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Collaborative decision making improves interpersonal psychotherapy efficiency: A randomized clinical trial with postpartum women

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Abstract

Background: Randomized controlled trials of Interpersonal Psychotherapy (IPT) and other psychotherapies for depression have required strict adherence to protocol and do not allow for clinical judgment in deciding frequency of sessions. To determine if such protocols were more effective than allowing therapists to use their clinical judgment, we compared “Clinician-Managed” IPT (CM-IPT), in which clinicians and patients with postpartum depression were allotted 12 sessions and determined collaboratively when to use them, to a once weekly 12 session protocol (“Standard IPT”). We hypothesized that CM-IPT would be more efficient, requiring fewer sessions to reach an equivalent acute outcome, and that CM-IPT would be superior over 12 months because “saved” sessions could be used for maintenance treatment.

Method: We conducted a clinical trial including 140 postpartum outpatients with DSM-IV major depression who were randomly assigned to “Standard” IPT ($N=69$) or CM-IPT ($N=71$).

Results: Both CM-IPT and S-IPT were highly efficacious with similar outcomes by 12 weeks but CM-IPT group utilized significantly fewer sessions. Both were superior to a waitlist control. Superiority comparisons at 12 months did not favor the CM-IPT condition.

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CRediT authorship contribution statement

Study concept and design: Stuart, O'Hara.

Acquisition, analysis, or interpretation of data: Stuart, O'Hara, Brock, Arndt.

Drafting of the manuscript: Stuart, O'Hara, Brock, Arndt.

Critical revision of the manuscript for important intellectual content: Stuart, O'Hara, Brock, Ramsdell, Arndt.

Statistical analysis: Brock, Arndt.

Obtained funding: Stuart, O'Hara.

Administrative, technical, or material support: Stuart, O'Hara, Brock, Arndt.

Study supervision: Stuart, O'Hara.

Drs. Stuart and O'Hara had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Limitations: Results should be replicated in a more diverse sample to increase generalizability.

Conclusions: CM-IPT is more efficient in treating acute depression than mandated weekly IPT. Further, permitting clinicians and patients to use their collaborative judgment is likely to be a more efficient and effective way to conduct future research and to implement evidence-based psychotherapy in the community.

Keywords

Postpartum depression; Interpersonal psychotherapy; Depression; Perinatal

1. Introduction

The postpartum period is a time marked by significant adjustment when mothers must adapt to new or modified caregiving roles (Cox and Paley, 2003), navigate physical challenges (e.g., back pain, perineal pain, pain related to cesarian wound; Cooklin et al., 2015), and (when applicable) balance demands of other family relationships (Kuersten-Hogan and McHale, 2021). These demands result in time constraints and unpredictable schedules which serve as barriers to seeking mental health treatment despite a notable increase in risk for depression during the postpartum period (Smythe et al., 2022; Ugarriza, 2004). While there are several barriers unique to perinatal women, most patients seeking psychological treatments face barriers such as time constraints, transportation, and other competing demands such as jobs which make regular weekly scheduling of appointments difficult.

These barriers inform two longstanding questions regarding treatment delivery which have yet to be empirically addressed. First, is the requirement of fixed treatment intensity the most efficient way to conduct clinical trials, or would outcomes be different if more collaborative decision making was incorporated into the study design? Indeed, research has suggested that terminating acute treatment after a fixed number of weekly sessions does not prevent relapse (Frank et al., 2007,1990; Keller et al., 1982; Shea et al., 1992). Second, as is the case with some treatment protocols implemented in community settings, should therapists in the community be required to rigidly adhere to treatment manuals constructed for use in controlled research settings (Talley et al., 1994; Chambless and Ollendick, 2001; Castonguay, 2013; Wampold, 2007), or would outcomes be improved with flexible treatments tailored to each individual? The answers to these questions have the potential to significantly impact the ways in which future clinical trials are designed, community therapists are trained, and psychotherapy is implemented.

These questions arose in our previous randomized control trial (O'Hara et al., 2000) in which 12 weekly sessions of Interpersonal Psychotherapy (IPT) (Klerman et al., 1984; Stuart and Robertson, 2003, 2012) were compared to a waiting list control (WLC) for postpartum depression. Outcomes were excellent, with significant differences on the Hamilton Rating Scale for Depression (HRSD; Hamilton, 1960), the Beck Depression Inventory (BDI; Beck et al., 1961), and recovery rates. However, patients and clinicians reported that they wanted to determine collaboratively when to meet rather than being required by the protocol to meet weekly. Patients also desired to have a continuing

relationship with their clinician rather than having to terminate; this was echoed by clinicians.

To address these questions, we developed an IPT treatment trial in which a tightly controlled protocol could be compared to collaborative decision making used to determine when and how often therapy were scheduled. This “Clinician-Managed” intervention (CM-IPT) provided clinicians and postpartum patients a total of 12 sessions to use as they wished over a year period. The CM-IPT intervention mirrored community settings in which each patient and therapist dyad negotiate when to schedule sessions—community therapists typically do not insist that their patients attend weekly sessions for the sole purpose of following a research protocol. The CM-IPT condition did not require patient improvement as a condition for changing treatment intensity (e.g., adjusting meeting frequency from weekly to bi-weekly), but relied instead on clinical judgment in collaboration with individual patients. The Standard IPT condition (S-IPT) required 12 weekly sessions with a termination after 12 weeks, mirroring the way in which most clinical trials are conducted. We hypothesized that CM-IPT would be more efficient than S-IPT – i.e., on average, the CM-IPT clients would have similar treatment gains as the S-IPT over the first 12 weeks despite significantly fewer sessions. We also predicted that sessions not used during the first twelve weeks of the CM-IPT treatment would be deployed over the subsequent nine months to maintain or improve upon gains made during acute treatment (i.e., the first 12 weeks of treatment). Thus, we hypothesized that CM-IPT patients would have significantly greater improvement over 12 months than S-IPT patients.

