Enhancing stress reactivity and wellbeing in early schizophrenia: A randomized controlled trial of Integrated Coping Awareness Therapy (I-CAT)

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ABSTRACT

Individuals with schizophrenia spectrum disorders (SSD) are at heightened risk for exposure to stressful life events which can lead to increased sensitivity to stress and a dysregulated stress response, which are in turn associated with poor long-term functioning. Stress reactivity is thus a promising treatment target in the early stages of SSD. Integrated-Coping Awareness Therapy (I-CAT) is a manualized intervention integrating mindfulness and positive psychology to target a dysregulated stress response in SSD. The current study is a preliminary randomized-controlled trial (RCT) comparing I-CAT ($n = 18$) with treatment as usual (TAU; $n = 18$) in individuals in the early stages of SSD. I-CAT was hypothesized to be more effective than TAU on primary outcomes: increasing positive emotions, decreasing negative emotions, reducing stress, and improving functioning and quality of life; and secondary outcomes: reducing symptoms, increasing mindfulness, and improving overall wellbeing. Excellent therapy attendance rates, low study attrition, and positive participant feedback demonstrated that I-CAT was a feasible and well-tolerated psychosocial intervention. Results suggest I-CAT led to greater reduction in symptoms (i.e., overall, negative, and disorganized symptoms), increased observational mindfulness, increased endorsement of a sense of purpose in life, and preservation of work abilities and school social functioning compared with TAU. Future work should replicate and extend these findings in a larger-scale RCT.

1. Introduction

Schizophrenia spectrum disorder (SSD) is a severe mental illness marked by positive and negative symptoms and impairments in functioning. While the potential for recovery is well-documented (Jääskeläinen et al., 2013; Vita and Barlati, 2018), relapse is common and associated with residual deficits (e.g., low motivation, social and cognitive deficits) that interfere with long-term functioning (Lambert et al., 2006). The costs of long-term functioning impairments are devastating and include shortened life expectancy, high rates of disability, and excess mortality rates from cardiovascular disease (Cloutier et al., 2016; Hjorthøj et al., 2019; Olfson et al., 2019). Health

outcomes linked to chronic stress (e.g., cardiovascular disease) also reflect high rates of stressful life events that both precede the onset of illness and contribute to repeated relapse (DeTore et al., 2019; Mauritz et al., 2013). Alterations in physiology, endocrine, and immune functioning, consistent with a dysregulated stress response, are observed in individuals with SSD (Chiappelli et al., 2016; Gispen-De Wied, 2000). Moreover, evidence of a dysregulated stress response (e.g., impaired hypothalamic-pituitary-adrenal axis response, flattened cortisol response) is found in the early stages of SSD (Van Venrooij et al., 2012).

One theory explaining a dysregulated stress response is that individuals with SSD experience high allostatic load, an index of neuroendocrine, immune, and metabolic dysregulation associated with

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chronic stress (Berger et al., 2018; Misiak et al., 2014). Individuals with SSD are at heightened risk for exposure to stressful events; greater exposure to stress can lead to increased stress sensitivity and difficulties regulating the stress response (Docherty et al., 2009). Psychosis can also be considered a stressful life event that disrupts functioning and can lead to additional psychosocial stressors (e.g., loss of job or school dropout, disrupted relationships). Additionally, there is evidence that individuals with SSD may be predisposed with a low capacity for handling stress and thus experience more events as stressful or distressing, further contributing to allostatic overload (e.g., Docherty et al., 2009).

Allostatic overload, and subsequent increased stress reactivity, is thus a promising intervention target to prevent relapse and improve long-term recovery outcomes in SSD, especially in the early stages when allostatic load is responsive to treatment (Berger et al., 2018). Improvements in stress reactivity may prevent relapse, often triggered by stressful life events, and decrease long-term residual symptoms which in turn adversely impact functioning and treatment response (e.g., Hassan and De Luca, 2015).

