Do Clients Get Better at The Family Institute?

A Study of Clinical Change and Therapist Effectiveness

The Family Institute Research Team

April 2018

Abstract

In this study we examined whether clients improve pre- to post-treatment across a variety of domains and systems at The Family Institute. Clients ($N = 503$) seeking individual, couple or family therapy from staff or student therapists at The Family Institute completed a series of questionnaires assessing depression, anxiety and general distress, as well as couple and family adjustment before and after treatment. Client outcomes were analyzed in general (across measures) and separately for each outcome. Results showed that clients significantly and clinically improved from pre- to post-treatment. Clients improved irrespective of therapy modality or area of functioning. In sum, we have empirical support for our contention that clients at The Family Institute improve over the course of therapy and that our therapists are making a difference in client's lives.

Do Clients Get Better at The Family Institute?

A Study of Clinical Change (and Therapist Effectiveness)

As therapists we believe passionately in helping our clients and, most of the time, we genuinely believe that our clients are getting better. Similarly, clients entrust us with their deepest secrets and pain, believing that we can help them feel better and/or improve their lives. However, is there any way to know whether we are truly helping our clients and whether our clients are getting better? In this paper we present the result of a three-year study[1] to answer these two related questions for therapists and clients at The Family Institute at Northwestern University.

Demonstrating that clients improve over the course of therapy at The Family Institute has important implications for many of us. Clients can be confident that the care they are getting at The Family Institute really works, and prospective clients might be more likely to choose The Family Institute because we can demonstrate evidence of positive outcomes. Therapists can get outside confirmation that the therapy they are offering is helping their clients *and* that they are effective therapists. Donors may base philanthropic support on evidence of positive outcomes and, for better or worse, insurance companies are increasingly tying reimbursement to evidence that therapy is "working." Finally, answering these questions speaks to the efficacy of The Family Institute as a whole and may shape clinical policy within the organization.

In sum, our purpose for conducting this study was to determine whether clients being treated at The Family Institute are getting better as a result of treatment. We examined client change at the individual, couple and family levels for clients based on their family structures. Thus, regardless of clients' presenting problems and regardless of the specific type of treatment they received, we were able to examine whether therapy benefited their functioning across

domains and systems (e.g., individual well-being and relationship well-being).

Method

Adults seeking psychotherapy at The Family Institute were recruited to participate in a randomized clinical trial (RCT) to evaluate the effectiveness of the Systemic Therapy Inventory of Change (STIC®) feedback system.[2] As such, clients and therapists completed additional measures and procedures beyond the scope of the present study that are not discussed in this paper.

Which Clients at The Family Institute Were Included in this Study?

The sample consisted of 503 adults who all received psychotherapy at The Family Institute at Northwestern University, a large not-for-profit outpatient mental health organization in Chicago, IL. Participants ranged in age from 18 to 78 years old (M = 36.3; SD = 12.4), with 37.4% male and 62.2% female (fewer than 1% of participants identified as either trans-male or trans-female). Most participants identified as heterosexual/straight (88.5%), 4.8% identified as homosexual/gay/lesbian and 6.8% identified as bisexual. For racial/ethnic identity, 78.7% of participants identified as White, 10.9% as Hispanic, 12.5% as Black/African American, 5% as Asian (e.g. Chinese, Japanese, Korean) and 8.8% as other. For education, 78.1% of participants held a bachelor's or advanced degree (i.e., master's degree, doctorate or equivalent), 2% obtained an Associate's degree, 1.8% held a technical school degree, 12.3% of participants attended some college, 5.2% obtained a high school diploma/GED and 0.6% did not graduate from high school. The median annual income range was between $61,000 and $100,000 (19.5%), with a relatively equal distribution across all other income brackets. For current relationship status, 41.7% of participants were married, 33.5% were in a serious relationship (e.g., dating, committed or engaged), 19.5% were not a relationship and 5.4% were widowed, separated or

divorced. Approximately two-thirds of the participants were in individual therapy (65.2%), 31% were in couple therapy and 3.8% were in family therapy and the average length of treatment was 20.7 sessions (*SD* = 20.7).

Which Therapists at The Family Institute Were Included in this Study?