2. Method

2.1. Design

The study design had two major components: (1) an equivalency study comparing CM-IPT to S-IPT over the acute treatment phase of 12 weeks, and (2) an effectiveness study comparing CM-IPT to S-IPT over one year. One hundred and forty women experiencing a major depressive episode within the first 6 months postpartum were randomly assigned to either CM-IPT ($N=71$) or to S-IPT ($N=69$), both of which were delivered by therapists in the communities from which participants were recruited. Outcomes in the IPT groups were subsequently compared to a waitlist control group from a previous treatment trial conducted by the investigative team (O’Hara et al., 2000).

2.2. Participants and procedures

Potential participants were identified using State of Iowa birth records. The study was approved by the University of Iowa Institutional Review Board and informed consent was obtained from all participants, using informed consent by letter for initial screening, verbal and written consent for phone interviews, and verbal and written consent for randomization to treatment. Letters describing the study were sent to all eligible participants, who were then contacted by phone. If they were interested in participating, a sociodemographic interview was conducted by phone. Women with babies less than 36 weeks gestation at birth or requiring care in the neonatal ICU for more than two days were excluded. On

average, women were within 6 months of childbirth ($M= 20.31$ weeks since birth, $SD= 3.85$) at enrollment. The CONSORT diagram for the study is presented in Fig. 1.

Data collection took place during 2002–2007. Eligible women were mailed the Inventory to Diagnose Depression (IDD) (Zimmerman and Coryell, 1987). Those meeting criteria for major depression on the IDD participated in a second phone interview, which included the Structured Clinical Interview for DSM-IV (SCID) (Spitzer et al., 1992) and the HRSD (Hamilton, 1960). Participants who met DSM-IV (American Psychiatric Association, 1994) criteria for a major depressive episode, according to the SCID, and scored 12 or more on the 17-item HRSD (Elkin et al., 1989), were then interviewed a final time in their home. During the home visit, participants completed the Major Depressive Episode module of the SCID and the HRSD to confirm diagnosis and eligibility. Participants were randomly assigned on a one-to-one basis to either S-IPT or CM-IPT and then assigned to the next available therapist. There were no blocking variables. All were treated by clinicians in the community with fees paid by the study.

Exclusion criteria assessed during the interviews included: (a) life-time history of bipolar disorder, schizophrenia, organic brain syndrome, intellectual disability, or antisocial personality; (b) a current diagnosis of substance abuse, panic disorder, somatization disorder, or two or more schizotypal features; (c) a current diagnosis of depression with psychotic features; (d) antisocial or schizotypal personality features, and (e) active suicidal ideation. Participants were required to be abstinent from psychotropic medications for at least two weeks prior to randomization and during the entire treatment phase. Please refer to Table 1 for detailed demographic information for the sample. Note that gender identity was not assessed and, therefore, it is possible that some participants identified as a gender other than woman.

2.3. Measures

Assessments were conducted to screen potential participants, and at baseline, 4, 8, and 12 weeks, and at 6, 9, and 12 months after treatment assignment. Twelve weeks post-randomization was determined a priori as the termination point of S-IPT and of acute treatment. Primary outcome measures were the HRSD (Hamilton, 1960), BDI (Beck et al., 1961), and the DSM-IV criteria for MDE as assessed by the SCID (First et al., 1995). All interview-based assessments were conducted by masters-level research assistants who were blinded to treatment condition.

2.4. Screening instrument

The Inventory to Diagnose Depression (IDD) (Zimmerman and Coryell, 1987) was used for initial screening of postpartum women. The IDD is a 25-item measure that was developed to assess criteria for DSM-III major depression, which we revised to assess criteria for DSM-IV major depressive episode to be consistent with our use of the SCID for the DSM-IV which was the established version of the diagnostic manual used at the time of the clinical trial.

2.4.1. Primary outcome measures—The amended 17-item version of the Hamilton Rating Scale for Depression (HRSD), which was used in the NIMH Treatment for Depression Collaborative Research Program (NIMH-TDCRP; Elkin et al., 1989) (adding items on hypersomnia, hyperphagia, and weight gain) and in previous studies of postpartum depression (O’Hara et al., 2000; O’Hara et al., 2019), was the other primary outcome measure. The 17-item HRSD was used because it is a valid indicator of depression severity in postpartum depression despite the overlap between somatic HRSD items and typical experiences of postpartum women (Thompson et al., 1998) (Ross et al., 2003). Scores range from 0 to 58. Raters were blinded to treatment condition; raters conducting assessments had intraclass correlations between 0.88 and 0.94.

Although the HRSD was selected as the primary outcome measure, we also administered the Beck Depression Inventory (BDI) (Beck et al., 1961) given it is a widely used measure of depressive symptomatology in both psychotherapeutic and psychopharmacologic outcome studies (Elkin et al., 1989). Scores range from 0 to 63. Its psychometric properties have been well established and it has been found to be sensitive to longitudinal change in depressive symptoms (Beck et al., 1988); in the present study, internal consistency was excellent (Cronbach’s alpha = 0.89).

2.4.2. Secondary measures—DSM-IV clinical diagnoses were assessed using the Structured Clinical Interview for DSM-IV (SCID) (First et al., 1995). The SCID was administered to prospective participants whose IDD score indicated MDD. All diagnostic interviews, including the SCID, were conducted by master’s level research assistants who were blinded to treatment condition. Six, nine, and twelve month assessments also used the SCID. Reliability of SCID diagnoses was established through an elaborate training procedure that included thorough review of the SCID and DSM, guidance from experienced clinicians, and establishment of consensus ratings on several interviews of depressed and non-depressed participants. Across 28 cases, Kappa was 0.640, indicating substantial agreement among interviewers (Sim and Wright, 2005).