To date, no psychosocial interventions specifically target allostatic load in the early stages of SSD, although two widely disseminated approaches, positive psychotherapy and mindfulness, demonstrate efficacy in reducing stress and building resources to cope with future stressors in chronic SSD (Jansen et al., 2020; Khoury et al., 2013b; Meyer et al., 2012; Schrank et al., 2016). Mindfulness-based approaches in particular have garnered increasing attention and demonstrate consistent efficacy across a range of outcomes (e.g., symptom reduction, functioning) in psychosis (Hodann-Caudevilla et al., 2020; Louise et al., 2018; Sabe et al., 2019). Integrated-Coping Awareness Therapy (I-CAT), the manualized psychosocial treatment used in this study, integrates these two approaches specifically structured for individuals in the early stages of SSD. The positive psychotherapy aspect of I-CAT is based on the broaden-and-build hypothesis of positive emotions which theorizes that increased positive emotions may create more behavioral flexibility (e.g., openness to participate in social situations that individuals may typically avoid due to increased anxiety; Fredrickson, 2001). This behavioral flexibility may lead to even more positive emotions (e.g., individual participates in a social event and enjoys themself) and increase participation in a greater array of activities which can improve functioning through increased social support (e.g., making friends) and economic resources (e.g., maintaining a job). Mindfulness, defined as training in present-centered awareness, has been shown to decrease response to stress and reduce allostatic load in individuals with psychosis (e.g., Khoury et al., 2013a; Pascoe et al., 2017). I-CAT aims to target allostatic load through integration of positive psychology to increase positive emotions and behavioral flexibility, and mindfulness to increase capacity for stress and build resilience.

Results of a small pilot study demonstrated I-CAT was feasible and suggested that I-CAT may reduce stress, alleviate symptoms, and improve quality of life and well-being in the early stages of SSD (Meyer-Kalos et al., 2018). The current study is a preliminary randomized controlled trial (RCT) comparing I-CAT with treatment as usual (TAU) in a larger sample of individuals in the early stages of SSD. The primary pre-registered outcome of interest was quality of life based on improvements observed in the I-CAT pilot study. The primary hypothesis was that I-CAT would be more effective than TAU in regard to increasing positive emotions, decreasing negative emotions, improving social functioning and quality of life, and reducing daily stress (i.e., primary outcomes); The study's secondary hypothesis was that I-CAT would be more effective than TAU in regard to decreasing symptoms and increasing mindfulness and overall well-being (i.e., secondary outcomes).

2. Methods

2.1. Study design, participants, and randomization

Individuals in the early stages of SSD (i.e., diagnosis made within eight years) participated in an RCT between November 2016 and March 2020. Inclusion criteria included meeting Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition (DSM-IV; American Psychiatric Association, 2000) criteria for SSD according to the Structured Clinical Interview for DSM-IV (SCID; First et al., 2002), being 18–35 years of age, IQ greater than 80 as determined by the Wechsler Abbreviated Scale of Intelligence – 2nd edition (WASI; Wechsler et al., 2011), not meeting criteria for current substance use disorder as determined by the SCID and the interviewer-rated Clinical Alcohol Use Scale and Clinical Drug Use Scale (AUS/DUS; Drake et al., 1996), no hospitalizations within the past three months, and no history of meditation workshops or practicing meditation in the past year. The AUS/DUS was administered at all follow-up assessments to ensure participants did not meet current substance use disorder criteria during study participation.

Participants were recruited from a first-episode specialty clinic, community clinics, and community advertisements (see Fig. 1 for CONSORT diagram). The study took place at two sites, the University of North Carolina at Chapel Hill ($n = 35$) and The University of Minnesota – Twin Cities ($n = 3$). After an initial screening visit, eligible participants completed assessment visits at baseline, mid-treatment (i.e., 4.5 months), post-treatment (i.e., nine months), and a three-month follow-up. Participants were randomly assigned in blocks of four, stratified by sex to I-CAT ($n = 19$) or TAU ($n = 19$) in a 1:1 ratio. Randomization was performed using PROCPLAN in SAS Version 9.3 by an independent statistician blind to study hypotheses. Institutional Review Boards at both study sites approved all procedures (clinicaltials.gov identifier NCT03067311).

2.2. Intervention

I-CAT was compared with TAU, defined as individual therapy delivered within coordinated specialty care (CSC), to include common therapeutic effects for a conservative comparison of treatment effects (Mohr et al., 2009).

2.2.1. Integrated coping awareness therapy

I-CAT is a manual-based intervention (manual available from the authors by request). Sessions include collaborative agenda setting, practice of skills, refining and problem-solving obstacles, and collaborative homework assignments.

Part I of I-CAT includes psychoeducation on stress reactivity and mindfulness and assessment of stressors. Part II of I-CAT integrates practice of mindfulness (e.g., sitting meditation, body scan) and positive coping strategies (e.g., identification of personal strengths, setting positive goals, active/constructive responding). Sessions focus on a new strategy broken down into small steps demonstrated and practiced in session. Handouts are provided to increase integration of new skills in daily routines and track practice of skills between sessions. Part III of I-CAT focuses on 1) development of an individualized daily routine integrating mindfulness and meaningful coping skills, and 2) development of positive and personally meaningful goals (e.g., return to school). Handouts are also utilized in Part III to break goals into small steps, track progress, and identify barriers to goal achievement.

