older with a mean age of 32.23 (s.d. 9.69) as compared to 27.03 (s.d. 9.32) ( $t = -2.33$ ,  $df = 72$ ,  $p < .05$ ). No other differences were found for individuals who stayed in the study in comparison to those who were lost to follow-up at each time-point.

*Figure 1 (Consort Diagram) about here*

### *Demographic and Clinical Characteristics*

Table 2 shows the demographic and clinical characteristics of the entire sample.

Independent t-tests and non-parametric Mann Whitney U-tests were conducted to compare the two groups' demographic and clinical characteristics. No significant differences were found, suggesting that the two groups were equally matched at baseline for age, ethnicity, marital status and clinical history.

*Table 2 about here*

### *Primary Outcome*

In relation to the primary outcome, hours per week (hpw) of (paid) employment after six months, the mean hpw worked was 3.22 (s.d. 9.53) for the 37 individuals who were part of the control group, and 3.89 hpw (s.d. 10.60) for the 37 individuals who were part of the intervention group. At 12 months the mean number of hours worked by individuals who were part of the control group (N = 37) was 3.67 (s.d. 7.80) and 7.07 (s.d. 14.09) for individuals who were part of the intervention group (N = 37) (Table 3). Using the Mann-Whitney U test, no statistically significant difference was found between the intervention and control groups in relation to the main outcome; mean number of hours worked per week at 6 months ( $z = 0.57$ ,  $p = 0.56$ ) and this was also true at 12 months ( $z = 0.71$ ,  $p = 0.48$ ). Twenty five out of 74 people entered employment over the course of the study. Of this number, 12 were working full time, defined as 35-45 hours hpw, 3 worked 20-30 hpw, 6 worked 10-16 hpw and 4 less than 10 hpw.

There were no statistically significant differences between the two groups at any time point on the secondary outcome measures.

In terms of voluntary work and education/training, 12 participants started voluntary work and 9 entered education/training during the study. This group comprised 7 individuals from the control group and 5 individuals from the intervention group who were volunteering and 3 individuals from the control group and 6 individuals from the intervention group who were in education/training. There were no statistically significant differences for voluntary work between the two groups ( $\text{Chi}^2 = 0.39$ ,  $df = 1$ ,  $p = 0.53$ ) nor for education/training between the control or intervention group ( $\text{Chi}^2 = 1.14$ ,  $df = 1$ ,  $p = 0.28$ ).

### *Reasons for attrition*

The reasons for attrition are shown in the Consort Diagram (Fig 1). These are similar for both arms of the trial: equal numbers people declined IPS with treatment as usual (control), and the work-focussed counselling with IPS (intervention). Thereafter, the loss to study rates are not remarkably different: three people left the country following baseline assessment, all happened to be in the TAU arm of the trial, while one person from the intervention arm sadly died through suicide. Otherwise people were too unwell or declined the follow-up interviews, despite careful steps taken to engage their co-operation; letters were sent to participants who declined, informing them about the importance of staying in the study and their care coordinators were repeatedly contacted to try and re-engage them back into study. Generally, those who left the study were affected by severe mental illness or felt that they had gained little from participation. The people who obtained work remained in contact with the study, with one exception.

*Figure 1 about here*

### *Secondary Outcomes*

Table 4 shows that mean scores for self-esteem, stigma, physical and mental health and for problem-solving measures did not differ significantly between the two study groups. No difference was found at an individual level for most of the secondary outcomes between baseline and 6 months and baseline and 12 months, with three exceptions. Due to the number of t-tests applied, and given the contradictory interpretations of these findings, they may well be due to chance but they are reported here for future reference:

At an individual level, for the entire study sample, repeated measures t-tests indicated significant change in the mean health state score on the EQ-5D between baseline (65.78) and 6 months (70.63) ( $t = -1.98$ ,  $df = 51$ ,  $p < .05$ ) and this was also true comparing baseline (64.95) to 12 months (71.11) ( $t = -2.28$ ,  $df = 41$ ,  $p < .05$ ). The results suggest that individuals perceived their health status to worsen over time.

By contrast, significant difference was found in the vitality scale of the SF-12v2 measure. 'Vitality' measures how much of the time the respondent felt energetic. Vitality scores increased between baseline (2.83) and 12 months (3.19) ( $t = -2.35$ ,  $df = 41$ ,  $p < .05$ ).