Participating therapists (*N* = 61) included voluntary staff therapists at The Family Institute and students in the Marriage and Family Therapy master's degree program. Therapists in the study were diverse in their levels of experience, styles of therapy and areas of clinical focus. About half of therapists were licensed staff (with experience ranging from one-year post graduate to more than 20 years of practice). The other half of therapists were students in the master's in Marriage and Family Therapy program at The Family Institute — these student therapists all practiced Integrative Systemic Therapy (IST; Pinsof et al., 2017). Participating therapists were required to ask every new client to enroll in the study, thereby addressing selection bias in the sample. The result is a data set that represents well the practice of The Family Institute. Participating staff therapists received a bonus of $3,000. The average number of sessions for participants was 20.73 (*SD* = 20.72).

What Did We Ask Clients and Therapists to Do in this Study?

Individuals were recruited through invitations by participating therapists or through online advertisements. All eligible individuals who were seeking individual, couple or family psychotherapy from participating therapists were invited to participate in the larger study.[3] Eligibility requirements included verbal consent, over the age of 12, English or Spanish speaking and reading proficiency, internet access and computer literacy.

All participants completed a battery of measures online prior to their first therapy session (*N* = 695). Participants who did not complete the initial battery of measures prior to the first

session were subsequently excluded from the study. All participants completed a battery of measures identical to the initial battery upon completion and termination of therapy. Approximately 84% of initial participants completed the termination battery. Participants were compensated for completing the questionnaires ($20 for individuals and $50 for each partner in a couple for the initial battery of measures; $90 each for the termination battery). A research adherence team maintained contact with clients post-therapy in order to maximize completion of the termination battery.

Measures

Clients completed six questionnaires before beginning therapy and after termination. These measures were chosen for their shared assessment of aspects of client functioning, strong psychometric properties and current use in the scientific literature. Together, these measures provided a comprehensive picture of each client's degree of psychological functioning as well as the quality of his or her relationships. Client outcomes measured comprised anxiety and depressive symptoms (BAI, BDI-II), general psychological distress (OQ-45) and couple and family adjustment (RDAS, FAD).

The Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988) is a 21-item assessment used to measure global anxiety over the prior two weeks. Items are scored on a four-point scale ranging from "not at all" to "severely — it bothered me a lot." Example prompts include "Unable to relax," "Terrified or afraid" and "Difficulty breathing." The BAI has demonstrated high reliability and validity with alphas ranging from .84 to .91 (de Lima Osório, Crippa, & Loureiro, 2011; Muntingh, van der Feltz-Cornelis, van Marwijk, Spinhoven, Penninx, & van Balkom, 2011). The clinical cut off score for moderate anxiety symptoms is 16. Higher scores represent higher level of anxiety symptoms.

The Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996) is a widely-used measure of depression with strong reliability and validity (Aalto, Elovainio, Kivimäki, Uutela, & Pirkola, 2012; Brouwer, Meijer, & Zevalkink, 2013; Kühner, Bürger, Keller, & Hautzinger, 2007). The BDI-II consists of 21 items with four responses ranging from "not present" (score of 0) to "severe" (score of 3). Questions include items such as "I am sad all the time and I can't snap out of it," and "I blame myself all the time for my faults." The clinical cut off score for moderate depressive symptoms is 20. An overall higher score represents high levels of depressive symptoms.

The Outcome Questionnaire 45 (OQ-45; Lambert, Hansen, & Harmon, 2010; Lambert et al., 2004) is a measure of general psychological distress. It consists of 45 items separated into three subscales including social role functioning, symptomatic distress and interpersonal relationships. Responses to each item indicate the individual's agreement to statements about their life on a four-point scale ranging from 0 "never" to 4 "almost always." The clinical cut off score is 63, with scores higher than 63 indicating symptomology consistently valid with other clinical populations (Beckstead et al., 2003; Lunnen & Ogles, 1998).

The Revised Dyadic Adjustment Scale (RDAS; Busby, Crane, Larson, & Christensen, 1995) assesses the degree of couple agreement on relational dynamics, satisfaction and cohesion. The RDAS contains 14 items on a 5-point Likert scale ranging from 0 - 5 indicating the level of agreement to each statement, with a total score ranging from 0 - 69. Questions capture the amount of agreement between partners on topics such as religious matters, sex relations and demonstrations of affection, and how often partners engage in conflict and positive interactions (e.g., "Have a stimulating exchange of ideas"). Higher scores indicate better couple adjustment. The RDAS has shown to be reliable and valid (Hunsley, Pisent, Lefebvre, James-Tanner, & Vito,

1995; Motesino, Gómez, Fernández, & Rodriguez, 2013).