2.5. Therapists

The study therapists (4 women; 4 men) were community-based in private practice settings. All were extensively trained in IPT and in postpartum depression. Specifically, all completed Level C (Clinical Research Certification) training criteria in IPT as specified by the IPT Institute (2011) (<https://iptinstitute.com/ipt-certification/>). Seven were psychologists with Ph.D. degrees in clinical or counseling psychology (one was an MSW); mean experience was 16 years (median = 14 years; range 5 to 35 years). All conducted both Standard and CM-IPT and, as such, could not be blinded to treatment. All therapists reviewed videotapes of their sessions with the lead author in both individual (biweekly) and group (monthly) formats.

2.6. Treatments

IPT (Klerman et al., 1984) (Stuart and Robertson, 2003, 2012) is empirically validated for depression generally (Cuijpers et al., 2016; Elkin et al., 1989) and for postpartum depression specifically (Sockol, 2018; O’Hara et al., 2000; O’Hara et al., 2019) and is designed to

bring about symptom relief, improvement in interpersonal functioning, and increased social support (Stuart, 2004; Stuart and Robertson, 2012). IPT is grounded in Attachment Theory (Bartholomew and Horowitz, 1991; Bowlby, 1988) and Interpersonal Theory (Benjamin, 1996; Kiesler, 1996), and is based on a Biopsychosocial/Cultural/Spiritual Model of psychological functioning (Stuart and Robertson, 2012).

IPT treats psychiatric symptoms by focusing on patients' primary interpersonal relationships, particularly in the problem areas of grief and loss, interpersonal disputes, and role transitions (Stuart and Robertson, 2012). Symptom resolution occurs as patients are assisted in repairing their disrupted interpersonal relationships, learn new ways to communicate their need for emotional support, and successfully enlisting social support.

IPT is divided into 4 phases (Stuart and Robertson, 2003, 2012). In the Initial Phase, therapists work to develop a therapeutic alliance and complete an assessment including an Interpersonal Inventory (Klerman et al., 1984), Interpersonal Formulation (Stuart and Robertson, 2012), and Interpersonal Summary (Stuart et al., 2014). In the Middle Phase, therapists work with patients to resolve their interpersonal crises by identifying the support they need and helping them to communicate their needs more effectively. Increasing social support is strongly encouraged to decrease isolation and distress.

The third phase, Conclusion of Acute Treatment, differed between the two conditions. By design, S-IPT was terminated after 12 sessions. In contrast, in CM-IPT, the Conclusion of Treatment phase was conceptualized and addressed as the conclusion of acute or intensive treatment with provisions made for ongoing care as needed. Similarly, the 4th phase, Maintenance, differed between conditions. There was no Maintenance Phase with S-IPT. Instead, maintenance IPT was provided as determined by the therapist and patient in CM-IPT using the remainder of the 12 sessions. The goal of this phase was to reduce risk of relapse.

The IPT provided in both conditions was based on the model described by Stuart and Robertson (Stuart and Robertson, 2003, 2012) for depression and by Stuart and O'Hara for postpartum depression specifically (Stuart and O'Hara, 2005). The protocol for "Standard" IPT was based on the design of the NIMH-TDCRP (Elkin et al., 1985) (Elkin et al., 1989) modified for postpartum depression (O'Hara et al., 2000): 12 1-hour sessions were delivered once weekly with a complete termination after 12 weeks.

In "Clinician-Managed" IPT condition, therapists were encouraged to discuss the specific needs of the client as well as their practical limitations in the context of symptom severity. Decision points were not standardized, and therapy dyads were free to adjust frequency without limitations. As elaborated in the IPT training we provided to the therapists (Stuart and Robertson, 2012), a collaborative model is critical to the conduct of high quality IPT. Therapists and patients were allotted 12 1-hour sessions they could use as they wished over 12 months; no acute termination was required. The collaborative decision-making regarding sessions was permitted throughout all of the treatment phases.

2.7. Statistical analysis

We conducted equivalency analyses of the two treatments at 12 weeks in which we predicted that S-IPT and CM-IPT would not differ in either direction by more than a pre-specified amount of 3 points on the HRSD and 4 points on the BDI (i.e., roughly 0.5 SD based on descriptives reported in similar RCTs with postpartum women), and 5 percentage points for MDE diagnostic status. We judged these pre-specified differences as within a zone of indifference, meaning that clinicians would not judge those small differences as clinically significant. For each outcome, 95% confidence intervals (CIs) of estimated mean differences between conditions were calculated. Baseline levels were controlled for when estimating mean differences. In order to further evaluate the acute effectiveness of IPT in this study, mean symptom levels at 12 weeks (combining CM-IPT and S-IPT conditions) were subsequently compared to mean post-treatment (12 weeks) symptom levels from the Waiting List Control (WLC) group in a previous trial of IPT for postpartum depression, which used identical sampling procedures (O'Hara et al., 2000).

Superiority analyses comparing the two treatments over 12 months were conducted with linear mixed-model analyses with seven repeated measures (i.e., baseline, 4, 8, and 12 weeks, and 6, 9, and 12 months) nested within participants. Analyses were based on an intent-to-treat sample including all participants who were randomly assigned. For these analyses, there was 93% power ($\alpha=0.05$) with a sample size of $N=140$, assuming a small Time x Treatment effect. Reliable change indices (RCIs) were computed to examine the clinical significance of the primary intervention outcomes across the 12 months.