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3 Thirdly, change was found in the brief fear of negative evaluation scale scores between  
4 baseline (37.10) and 6 months (34.12) ( $t = 2.37$ ,  $df = 38$ ,  $p < .05$ ), suggesting that individuals'  
5 fear of negative evaluations significantly decreased between baseline and 6 months.  
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#### 10 *Additional Analysis*

11 As an aside from the ITT analysis, if we look post-hoc at the people who took up the  
12 opportunity to engage with the psychotherapeutic input, there is an indication that this  
13 made a difference. Of the 29 people who took up the experimental intervention, 12  
14 obtained employment (41%), compared to 13 of the 45 (29%) who did not receive the  
15 experimental intervention (37 who were randomised to IPS-only group plus 8 who were  
16 randomised to the IPS+ group but did not attend intervention). Although there were no  
17 statistically significant differences between groups ( $\text{Chi}^2 = 0.73$ ,  $p = 0.39$ ), for the people who  
18 received the experimental intervention, the odds ratio of obtaining employment was 1.74  
19 (95% CI = 0.65 – 4.63), suggesting a positive effect of receiving intervention.  
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30 Furthermore, in terms of retention within the trial and in IPS services, fewer of those who  
31 received the work-focussed counselling intervention dropped out than those who had not  
32 received the intervention. Nine of the 29 participants who received intervention dropped  
33 out of the RCT (31%), compared with 23 of the 45 participants who received IPS alone  
34 (51%). Again, this difference was not statistically significant ( $\text{Chi}^2 = 2.14$ ,  $df = 1$ ,  $p = 0.14$ ), but  
35 the odds ratio of 0.43 (95% CI = 0.16 - 1.14) suggests a positive effect of receiving the  
36 intervention.  
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#### 45 **Costs**

46 Table 4 provides means and standard deviations of paid hours, use of services, cost  
47 subtotals and total costs, by group, at baseline and during the subsequent 12-month time  
48 period. The data contained a number of missing values. Some individuals had no data  
49 beyond the baseline assessment. These were dropped from the cost-effectiveness analysis.  
50 Others had at least data for the 3-month period. All cost values, both pre- and post-  
51 baseline, are expressed as over a 3-month period.  
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3 Paid hours appear somewhat higher for the intervention group, both at baseline and during  
4 the 12-month, post-intervention period. Also, total costs are somewhat lower for the  
5 intervention group pre-baseline, and somewhat higher post-baseline, a difference that  
6 arises only partly from the cost of the intervention itself, which averages to £136. More  
7 detailed observation of the distribution of resource use and costs indicated that this  
8 difference was partly due to one participant assigned to the intervention group, who had an  
9 unusually long hospitalization (70 days) towards the end of the one-year post-baseline  
10 period. The participant with the next-highest number of days, who was assigned to the  
11 control group, had 12 days. No other participant was hospitalized. We removed the outlier  
12 from the sample and redid the above calculations as a sensitivity analysis, the results are  
13 shown in Table 4. In order to assess the influence of the multiple imputation procedure on  
14 the results, we also did the calculations, including the individual with a high number of  
15 hospital days, by prorating costs and paid hours rather than by using multiple imputation. It  
16 is important to note that in either case the data in Table 4 show no indication of a possible  
17 cost offset.  
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30 *Figures 2a & b about there*

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32 *Figures 3a & b about here*  
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36 Figure 2a represents the base case – multiple imputation with complete data. The data  
37 suggest that the intervention is associated with a greater number of paid hours (though the  
38 standard error is greater than the mean – the difference is not statistically significant); it is  
39 also more costly. Costs of the work-focussed intervention were estimated at £136 per  
40 person on average. Only if the decision-maker is willing to pay about £100 per paid hour  
41 does the intervention reach a 50% chance of being cost-effective. If we remove the  
42 individual who had 70 hospital days from the analysis, Figure 2b shows that the difference in  
43 cost between the groups diminishes, without affecting the difference in effectiveness, so  
44 that the apparent cost-effectiveness rises. (Recall that this individual had been assigned to  
45 the intervention group.) The decision-maker needs to be willing to pay about £30, rather  
46 than £100, per paid hour for the intervention to reach a 50% chance of being cost-effective.  
47 Still, even if the decision-maker were willing to pay £100 per paid hour, the probability of  
48 the intervention being cost-effective would only reach about 66%.  
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5 Finally, Figures 3a and 3b suggest that, if one abstracts from two unusual individuals with, in  
6 one case, no hours of intervention but a high number of paid hours per week, and in the  
7 other case, 9 hours of psychological intervention but no paid hours, there does seem to be a  
8 possible dose-response relationship between hours of work-focused psychological  
9 intervention and paid hours.  
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### 13 14 15 **Discussion and implications**