I-CAT can be flexibly administered with a minimum of 14 sessions recommended to cover all skills and participate in the individualized plan, or up to 24 sessions based on client needs. I-CAT was designed as a weekly intervention but can be administered bi-weekly. Participants in the I-CAT condition also completed CSC appointments (e.g., medication management, family therapy, supported employment, peer support).
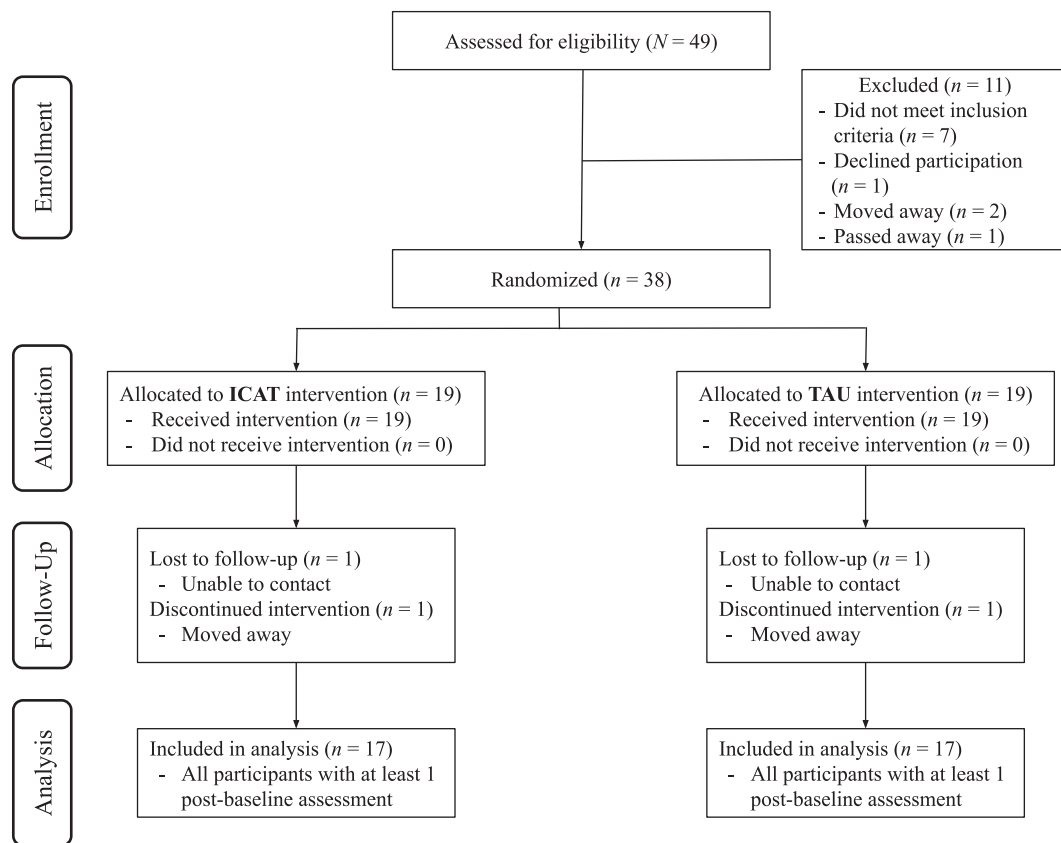
Fig. 1. CONSORT diagram.

2.2.2. Treatment as usual

Participants randomized to TAU participated in weekly or bi-weekly therapy sessions and CSC appointments. TAU consisted of supportive therapy and evidence-based treatment approaches associated with first episode psychosis. The three masters level clinicians received training in the NAVIGATE model (Kane et al., 2016; Mueser et al., 2015), which included incorporating the following elements into sessions: cognitive-behavioral therapy strategies, psychoeducation, skills training, relapse prevention planning, and coping skills training. Training in the NAVIGATE interventions included how to follow a standard session structure (i.e., follow-up on previous session and goals, review new materials, practice skills in session when possible, collaboratively develop a plan for home practice). The graduate student clinicians were given supervision on how to implement any evidence-based treatments that were relevant to the participants presenting clinical issues. All clinicians were instructed not to provide treatment that include teaching and practicing positive psychology or mindfulness strategies. The frequency and duration of TAU was the same as I-CAT (i.e., up to 24) with participants encouraged to complete at least 14 sessions.

2.2.3. Study therapists

Study therapists attended a two-day workshop to develop proficiency with I-CAT, theories of mindfulness and positive psychology and skills (e.g., how to utilize sitting meditation recordings and written materials), as well as structured goal setting. Study therapists had at least a masters-level degree and were full-time clinicians ($n = 2$) or doctoral students ($n = 10$). Study therapists attended bi-weekly group supervision with study PIs.