3. Results

3.1. Potential covariates

Demographic and clinical characteristics are reported in Table 1. There were no significant differences between treatment conditions with regard to demographic and clinical characteristics; thus, no covariates were included in the analyses.

3.2. 12 week acute treatment period

CM-IPT participants completed an average of 5.11 ($SD = 2.88$; $Md = 5$) sessions during the first 12 weeks which, as predicted, was significantly less than the S-IPT participants ($M = 8.54$, $SD = 3.67$; $Md = 10$), $t(138) = 6.15$, $p < .001$. Observed mean scores of depressive symptoms over time are reported in Table 2. The 95% CIs for estimated mean symptomatic differences between the conditions are reported in Figs. 2 (HRSD) and 3 (BDI). Although the CM-IPT intervention required significantly fewer sessions during the first 12 weeks, the 95% CI [-1.66, 2.78] for the HRSD suggests that the S-IPT and CM-IPT conditions do not differ in either direction by more than the pre-specified 3 points. However, the 95% CI [-1.22, 4.21] for the BDI suggests that the S-IPT and CM-IPT conditions differ by more than the pre-specified 4 points in favor of S-IPT. Outcomes for both groups were excellent: 87.3% of the CM-IPT women and 86.7% of the S-IPT women no longer met diagnostic criteria for MDE at 12 weeks. The 95% CI [-0.14, 0.13] suggests equivalence regarding diagnostic criteria.

Supplementary Analyses.—Post-treatment depressive symptoms were significantly lower in the combined treatment sample (CM-IPT and S-IPT) compared to the WLC group from a previous clinical trial as measured by the HRSD (IPT: $M= 10.11$, $SD= 6.50$; WLC: $M= 16.80$, $SD= 8.40$), $t(122) = 11.43$, $p < .001$. See Fig. 4 for a graphical depiction of this comparison. This demonstrates the improvement in both the S-IPT and CM-IPT conditions and suggests that change over time can be attributed to the treatment.

3.3. 12 month treatment period

When conducting superiority analyses to compare treatments over 12 months, significant linear change (improvement) was detected for the entire sample for the HRSD, $t(137) = -17.03$, $p < .001$ and the BDI, $t(137) = -13.95$, $p < .001$. There was significant between-subject variability in the effect of time (slope) for the BDI, $\chi^2(127) = 160.98$, $p = .022$, but not for the HRSD, $\chi^2(129) = 145.11$, $p = .158$. Time x Treatment interactions were not significant for HRSD, $t(667) = -1.38$, $p = .168$, or the BDI, $t(136) = -0.82$, $p = .412$.

Approximately 90% of women in the CM-IPT group, and 90% of the S-IPT group experienced clinically significant improvement (RCI) from pre-treatment to 12 months post-randomization as measured by the HRSD. Recovery status as determined by HRSD scores ≤ 7 was not significantly different for the S-IPT group (51%) compared to the CM-IPT group (62%), $\chi^2(1) = 1.14$, $p = .287$. Recovery status as determined by BDI scores ≤ 9 was not significantly different for the S-IPT group (49%) compared to the CM-IPT group (55%), $\chi^2(1) = 0.33$, $p = .564$. 88.5% of the women in the CM-IPT group and 91.8% in the S-IPT group did not meet diagnostic criteria for MDE, which did not differ significantly, $\chi^2(1) = 0.32$, $p = .570$.

Equivalence Testing.—We also conducted equivalence testing (parallel to the 12-week analysis) at 12 months. The 95% CI [-3.55, 0.76] for the HRSD suggests non-equivalence in favor of CM-IPT (Fig. 2). Further, the 95% CI [-4.30, 1.06] for the BDI also suggests non-equivalence in favor of CM-IPT (Fig. 3).

Sessions Over 12 Months. The average number of CM-IPT sessions completed during the 12 months was 8.66 ($SD = 4.28$; $Md = 11$), comparable to the average number of sessions of S-IPT completed during the first 12 weeks of the trial. Nine participants (CM-IPT=6; S-IPT=3) did not complete any sessions.

Number of weeks between sessions was examined. There was not a significant difference in time intervals between Session 1 and Session 2 for CM-IPT ($M= 1.27$ weeks, $SD = 0.66$) compared to S-IPT ($M= 1.33$ weeks, $SD = 0.68$), $t(92) = 0.44$, $p = .659$; however, intervals between all subsequent sessions were significantly greater for CM-IPT (t s ranged from 2.54 to 7.51, p s < 0.05). On average, for CM-IPT, the first 7 sessions were completed during the first 12 weeks. Average weeks between Sessions 1 and 12 was 12.11 ($SD=1.87$) for S-IPT and 36.70 ($SD=12.99$) for CM-IPT $t(44) = -7.53$, $p < .001$. Finally, pacing of sessions was not associated with treatment outcomes in the CM-IPT condition. Specifically, the average number of weeks between sessions in the CM-IPT group was not associated with HRSD scores at 12 months (controlling for baseline HRSD), $r = -0.16$, $p = .389$, BDI scores at 12

months (controlling for baseline BDI), $r = -0.10$, $p = .589$, or MDE at 12 months, $r = -0.11$, $p = .536$.

4. Discussion

The specific wording of the American Psychological Association regarding empirically-based treatments states that Evidence-Based Practice is, “the integration of the best available research with clinical expertise in the context of patient characteristics, culture, and preferences” (APA Presidential Task Force on Evidence-Based Practice, 2006). The statement that clinical expertise is necessary in the delivery of optimal treatment, as well as the specific term “Evidence-Based Practice (EBP)” as opposed to “Empirically-Validated Treatment,” both acknowledge the importance of clinical judgment. This study is the first to provide clear evidence of the benefits of collaborative clinical judgment in structuring the implementation and delivery of psychotherapy with postpartum women, who benefit from increased flexibility in the context of considerable change and adjustment, supporting the APA position with data.