The McMaster Family Assessment Device, General Functioning Scale (FAD-GF; Epstein, Baldwin, & Bishop, 1983) measures general family functioning (e.g. communication, defined roles and problem solving) and has been found to be valid and reliable (Boterhoven de Haan, Hafekost, Lawrence, Sawyer, & Zubrick, 2015; Staccini, Tomba, Grandi, & Keitner, 2015). The FAD consists of 53 items rated on a 4-point Likert scale indicating the level of agreement to statements that the person could make about his or her family such as "You only get the interest of others when something is important to them" and "People come right out and say things instead of hinting at them." Only the General Functioning (GF) subscale was included the current study. GF is considered as a global index for assessing family functioning and has been used in previous studies as a measure of family functioning for the detection of family dysfunction in large-scale studies (Staccini et al., 2015). Higher scores represent higher levels of distress and dysfunction.

Data Analyses

Due to the relatively small number of children in the data set, we included only clients 18 years or older in the analysis. Due to the potential bias from non-independent data in couple and family groups, we randomly selected one adult client from each couple or family to be a part of the analysis. To address data determined to be missing completely at random, we used the maximum likelihood method, which enables analyzing the full, incomplete dataset by using the data of each available case to compute maximum likelihood estimates (Kenward & Roger, 1997).

We conducted linear mixed-effects modeling using Stata 14.0 (Stata Corp, College Station, Texas, 2015). Mixed-effects modeling assumes that observations measured from the

same participant are dependent and, therefore, the regression coefficients vary across participants and are considered to be random. Alpha for all tests was set at $p < .05$ (two-tailed).

Results

The Effectiveness of The Family Institute's Psychotherapy

We converted all raw scores to standardized scores so that they could be included in the same model. (Standardized scores for RDAS were reverse-coded.) Higher scores indicate poorer adjustment. Clients' average scores on the outcome measures varied across the full range of possible scores, indicating there was sufficient variability in client scores to warrant conducting the analyses below.

Question 1: Do The Family Institute's Clients Get Better over the Course of Treatment?

We first conducted an omnibus test of client outcomes. Specifically, we included *all of the* outcome measures in one overall analysis of client change. This method is both statistically conservative (as it accounts for the possibility that clients may improve on some measures but get worse on others) and highly consistent with our systemic values at The Family Institute. Significant results would suggest that clients improved (or deteriorated) in terms of their overall functioning across domains and systems (i.e., across individual and relational challenges).

Statistically significant client improvement: To examine the overall effectiveness of psychotherapy services at The Family Institute, we entered the main effects of measure and time, as well as the two-way interaction of measure *x* time. As treatment condition (STIC® vs. TAU) was not significant when tested as a control variable in this model ($p = .16$), the final model did not include this variable. Alpha for all tests was set at $p < .05$ (two-tailed). The results indicated that the interaction of measure and time significantly predicted changes in the standardized clinical scores ($p = .0001$). Clinical scores across measures decreased (i.e., improved) from pre-

treatment (*M* = .06, *SD* = .92) to post-treatment (*M* = -.33, *SD* = .85). The effect size was moderate (Cohen's *d* = .44). These results indicate that, in general, clients who received therapy at The Family Institute improved significantly over the course of therapy with regard to individual, couple and family domains of functioning.

Clinically significant client improvement: Next, we examined whether clients improved at a clinically significant level. That is, just because we found a statistically significant change, that doesn't mean that clients moved from being clinically depressed to being mildly or not depressed after treatment. Thus, we examined whether clients experienced clinically significant change over the course of therapy. We conducted a series of paired *t*-tests for clients whose pre-therapy scores were above clinical cut-off scores that have been identified by psychotherapists and researchers who use these measures. Specifically, we included clients who were at least moderately distressed or functionally impaired on a given measure before starting therapy. For the purpose of these analyses, clients were analyzed as a group, regardless of presenting problem or type of treatment.