Therapy sessions were recorded and rated for I-CAT fidelity and therapeutic relationship on a five-point scale ($1 = $ *unsatisfactory*, $5 = $ *excellent*). Good fidelity ($M = 3.65$, $SD = 0.39$) and therapeutic relationships ($M = 4.92$, $SD = 0.24$) were observed across I-CAT

participants. Good therapeutic relationships ($M = 4.91$, $SD = 0.15$) but poor I-CAT fidelity ($M = 1.08$, $SD = 0.12$) were observed across TAU participants, confirming delivery of TAU without I-CAT components. No differences were observed between full-time clinicians and doctoral students on fidelity, therapeutic relationships, or randomization to treatment condition.

2.3. Measures

Trained assessors blind to treatment condition administered and scored measures at baseline, mid-treatment, post-treatment, and three-month follow-up. Assessor accuracy for guessing participant treatment condition was around chance (51.33%) confirming assessor blindness.

2.3.1. Primary outcome measures

2.3.1.1. Positive emotions. The modified self-report Differential Emotion Scale (mDES; Fredrickson et al., 2003) assessed the frequency of experiencing discrete emotions from the previous week. Items are endorsed on a five-point scale ($0 = $ *not at all*, $4 = $ *most of the time*) and averaged to yield positive and negative emotion subscales (range for both 0-4).

2.3.1.2. Quality of life. The abbreviated Quality of Life Scale (QLS; Bilker et al., 2003) is a seven-item semi-structured interview assessing domains of functioning (i.e., intrapsychic foundation, interpersonal relationships, instrumental role, and engagement in community). Items are rated on a six-point scale yielding a sum total score (range 0 - 42) with higher ratings reflecting better functioning.

2.3.1.3. Social functioning. The First Episode Social Functioning Scale (FESFS; Lecomte et al., 2014) is a 42-item self-report measure assessing

social functioning in early SSD. The FESFS includes a total score and eight subscales assessing: independent living skills, interacting with people in different contexts, social activities, intimacy, friendships, family relations, work, and school. Domain scores are averaged with higher scores reflecting better perceived functioning (range 0-4).

2.3.1.4. Stress reactivity. The Perceived Stress Scale (PSS; Cohen et al., 1983) is a ten-item self-report measure of the degree to which daily situations from the past week are perceived as stressful, unpredictable, uncontrollable, as well as how "overloaded" individuals feel (0 = *never,* 4 = *very often*). Items are summed for a total score (range 0–40) with higher scores indicating more perceived stress.

The Daily Stress Inventory (DSI; Brantley et al., 1987) is a 58-item self-report measure assessing the frequency and intensity of stressful events within the past 24-h. If an event is endorsed, participants rate the amount of stress the event caused (0 = *did not occur,* 1 = *occurred but was not stressful* to 7 = *occurred and caused me to panic*). The DSI yields three scores: frequency (number of events endorsed as occurred; range 0 - 58), sum (sum of the total impact rating of endorsed events; range 0 - 406), average impact rating (AIR; average impact of ratings given items endorsed [sum/frequency]).

2.3.2. Secondary outcome measures

2.3.2.1. Symptoms. The Positive and Negative Syndrome Scale (PANSS; Kay et al., 1987) assessed current symptoms. PANSS items are rated on a seven-point scale with higher scores reflecting more severe symptoms (ICCs for study assessors >0.90). Items are summed for a total score (range 30–210). Items were also averaged according to the five-factor structure with the most consensus across studies (Wallwork et al., 2012) to yield five subscales (range 1-7) assessing negative, positive, depression, excited, and disorganization symptoms.

2.3.2.2. Mindfulness. The Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006) is a 39-item self-report measure assessing facets of being mindful in daily life (i.e., observing, describing, acting with awareness, non-reactivity to inner experience, and non-judging of inner experience). The FFMQ measures constructs needed to effectively process and attend to information available in the present moment to produce adaptive behavioral responses and can also be considered a measure of behavioral flexibility (Bednar et al., 2020). Items are endorsed on a five-point scale (1 = *never or rarely true* to 5 = *very often or always true*) and averaged for a total score and five subscale scores for each facet of mindfulness (range 1-5).

The Self-Compassion Scale Short Form (SCS-; Raes et al., 2011) is a 12-item self-report measure of self-compassion. SCS items are endorsed on a five-point scale (1 = *almost never* to 5 = *almost always*) and are summed for a total score (range 12–60) and six subscales (i.e., self-kindness, self-judgment, common humanity, isolation, mindfulness, and over-identified; range 2–10).

2.3.2.3. Well-being. The Psychological Well-Being Scale (PWB; Ryff, 1989) is a 54-item self-report measure with items endorsed on a seven-point scale (1 = *strongly disagree* to 6 = *strongly agree*). Items are summed for a total score (range 54 - 324) and six subscale scores (i.e., autonomy, environmental mastery, personal growth, positive relations with others, purpose in life, self-acceptance; range 9 - 54).