Two critical elements of clinical judgment addressed in this study are the decisions about how to structure therapy frequency and whether to terminate treatment. Seligman (1995) noted decades ago that community-based psychotherapy that is not confined by a protocol is self-correcting—i.e., the therapist and patient work together, give each other feedback, and utilize different techniques or structure if the current treatment is not effective. They also determine when and how to conclude treatment and whether maintenance is needed. The self-correcting properties of therapy allow community-based clinicians and patients to intensify treatment if needed, and to meet less frequently if the patient is doing well. Therapy can be tailored to individual patients. This is the essence of CM-IPT.

It is important to note that both S-IPT and CM-IPT resulted in excellent outcomes at 12 weeks and 12 months. There were no significant differences between treatment conditions with regard to improvement across 12 weeks; however, the CM-IPT group utilized significantly fewer sessions to reach an equivalent acute outcome on the primary outcome measure HRSD.

The findings at 12 months did not support greater effectiveness for CM-IPT over S-IPT (i.e., rate of improvement did not differ significantly between the groups). The excellent performance of both treatments at 12 weeks (88.5% of the CM-IPT group and 91.8% of the S-IPT group no longer met diagnostic criteria for MDE at 12 weeks) likely left little opportunity for the extra sessions afforded by the CM-IPT condition to lead to a significantly better 12-month outcome relative to the S-IPT condition (in other words, when improvement is already maximized, extra sessions are of no extra benefit). A visual inspection of the results (Fig. 4) suggests that the S-IPT group remained stable or showed slight improvement over the period between the end of therapy at 12-weeks and the 12-month assessment, while the CM-IPT group continued to improve until the 12-month assessment; both likely reached an asymptote with respect to symptomatic recovery. Finally, pacing of sessions in the CM-IPT condition was not associated with depressive symptoms or MDE at 12 months, suggesting that there was not an optimal pattern of treatment delivery.

This provides further evidence in support of flexible and collaborative treatment-planning between provider and patient rather than a prescribed approach.

There are several limitations to this study. Most notable is that a single modality of therapy was utilized. Though it is reasonable that the findings would be equally applicable to other EBPs, this remains to be empirically tested. Likewise, the findings may not be generalizable beyond postpartum women, or to people experiencing more severe levels of depression, though again it is reasonable that they would apply to other patient populations as well. An additional limitation is that the study therapists were all extremely well trained and highly experienced. Moreover, the therapists could not be blinded to treatment. While therapists' allegiance to one treatment model over the other (e.g., greater commitment to clinician managed versus standard) may have played a role in outcome, that bias, if present, likely reflects the bias that community clinicians would have towards treatment flexibility. We note however that both groups did extremely well with respect to improvement, suggesting that the bias, if present, was not significant.

It is possible that the participants who agreed to participate in the study differed from those that did not because they had characteristics that made them more likely to agree to a structured treatment protocol. For example, they may have had more access to childcare, or to have been on longer maternity leave. We do not have data to confirm or reject these hypotheses.

A final limitation is that the demographic characteristics of our patient population are not representative of all public settings. Although they accurately reflect the demographics of the State of Iowa, compared to the US as a whole, minorities were under-represented and socioeconomic and educational levels were higher. In the future, study aims should be pursued in a sample more representative of US demographics, to improve the generalizability of results.

Nonetheless, the study does provide evidence that acute therapy does not need to be terminated to be effective. As Stuart and Robertson (2012) have noted, there is a critical distinction between "terminating" therapy and "concluding" therapy. The former is a literal end after which therapy is not expected or permitted to resume. Despite the fact that there are no data that termination is a necessary ingredient in any treatment (Gelso and Woodhouse, 2002), it has become engrained as an element of psychotherapy both because of its historical roots (Wachtel, 2002) and because of the requirements of most efficacy trials. In contrast, "concluding" therapy is an approach which simply shifts from a more intensive acute treatment to a maintenance phase, and the relationship between therapist and patient continues over time as needed (Stuart and Robertson, 2012). This approach is consistent with the data that many patients are at high risk for relapse, and that maintenance treatment reduces that risk. It also reflects the commitment of community-based clinicians to continue or resume therapy, despite what a research manual may dictate, if their patient is suffering and in need of additional treatment.

Another potential implication of the findings is that clinicians should feel free to offer fewer sessions than what is typically recommended for IPT (Klerman et al., 1984) (Elkin

et al., 1989) (O'Hara et al., 2000). In our study the median number of sessions in the acute treatment phase of the CM-IPT condition was five; this is fewer sessions than has been used in versions of "brief" IPT (Swartz, Grote, & Graham, 2014) in which eight sessions of IPT were required.

Although gains were maintained in the S-IPT condition to the 12-month assessment, there is no way to know if the gains achieved by the women in the CM-IPT condition would have been similarly maintained in the absence of the additional sessions. In other words, the gains sustained by women in the CM-IPT condition might have been due to a combination of completing the acute phase of treatment and their ability to attend additional maintenance sessions as needed. This is a question for future research. The overall implication from our study, however, is that clinicians and patients should have collaborative input into decisions about treatment planning which optimally should be tailored to the individual patient.

5. Conclusion

The delivery of IPT which allows clinicians and patients to collaboratively determine when and how often to meet is equal in efficacy to rigidly structured IPT during acute treatment. Clinician-Managed IPT is more efficient. CM-IPT does not require a pre-determined termination date and, instead, allows for additional sessions following acute treatment; termination does not appear to be necessary for positive outcome. The Clinician-Managed approach to therapy bridges the gap between highly rigid research protocols and clinical reality, and guides clinicians in the provision of effective and efficient evidence-based practice in the community.