With regard to clinical anxiety, 180 clients reported having at least moderate levels of anxiety symptoms before starting treatment (based on the BAI clinical cut-off score of 16). On average, clients who started therapy in the clinically anxious range moved to the non-clinically anxious range (none or only mild anxiety symptoms) by the end of treatment (*p = .000, Cohen's d = -1.17; BAI pre-treatment: M = 24.98, SD = 8.27; BAI post-treatment: M = 14.42, SD = 10.46*). With regard to clinical depression, 168 individuals reported having at least moderate depressive symptoms based on the BDI-II clinical cut-off score of 20. On average, clients who started therapy in the clinically depressed range moved to the non-clinically depressed range by the end of treatment (*p = .000, Cohen's d = -1.39; BDI-II pre-treatment: M = 29.19, SD = 7.38;*

BDI-II post-treatment: M = 16.92, SD = 11.05). With regard to general distress (OQ-45), 248 clients were in the clinical range before starting treatment (above the clinical cut-off score of 63). On average, clients who started therapy in the clinically distressed range moved to the non-clinically distressed range by the end of treatment (*p = .000, Cohen's d = -1.49; OQ-45 pre-treatment: M = 84.67, SD = 15.02; OQ-45 post-treatment: M = 61, SD = 23.56*). Finally, with regard to couple distress/adjustment (RDAS), 85 individual clients scored in the clinically distressed range before starting couple therapy treatment (below the clinical cut-off score of 48). On average, clients improve their couple adjustment from pre-treatment to post-treatment while the scores still fall into the clinical range (*p = .029, Cohen's d = .41; RDAS pre-treatment: M = 38.27, SD = 6.48; RDAS post-treatment: M = 40.48, SD = 9.25*). (RDAS analyses are based on the entire sample.) With regard to family maladjustment, across all treatments, 98 clients reported having at least moderate levels of family distress before starting treatment (based on the FAD-GF clinical cut-off score of 24). In general, clients who were dissatisfied with their family functioning prior to therapy reported higher level of family adjustment at the end of treatment (*p = .000, Cohen's d = -0.86; FAD-GF pre-treatment: M = 30.61, SD = 5.16; FAD-GF post-treatment: M = 26.88, SD = 6.42*) despite of it still being in the clinical range. (FAD analyses were conducted for the entire sample.) In sum, clients who began treatment in the clinically significant range of symptoms and/or improved to the extent that their symptoms and levels of distress were no longer in the clinical range. Effect sizes were large, ranging from -1.17 to -1.49.

Discussion

This study examined outcomes in a representative sample of clients receiving therapy at The Family Institute. We examined self-reported symptoms of depression, anxiety and general distress, as well as couple and family adjustment and functioning. The results demonstrated that

clients' symptoms, distress and relationship functioning improved over the course of therapy. We found evidence for both statistically significant change and clinically significant changes. That is, even clients who were in the clinical ranges of symptoms, distress or functioning before treatment improved such that they were generally in the nonclinical ranges of functioning and symptoms after treatment. Moreover, because we recruited a racially and ethnically diverse and representative sample of clients, assessing those clients broadly across a range of systemic domains, and analyzing the data using conservative, omnibus tests, we may confidently conclude that these findings support our general contention at The Family Institute that our therapists are effective and that clients generally improve over the course of therapy.

In keeping with the systemically-oriented values and focus of The Family Institute, we were particularly interested in assessing for a *systemic impact* of therapy — whether clients generally improved and whether that improvement transcended the focus of their specific therapy approach (individual, couple of family therapy). In sum, it doesn't matter how we measured change; clients simply improved.

Put another way, we found support that therapists at The Family Institute are effective. These therapists' clients experienced change *generally* — the change was not specific to one type of treatment or one domain of functioning — which speaks to Goodyear et al.'s (2017) definition of therapist expertise as being defined in terms of *generally* positive outcomes with clients. This finding also speaks to The Family Institute's emphasis on systemic change: therapists who are effective have clients who change on multiple domains or systems (Nissen-Lie, et al., 2016).

There are some caveats that should be noted. First, our purpose in conducting this study was to examine client outcomes at The Family Institute. We sought to recruit a representative

sample of clients from a representative sample of therapists at The Family Institute to allow for generalizability across The Family Institute. Because all therapists in the study were either students of, or employed by, The Family Institute, the results may not be generalizable beyond The Family Institute itself. Second, we analyzed clients' own scores pre- and post-therapy, as opposed to comparing clients' scores to some external benchmark or to a non-treatment population (e.g., a waitlist group or control). This limitation makes it difficult to compare the results of this study directly with other types of outcome studies or with meta-analyses of therapy outcome, which typically examine therapy in comparison to a control group.