2.4. Statistical analysis

Differences between group demographics were tested with independent samples *t*-tests (continuous variables) or Pearson chi-square tests (categorical variables). Little's Missing Completely at Random (MCAR) test was not significant ($X^2(297) = 286.89$, $p = .65$) suggesting data was missing completely at random and therefore no data

imputation was performed.

To test whether groups differed in their amount of change on treatment outcomes over time, data were analyzed according to the intent-to-treat (ITT) principle, in which all subjects randomized were included in the analysis. This was accomplished via a linear mixed- effects model (LMM), using restricted maximum likelihood (REML) estimation where missing data was handled via full information maximum likelihood (FIML). The LMM included fixed effects of time, group, and a group × time interaction, with random intercepts for participants to account for baseline differences on outcome variables. Observations classified as outliers (i.e., residual values less than or greater than 1% of all observations) were excluded. Changes from baseline were estimated with standardized least-squares means (LSMs) for each treatment group. Standardized least-squares mean differences (LSMDs) between treatment groups were estimated for effects of treatment differences.

3. Results

3.1. Baseline demographics, clinical characteristics, and outcome values

Participant demographic and clinical characteristics are presented in Table 1. Participants were moderately symptomatic at baseline (PANSS total score $M = 60.32$, $SD = 16.52$; Leucht et al., 2005). No significant group differences in demographic or clinical characteristics were present with the exception of employment status (84.21% employment in I-CAT versus 52.63% TAU, $X^2(1) = 4.39$, $p = .04$). There were no significant differences in baseline values on treatment outcomes (see Table 2).

3.2. Feasibility and tolerability

All participants randomized to a treatment condition attended at least one therapy session. Attendance rates (i.e., ratio of attended to scheduled therapy sessions) were comparable between treatment groups (91.61% I-CAT, 91.99% TAU, $t(36) = 0.78$, $p = .44$). Treatment frequency (i.e., total number of completed therapy sessions) was also comparable between I-CAT ($M = 18.63$, $SD = 6.86$) and TAU ($M = $

Table 1
Baseline demographic and clinical characteristics.

	I-CAT $n = 19$	TAU $n = 19$	p values
Age, years	23.6 ± 4.3	24.9 ± 3.86	.34
Male % (*n*)	53 (10)	53 (10)	.99
Education, years	12.6 ± 1.8	13.8 ± 1.9	.56
Race % (*n*)			
White	57.9 (11)	73.7 (14)	.31
Black	26.3 (5)	1.5 (2)	.21
Asian	1.5 (2)	1.5 (2)	.19
American Indian/Alaskan Native	5.3 (1)	5.3 (1)	.99
Ethnicity % (*n*)			
Latino	21.1 (4)	5.3 (1)	.15
WASI-II IQ Score	107.7 (14.1)	111.5 (12.0)	.37
Duration of illness, years[a]	1.7 (1.5)	1.8 (2.0)	.85
Employed/Student % (*n*)	84.2 (16)	52.6 (10)	.04
PANSS			
Total	62.3 ± 17.2	58.4 ± 16.0	.47
Positive	2.4 ± 1.1	2.3 ± 1.0	.75
Negative	2.1 ± 1.0	1.8 ± 1.0	.25
Disorganized	2.0 ± 0.7	1.7 ± 0.6	.22
Excited	1.3 ± 0.4	1.3 ± 0.5	.63
Depressed	3.3 ± 1.2	3.1 ± 0.8	.49
Medications % (*n*)			
1st generation antipsychotics	78.9 (15)	84.2 (16)	.68
2nd generation antipsychotics	5.3 (1)	0 (0)	–
Combination	5.3 (1)	5.3 (1)	.99
No antipsychotic	1.5 (2)	1.5 (2)	.99

Note: Data presented as mean ± standard deviation unless otherwise indicated. Indicates years since initial schizophrenia diagnosis.; WASI-II – Wechsler Abbreviated Scale of Intelligence – Second Edition; PANSS – Positive and Negative Symptom Scale.

Table 2
Baseline outcome values.