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Role of the funder/sponsor

The funding source had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Declaration of Competing Interest

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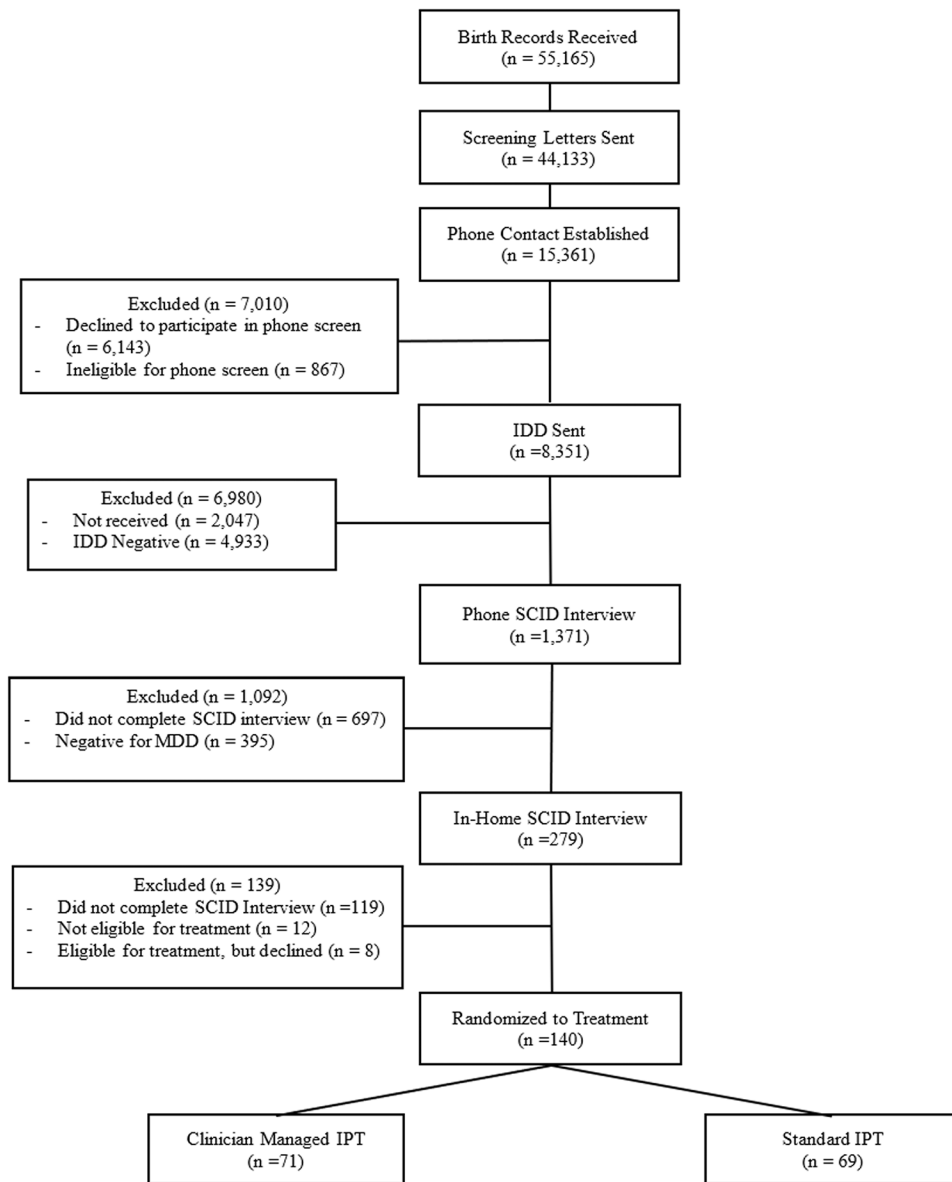


Fig. 1.
Consort Diagram.