Conclusion

In this study we examined whether clients improve pre- to post-treatment across a variety of domains and systems at The Family Institute. Clients ($N = 503$) seeking individual, couple or family therapy from staff or student therapists at The Family Institute completed a series of questionnaires assessing depression, anxiety and general distress, as well as couple and family adjustment before and after treatment. Client outcomes were analyzed in general (across measures) and separately for each outcome. Results showed that clients significantly and clinically improved from pre- to post-treatment. Clients improved irrespective of therapy modality or area of functioning. In sum, we have empirical support for our contention that clients at The Family Institute improve over the course of therapy and that our therapists are making a difference in client's lives.

References

Aalto, A. M., Elovainio, M., Kivimäki, M., Uutela, A., & Pirkola, S. (2012). The Beck Depression Inventory and General Health Questionnaire as measures of depression in the general population: a validation study using the Composite International Diagnostic Interview as the gold standard. *Psychiatry research*, *197*, 163-171.

Beck, A. T., Epstein, N., Brown, G., & Steer, R. A. (1988). An inventory for measuring clinical anxiety: psychometric properties. *Journal of consulting and clinical psychology*, *56*, 893.

Beck, A. T., Steer, R. A., & Brown, G. K. (1996). Beck depression inventory-II. *San Antonio*, *78*(2), 490-8.

Beckstead, D. J., Hatch, A. L., Lambert, M. J., Eggett, D. L., Goates, M. K., & Vermeersch, D. A. (2003). Clinical significance of the Outcome Questionnaire (OQ-45.2). *The behavior analyst today, 4*, 86.

Boswell, J. F., Kraus, D. R., Miller, S. D., & Lambert, M. J. (2015). Implementing routine outcome monitoring in clinical practice: Benefits, challenges, and solutions. *Psychotherapy research*, *25*(1), 6-19.

Boterhoven de Haan, K. L., Hafekost, J., Lawrence, D., Sawyer, M. G., & Zubrick, S. R. (2015). Reliability and validity of a short version of the general functioning subscale of the McMaster Family Assessment Device. *Family process*, *54*(1), 116-123.

Brouwer, D., Meijer, R. R., & Zevalkink, J. (2013). On the factor structure of the Beck Depression Inventory–II: G is the key. *Psychological assessment*, *25*(1), 136.

Busby, D. M., Christensen, C., Crane, D. R., & Larson, J. H. (1995). A revision of the Dyadic Adjustment Scale for use with distressed and nondistressed couples: Construct hierarchy and multidimensional scales. *Journal of Marital and family Therapy*, *21*(3), 289-308.

de Lima Osório, F., Crippa, J. A. S., & Loureiro, S. R. (2011). Further psychometric study of the Beck Anxiety Inventory including factorial analysis and social anxiety disorder screening. *International Journal of Psychiatry in Clinical Practice*, *15*(4), 255-262.

Epstein, N. B., Baldwin, L. M., & Bishop, D. S. (1983). The McMaster family assessment device. *Journal of marital and family therapy*, *9*(2), 171-180.

Goodyear, R. K., Wampold, B. E., Tracey, T. J., & Lichtenberg, J. W. (2017). Psychotherapy expertise should mean superior outcomes and demonstrable improvement over time. *The Counseling Psychologist*, *45*(1), 54-65.

Hunsley, J., Pinsent, C., Lefebvre, M., James-Tanner, S., & Vito, D. (1995). Construct validity of the short forms of the Dyadic Adjustment Scale. *Family Relations*, 231-237.

Kenward, M. G., & Roger, J. H. (1997). Small sample inference for fixed effects from restricted maximum likelihood. *Biometrics*, 983-997.

Kühner, C., Bürger, C., Keller, F., & Hautzinger, M. (2007). Reliabilität und validität des revidierten beck-depressionsinventars (BDI-II). *Der Nervenarzt*, *78*(6), 651-656.