	I-CAT $n = 19$	TAU $n = 19$	p values
Primary outcomes			
mDES – positive emotions	21.3 ± 6.9	20.9 ± 9.3	.88
mDES – negative emotions	15.6 ± 8.7	18.2 ± 10.6	.42
Quality of Life Scale	26.0 ± 8.3	25.3 ± 7.2	.77
First Episode Social Functioning Scale	3.0 ± 0.4	3.2 ± 0.5	.31
Perceived Stress Scale	18.8 ± 6.3	20.9 ± 8.5	.40
Daily Stress Inventory[a]	3.0 ± 1.3	2.9 ± 1.2	.74
Secondary outcomes			
Five Facets of Mindfulness Questionnaire	3.0 ± 0.4	3.0 ± 0.6	.78
Self-Compassion Scale	34.7 ± 7.0	35.7 ± 9.7	.72
Perceived Well-Being Scale	207.9 ± 36.8	209.32 ± 46.8	.92

Note: Data presented as mean ± standard deviation unless otherwise indicated.
[a] average impact of stressors score; mDES = modified Differential Emotions Scale.

14.16, $SD = 7.21$, $t(36) = 1.96$, $p = .06$). Treatment "completers" were a priori defined in the study protocol as participants attending at least nine therapy sessions corresponding to participation in at least one session of all three phases of I-CAT and attendance to at least 50% of sessions (Mueser and Drake, 2011). Frequency of treatment completers (84.21%, I-CAT, 73.68% TAU, $X^2(1) = 0.63$, $p = .43$) was comparable between groups. There were no differences in demographic or clinical characteristics between completers and non-completers.

Four participants (2 I-CAT, 2 TAU) withdrew from the study before completing mid-treatment assessments and were thus excluded from analyses. 78.95% of participants completed mid-treatment assessments, 84.21% completed post-treatment assessments, and 78.95% completed three-month follow-up assessments. There were no group differences on rates of assessment completion.

I-CAT participants provided feedback after treatment completion to assess tolerability on a three-point scale with higher scores indicating favorable feedback. This feedback scale has been used in previous treatment studies (e.g., Waldheter et al., 2008). Participants found I-CAT easy to follow ($M = 2.35$, $SD = 0.49$), enjoyable ($M = 2.47$, $SD = 0.62$), useful ($M = 2.29$, $SD = 0.69$), respectful ($M = 2.53$, $SD = 0.51$), helpful to improve skills with being around others ($M = 2.18$, $SD = 0.64$), and helpful to find enjoyment in daily life ($M = 2.25$, $SD = 0.45$).

3.3. Primary outcomes

There were significant differences observed on primary outcome measures between I-CAT and TAU (i.e., treatment effects). Individuals in ICAT maintained QLS work abilities at follow-up compared with TAU (LSMD = 0.87, $p = .02$) and this finding approached statistical significance at post-treatment (LSMD = 0.63, $p = .05$). Individuals in ICAT also maintained QLS school relationships and social activities at post-treatment compared with TAU (LSMD = 1.17, $p = .01$). Models demonstrating significant treatment effects were repeated with employment status as a covariate to address baseline differences in rates of employment with robust results (all ps still <.05). Models were also repeated with total sessions as a covariate to address trend-level baseline differences with robust treatment effect results (all ps still <.05). No other significant differences were observed on primary outcomes.

Within-group changes on primary outcomes are presented in Table 3 (i.e., standardized LSM changes from baseline [Δ LSM]; see Supplementary Table 1 for unstandardized Δ LSM).

3.4. Secondary outcomes

I-CAT was more effective than TAU in reducing total symptoms at

post-treatment (LSMD = 0.52, $p = .02$), decreasing negative symptoms at both post-treatment (LSMD = 0.96, $p < .01$) and follow-up (LSMD = 0.76, $p = .02$), and decreasing disorganized symptoms at post-treatment (LSMD = 0.42, $p < .01$). Models demonstrating significant treatment effects were repeated with employment status as a covariate with robust results. Fig. 2 presents treatment group changes on total and negative symptoms. Models were also repeated with total sessions as a covariate with robust treatment effect results (all ps still <0.05). Within-group changes on symptoms are presented in Table 4 (i.e., standardized Δ LSM; see Supplementary Table 2 for unstandardized Δ LSM).

Standardized LSM changes according to the three-factor PANSS model are presented in Supplementary Table 3. Similar significant results were observed between the five-factor and three-factor PANSS.

In terms of mindfulness and well-being secondary outcomes, I-CAT was more effective than TAU in increasing mindfulness as measured by the FFMQ Observation subscale at post-treatment (LSMD = 0.73, $p < .01$) and follow-up (LSMD = 0.62, $p = .03$). I-CAT was also more effective than TAU in improving well-being on the PWB Purpose in Life subscale at post-treatment (LSMD = 0.78, $p < .01$) and follow-up (LSMD = 0.69, $p < .01$). Models were repeated with employment status as a covariate to address baseline differences in rates of employment with robust results (all ps still <.05). Models were also repeated with total sessions as a covariate with robust treatment effect results (all ps still <.05) with the exception of FFMQ Observation subscale which no longer demonstrated significant treatment effects at post-treatment ($p = .05$) and follow-up ($p = .13$). See Fig. 2 for treatment group changes on the FFMQ Observation and the PWB Purpose in Life subscales.