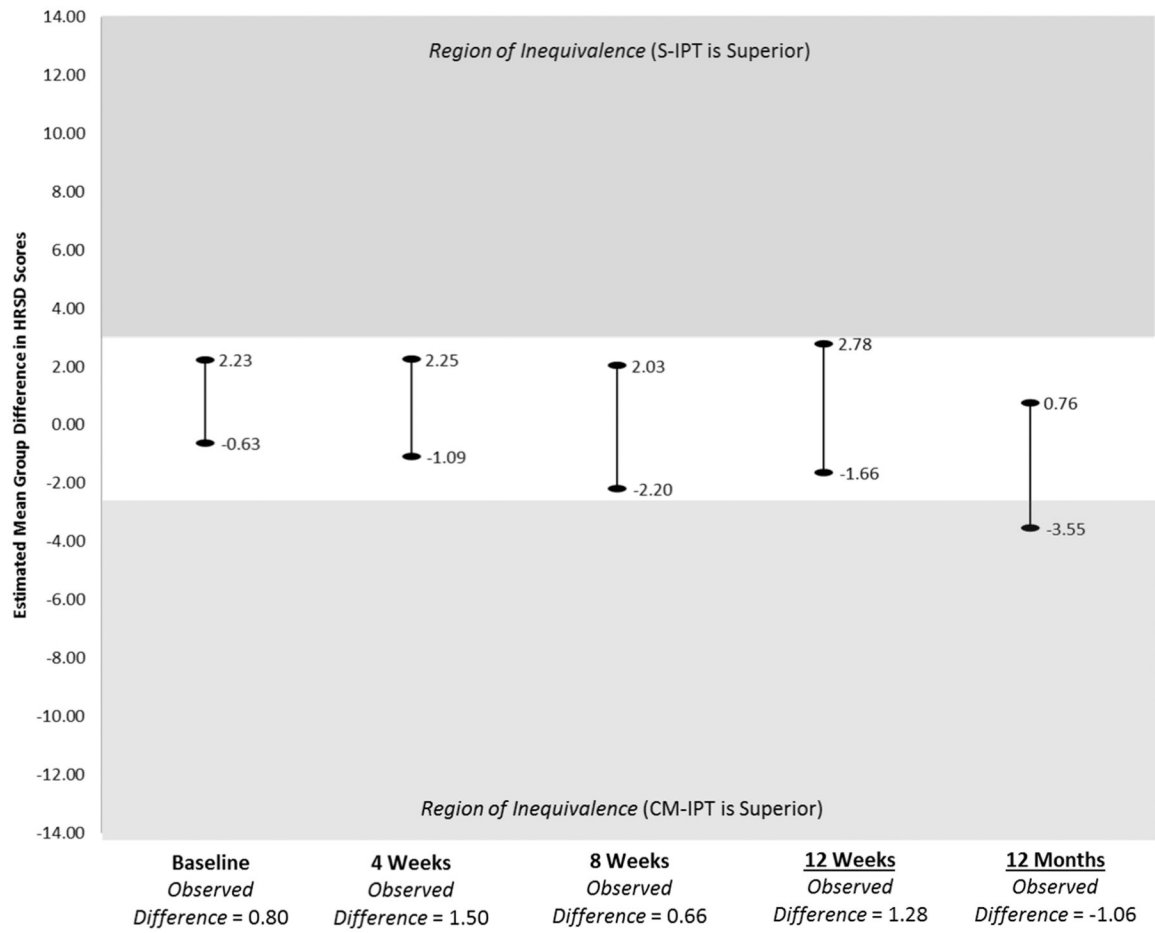


Fig. 2. Equivalency Results for the HRSD.

95% CIs for estimated mean differences in HRSD scores between conditions. There was non-equivalence at 12 months in favor of CM-IPT.

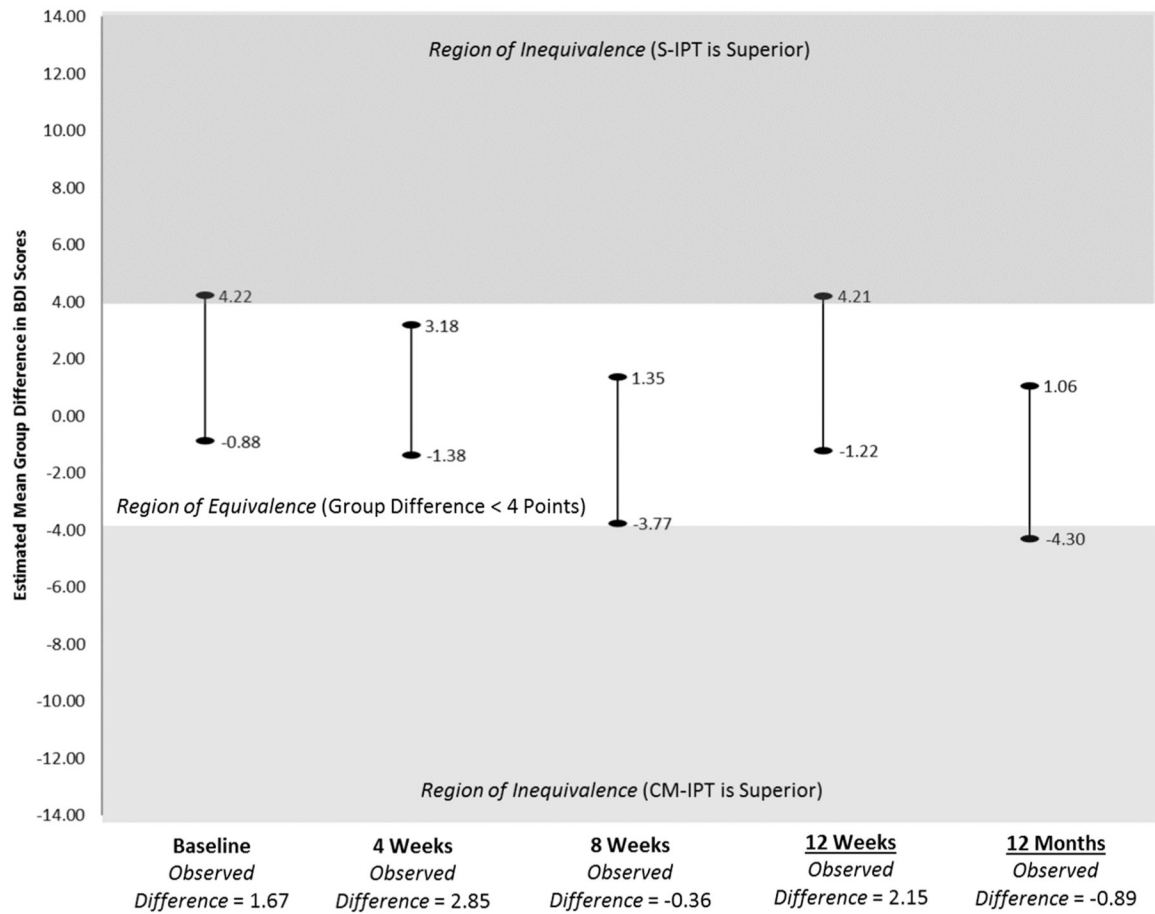


Fig. 3. Equivalency Results for the BDI.

95% CIs for estimated mean differences in BDI scores between conditions. There was non-equivalence at 12 weeks in favor of S-IPT, and non-equivalence 12 months in favor of CM-IPT.