Lambert, M. J., Hansen, N. B., & Harmon, S. C. (2010). Outcome Questionnaire System (The OQ System): Development and practical applications in healthcare settings. *Developing and delivering practice-based evidence: A guide for the psychological therapies*, 141-154.

Lambert, M. J., Morton, J. J., Hatfield, D. R., Harmon, C., Hamilton, S., Shimokawa, K., et al. (2004). Administration and scoring manual for the Outcome Questionnaire (OQ 45.2). (3 ed.). Wilmington, DE: American Professional Credentialling Services LLC.

Lunnen, K. M., & Ogles, B. M. (1998). A multiperspective, multivariable evaluation of reliable change. *Journal of*

Consulting and Clinical Psychology, *66*(2), 400.

Montesino, M. L. C., Gómez, J. L. G., Fernández, M. E. P., & Rodríguez, J. M. A. (2013). Psychometric properties of the dyadic adjustment scale (DAS) in a community sample of couples. *Psicothema*, *25*(4), 536-541.

Muntingh, A. D., van der Feltz-Cornelis, C. M., van Marwijk, H. W., Spinhoven, P., Penninx, B. W., & van Balkom, A. J. (2011). Is the beck anxiety inventory a good tool to assess the severity of anxiety? A primary care study in The Netherlands study of depression and anxiety (NESDA). *BMC family practice*, *12*(1), 66.

Nissen-Lie, H. A., Goldberg, S. B., Hoyt, W. T., Falkenström, F., Holmqvist, R., Nielsen, S. L., & Wampold, B. E. (2016). Are therapists uniformly effective across patient outcome domains? A study on therapist effectiveness in two different treatment contexts. *Journal of counseling psychology*, *63*(4), 367.

Norcross, J.C., Beutler, L.E., Levant, R.F. (2006) (Eds). Evidence-based practices in mental health: Debate and dialogue on the fundamental questions. Washington, DC, US: American Psychological Association.

Pinsof, W. M., Breunlin, D. C., Russell, W. P. , Rampage, C. & Chambers, A. L. (2017). *Integrative Systemic Therapy: Metaframeworks for Problem Solving with Individuals, Couples and Families.* Washington D.C.: APA Books, American Psychological Association.

Staccini, L., Tomba, E., Grandi, S., & Keitner, G. I. (2015). The evaluation of family functioning by the family assessment device: A systematic review of studies in adult clinical populations. *Family process*, *54*(1), 94-115.

StataCorp. (2015). Stata Statistical Software: Release 14. College Station, TX: StataCorp LP.

Walfish, S., McAlister, B., O'donnell, P., & Lambert, M. J. (2012). An investigation of self-assessment bias in mental health providers. *Psychological Reports*, *110*(2), 639-644.

Wampold, B. E., & Imel, Z. E. (2015). The great psychotherapy debate: The evidence for what makes psychotherapy work. Routledge.

Footnotes

[1] The entire study took five years to complete. Data collection took three years to complete.

[2] Adults seeking psychotherapy at The Family Institute were recruited to participate in a larger study — a randomized clinical trial (RCT) comparing client change when therapists used the STIC® (n = 255) versus treatment as usual (n = 248). Chi-square tests revealed no significant differences across clients the two conditions in the findings presented in this paper. Nevertheless, results did not differ across conditions.

[3] The goal of the study was *not* to determine whether some therapists at The Family Institute had better outcomes than others, but rather to assess the efficacy of therapists at The Family Institute as a group. However, given the significant differences between The Family Institute's staff and students in levels of experience, client populations and therapy styles (students all practicing IST whereas staff practice a range of therapies), we also compared findings between these two groups of therapists.

To explore whether student and staff had different levels of therapy effectiveness, we entered the main effects of client outcome, time and therapist status (student vs. staff), as well as a three-way interaction among the measure, time and therapist status. Results were not significantly different for students versus staff therapists, which is consistent with prior studies at different clinical sites (e.g., Goodyear et al., 2017). This finding may suggest that: we are enrolling talented clinicians into our graduate programs; we are effectively training and supervising our student therapists and/or that we are doing a good job of matching clients to therapists' skills and experience levels.

Finally, because all of these students exclusively practiced Integrative Systemic Therapy, the student therapist results may be seen as preliminary support for IST itself (with the caveat that some staff therapists also practiced IST, and therefore this study should not be seen as a direct comparison of IST to treatment as usual).