Several treatment differences were observed at a trend-level (i.e., $p \leq .08$) on well-being outcomes. ICAT demonstrated trend-level improvements compared with TAU on the PWB total score at post-treatment (LSMD = 0.37, $p = .08$), PWB Personal Growth subscale at post-treatment (LSMD = 0.46, $p = .06$) and follow-up (LSMD = 0.47, $p = .07$), and the PWB self-acceptance subscale at post-treatment (LSMD = 0.42, $p = .08$).

Interestingly, TAU was more effective than I-CAT in increasing self-compassion measured with the SCS Self-Kindness subscale at follow-up (LSMD = 0.75, $p = .03$) and the SCS Common Humanity subscale at mid-treatment (LSMD = 0.80, $p < .01$). All other changes in secondary outcomes were non-significant between treatment groups across timepoints.

Within-group changes on mindfulness and well-being outcomes are presented in Table 5 (i.e., standardized Δ LSM; see Supplementary Table 4 for unstandardized Δ LSM).

4. Discussion

Excellent therapy attendance rates, low study attrition, and positive participant feedback in this preliminary RCT suggest I-CAT is a feasible and well-tolerated psychosocial intervention for individuals in the early stages of SSD. I-CAT was equivalent to TAU across several domains with results suggesting I-CAT improved treatment outcomes within specific domains including reduction in symptoms (i.e., overall, negative, and disorganized symptoms), increased observational mindfulness, increased endorsement of a sense of purpose in life, and preservation of work abilities and school social functioning.

The primary hypothesis was partially supported. I-CAT was more effective in *maintaining* work abilities and school social functioning compared with TAU, suggesting I-CAT may offer extra support with regards to occupational functioning. However, I-CAT did not demonstrate significant reductions in stress reactivity compared with TAU. One explanation for this finding may be that factors common to therapy, regardless of approach, target stress reactivity. Another explanation may relate to *how* stress reactivity was measured. Stress reactivity was assessed retrospectively and aggregated (i.e., past week, past month) which may be prone to bias (e.g., Ben-Zeev et al., 2012; Blum et al., 2015). Additionally, stress reactivity was measured by self or informant-

Table 3

Standardized change from baseline for primary outcomes.