16 We found no statistically significant differences between IPS alone and IPS with work-  
17 focussed counselling at any time point on the primary or secondary outcome measures.  
18 While the study does provide some modest encouragement for exploring further the  
19 potential for enhancing IPS with some form of work-focussed counselling, the adjunct  
20 intervention would need to produce a practically significant increase in hours worked to be  
21 considered cost-effective. Waghorn et al. (2009, Table 2) list a range of opportunities for  
22 occupational therapists to enhance employment support for people with mental health  
23 problems, through their professional input as advocates, consultants and practitioners. The  
24 findings reported here may be read in the light of other evidence about 'work-related self-  
25 efficacy', which the same authors define as 'confidence to perform core activities at a  
26 specific task level', and put forward as an area where occupational therapy expertise is  
27 relevant.  
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40 The results also raise a number of learning points which should inform the implementation  
41 of such interventions and the design of future trials of this or similar occupational therapy  
42 interventions. First, the planned sample size was overoptimistic. Despite full co-operation  
43 from senior managers in the service studied and a context amenable to research,  
44 organisational issues – reorganisation, overcrowded offices, and the availability of care co-  
45 ordinators to provide the practical help required to implement the trial, proved  
46 disadvantageous. Second, provision of employment specialists proved more irregular than  
47 intended. Altogether there were 30 months of employment support worker time invested in  
48 the study over a time period of 2 years to treat 74 people. In fact, some people (N = 10)  
49 received only two months of employment specialist support. Studies of IPS (e.g. Perkins,  
50 2005; Rinaldi and Perkins, 2007; Boyce et al., 2008) highlight the importance to service  
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3 users' confidence of the continuity of this contact. Thirdly, the work-focused counselling  
4 intervention was very much a pilot. Six sessions were offered, but participants could stop at  
5 any point. Only six people took up all available sessions and it is unlikely that a low-intensity  
6 intervention would be very powerful. It is also possible that study's intervention was not  
7 sufficiently different from standard IPS in the benefits derived by individual service users.  
8 Both constituted a supportive relationship with a focus on real-world problems; perhaps  
9 that is sufficient to enable a person to pursue his or her work aspirations effectively.  
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17 Two further issues were raised in the implementation of the study. Difficulties were  
18 experienced in completing some of the psychosocial measures, in particular the DEX and  
19 BFNE. More straightforward and user-friendly measures would be preferable if the trial  
20 were to be repeated. Furthermore, the addition of specific anxiety and depression  
21 measures would be helpful considering the popularity of the anxiety and depression topics  
22 among participants. Although receiving CBT was an exclusion criterion for the study, it  
23 emerged that a number of participants (N= 8; 5 intervention and 3 control) did in fact start  
24 seeing clinical psychologists receiving CBT-type therapy after entering the study, either  
25 weekly (3) or fortnightly (5). Given the strong CBT evidence base, future trials should  
26 postpone the start of generic CBT while employment-focused interventions are being  
27 studied.  
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### 38 **Limitations**

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40 The high drop-out rate is the major limitation to this study. Of the 32 who dropped out, 15  
41 were part of the intervention arm and 17 were lost to the control arm. Although no  
42 differences were found in the clinical profile nor the psychometric scores of these two arms,  
43 younger individuals and those who were not actively using the services on offer were more  
44 likely to drop out of the study. Younger individuals present greater likelihood of relapse and  
45 therefore this could have increased the probability of their dropping out (Lysaker and  
46 France, 1999).  
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54 A hostile labour market prevailed throughout the period of the trial with escalating  
55 unemployment figures in the general population. The effects on the trial cannot be  
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3 ascertained, but comparison can be made between the study participants and people across  
4 England and Wales who were unemployed and receiving Job Seeker Allowance during the  
5 same period: The Department of Work and Pensions (DWP) apply an outcome criterion of  
6 13 weeks of continuous paid work, and the national results of the DWP Work Programme  
7 were reported in September 2013 (Centre for Economic and Social Inclusion, 2013). This  
8 found that 11% of the general unemployed population, who were not known to have severe  
9 mental illness, succeeded in attaining employment between July 2012 and June 2013. If we  
10 apply the same 13-week continuous employment measure, 20% of the participants in this  
11 study succeeded retaining work for 13 weeks within 12 months despite the disadvantage of  
12 severe mental health problems.

### 21 **Conclusion**

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24 The learning points about the study could inform future studies. While the hypothesis that  
25 work-focussed counselling would make a significant improvement to IPS outcomes was not  
26 supported by the trial, the data demonstrate that, even during a recession, people with  
27 severe mental health problems can be helped to attain employment through the IPS  
28 approach. Comparison with the general population suggests that the effects of the  
29 recession were not as detrimental to the participants in our study as to the unemployed  
30 population as a whole. This may arguably be because the IPS approach is more effective  
31 than other employment support approaches available to the general population.

### 38 **Key message**

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41 Occupational therapy can offer promising enhancements to IPS, but evaluating their  
42 marginal benefit would require a robust design that is protected against the vicissitudes of  
43 organisational change in the care environment.

### 47 **What the study has added**

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50 The study has shown that IPS can be successfully delivered despite a negative economic  
51 climate in a UK context, and that it is feasible deliver work-focussed counselling as an  
52 adjunct intervention.

### 57 **Competing interests**

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3 The authors declare that they have no competing interests.  
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7 **Authors' contributions**

8 AA obtained ethical clearance, collected the data and undertook data analysis, NC designed,  
9 delivered and evaluated the psychological intervention, overseen by MM who also  
10 undertook the additional analysis. BG analysed the data and generated the statistical  
11 comparisons. EL oversaw the costs analysis, while ZC performed this. JS conceived, managed  
12 and led the study. All authors contributed to the manuscript and approved the final version.  
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