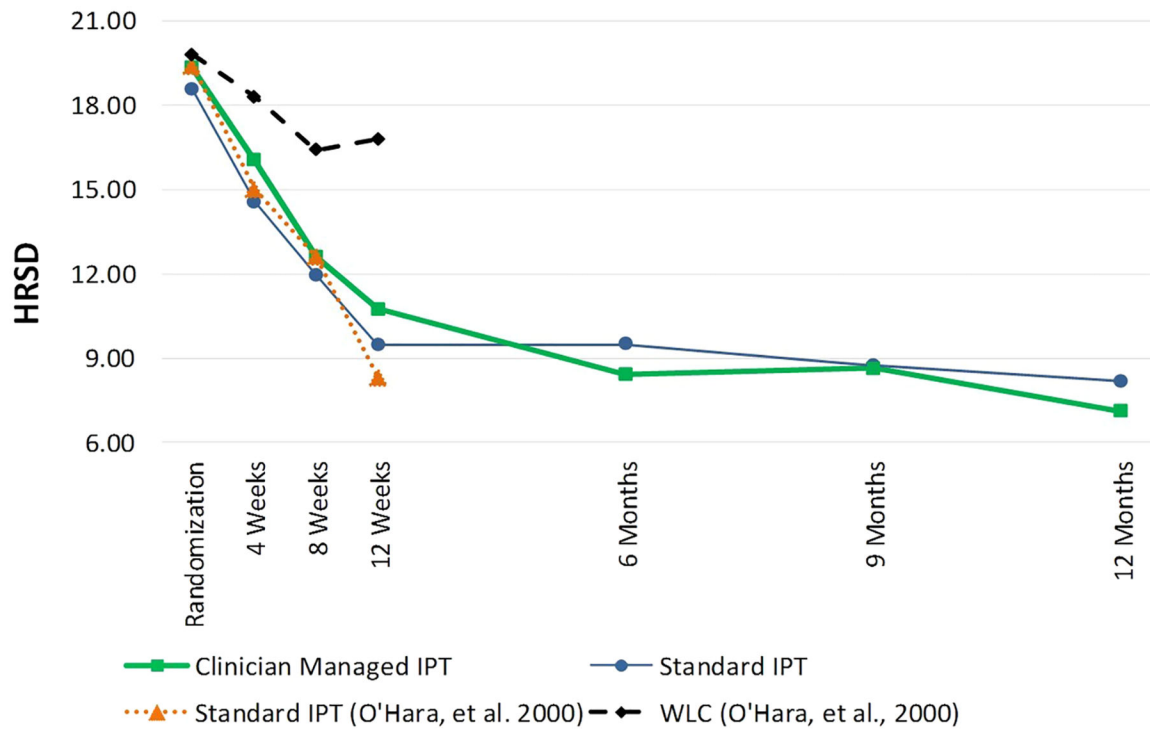


Fig. 4. Mean (observed) depression scores across time as measured by the HRSD for Clinical Managed IPT and Standard IPT conditions (current study) versus Standard IPT and Waiting List Control from O’Hara et al. 2000.

Table 1

Baseline Demographic and Clinical Characteristics of Participants.

	Total Sample (N= 140)		S-IPT (N= 69)		CM-IPT (N= 71)	
	Mean	SD	Mean	SD	Mean	SD
Age	29.89	5.13	29.95	4.81	29.84	5.45
Years of Education	15.24	2.03	15.26	1.92	15.21	2.15
Parity (Live Births)	2.06	1.02	2.09	1.03	2.04	1.02
	N	%	N	%	N	%
Employed	86	61.4	39	56.5	47	66.2
Income (Mode: \$30–30,999)	25	17.9	13	18.8	12	16.9
Race (White)	136	97.1	68	98.6	68	95.8
Ethnicity (Non-Hispanic)	137	97.9	69	100	68	95.8
Relationship Status (Married)	118	84.3	61	88.4	57	80.3
Cohabiting with Partner	133	95.0	66	95.7	67	94.4
	Mean	SD	Mean	SD	Mean	SD
Pre-Treatment HRSD	18.96	4.28	18.55	3.96	19.35	4.56
Pre-Treatment BDI	21.80	7.61	20.96	6.93	22.63	8.20

Note. Treatment conditions did not differ with regard to demographic characteristics and clinical characteristics at randomization. Valid percentage is reported (based on proportion of participants with complete data).

Table 2

Observed Mean Scores of Depressive Symptoms over Time.

	HRSD		BDI	
	M	SD	M	SD
Baseline	18.96	4.28	21.80	7.61
S-IPT	18.55	3.96	20.96	6.93
CM-IPT	19.35	4.56	22.63	8.20
Week 4	15.29	5.25	18.59	8.20
S-IPT	14.55	5.13	17.17	7.89
CM-IPT	16.05	5.31	20.02	8.32
Week 8	12.29	6.12	14.81	7.29
S-IPT	11.95	6.33	15.00	7.01
CM-IPT	12.61	5.95	14.64	7.59
Week 12	10.11	6.50	11.81	7.67
S-IPT	9.45	6.62	10.73	6.84
CM-IPT	10.73	6.37	12.88	8.33
Month 6	8.95	5.77	10.65	8.15
S-IPT	9.51	6.11	10.29	8.58
CM-IPT	8.42	5.43	10.96	7.82
Month 9	8.67	5.75	10.83	7.58
S-IPT	8.72	5.60	10.54	7.35
CM-IPT	8.63	5.93	11.07	7.82
Month 12	7.63	5.51	10.36	7.14
S-IPT	8.18	5.36	10.83	7.43
CM-IPT	7.12	5.66	9.94	6.91