Primary outcome measure	Timepoint	Within-group						Between-group		
		I-CAT			TAU					
		LSM (SE)	d	p	LSM (SE)	d	p	LSMD	d	p
Positive emotions										
Modified Differential Emotions Scale										
Positive emotions	Mid	0.35 (0.19)	0.45	.07	**0.42 (0.20)**	0.59	.04	0.07	0.06	.80
	Post	**0.62 (0.19)**	0.80	<.01	0.25 (0.19)	0.35	.18	0.37	0.30	.18
	Follow-up	0.28 (0.19)	0.37	.16	0.38 (0.21)	0.52	.08	0.10	0.08	.72
Negative emotions	Mid	0.01 (0.17)	0.01	.98	−0.38 (0.20)	0.52	.07	0.39	0.31	.16
	Post	−0.27 (0.17)	0.38	.12	−0.19 (0.19)	0.26	.31	0.08	0.07	.75
	Follow-up	−0.01 (0.19)	0.00	.99	−0.24 (0.20)	0.35	.23	0.23	0.19	.39
Quality of life										
Quality of Life Scale										
Total	Mid	0.10 (0.16)	0.15	.54	**0.36 (0.78)**	0.55	.04	0.26	0.23	.28
	Post	0.26 (0.16)	0.40	.11	0.28 (0.18)	0.41	.12	0.02	0.02	.95
	Follow-up	**0.74 (0.16)**	1.14	<.01	**0.91 (0.18)**	1.38	<.01	0.17	0.16	.47
Social functioning										
First Episode Social Functioning Scale										
Total	Mid	−0.07 (0.14)	0.12	.63	0.04 (0.16)	0.07	.80	0.11	0.11	.61
	Post	0.22 (0.15)	0.36	.14	0.20 (0.15)	0.35	.19	0.02	0.02	.95
	Follow-up	**0.40 (0.15)**	0.68	.01	**0.33 (0.17)**	0.58	.04	0.07	0.07	.75
Independent living skills	Mid	0.13 (0.17)	0.18	.45	−0.30 (0.18)	0.45	.11	0.43	0.37	.09
	Post	0.17 (0.17)	0.24	.33	0.05 (0.18)	0.07	.80	0.12	0.11	.62
	Follow-up	0.15 (0.17)	0.22	.40	−0.09 (0.19)	0.14	.63	0.24	0.20	.36
Interacting with people	Mid	0.09 (0.16)	0.14	.58	0.18 (0.17)	0.29	.30	0.09	0.09	.68
	Post	0.25 (0.16)	0.39	.11	0.27 (0.17)	0.42	.11	0.02	0.02	.94
	Follow-up	**0.48 (0.16)**	0.76	<.01	**0.38 (0.19)**	0.58	.04	0.10	0.08	.71
Friends and activities	Mid	−0.26 (0.19)	0.34	.17	0.14 (0.20)	0.19	.49	0.40	0.32	.15
	Post	**0.37 (0.18)**	0.50	.04	0.28 (0.19)	0.38	.15	0.09	0.08	.73
	Follow-up	**0.41 (0.19)**	0.56	.03	0.41 (0.21)	0.56	.05	0.00	0.00	.99
Intimacy	Mid	−0.10 (0.14)	0.17	.49	−0.13 (0.16)	0.22	.43	0.03	0.03	.90
	Post	0.27 (0.14)	0.45	.07	0.04 (0.15)	0.07	.79	0.23	0.24	.28
	Follow-up	0.21 (0.15)	0.36	.16	0.33 (0.17)	0.57	.05	0.12	0.12	.60
Family	Mid	0.20 (0.21)	0.23	.35	0.37 (0.23)	0.44	.12	0.17	0.11	.61
	Post	−0.05 (0.22)	0.05	.82	0.19 (0.22)	0.23	.39	0.24	0.17	.44
	Follow-up	0.08 (0.22)	0.09	.73	0.23 (0.24)	0.28	.34	0.15	0.10	.64
Work abilities	Mid	−0.27 (0.22)	0.33	.23	−0.20 (0.26)	0.26	.45	0.07	0.05	.84
	Post	0.35 (0.22)	0.44	.11	−0.28 (0.24)	0.34	.24	0.63	0.50	.05
	Follow-up	0.25 (0.23)	0.31	.28	**−0.62 (0.28)**	0.80	.02	**0.87**	0.61	.02
Work relationships/social activities	Mid	−0.02 (0.25)	0.02	.93	−0.13 (0.30)	0.14	.67	0.11	0.07	.78
	Post	−0.40 (0.26)	0.42	.12	−0.10 (0.27)	0.11	.71	0.30	0.20	.43
	Follow-up	0.03 (0.26)	0.03	.93	−0.34 (0.31)	0.38	.28	0.37	0.22	.38
School relationships/social activities	Mid	−0.23 (0.32)	0.26	.47	−0.25 (0.39)	0.31	.54	0.02	0.01	.98
	Post	0.24 (0.30)	0.27	.42	**−0.93 (0.34)**	1.13	.01	**1.17**	0.96	.01
	Follow-up	0.08 (0.32)	0.10	.80	−0.41 (0.39)	0.53	.30	0.49	0.36	.34
School abilities	Mid	0.32 (0.22)	0.52	.15	0.23 (0.28)	0.40	.43	0.09	0.10	.79
	Post	**0.49 (0.23)**	0.71	.04	−0.05 (0.24)	0.09	.83	0.54	0.61	.11
	Follow-up	**0.56 (0.23)**	0.91	.02	0.26 (0.28)	0.45	.37	0.30	0.31	.42
Stress Reactivity										
Perceived Stress Scale										
Total	Mid	−0.26 (0.19)	0.33	.19	**−0.46 (0.23)**	0.60	.04	0.20	0.15	.51
	Post	−0.36 (0.19)	0.46	.06	**−0.44 (0.20)**	0.56	.03	0.08	0.06	.77
	Follow-up	−0.16 (0.20)	0.20	.45	**−0.52 (0.22)**	0.67	.02	0.36	0.27	.23
Daily Stress Inventory										
Sum	Post	0.09 (0.23)	0.09	.70	−0.09 (0.23)	0.10	.71	0.18	0.19	.59
Frequency	Post	**0.46 (0.22)**	0.51	.04	−0.12 (0.23)	0.13	.61	0.58	0.64	.08
Average impact rating	Post	−0.41 (0.24)	0.41	.10	**−0.51 (0.25)**	0.53	.04	0.10	0.10	.78

Note: *d* = Cohen's effect size, *p* = *p*-value, LSM = least squares means, LSMD = least squares means differences; Bold values indicate significant change from baseline (LSM) or significant treatment condition by time interaction (LSMD), $p < .05$.

report with an emphasis on *perceived* stress which may not comprehensively capture all dimensions of stress reactivity (e.g., ecological momentary assessment approaches or biological markers of stress such as salivary or plasma cortisol levels that may be more objective or sensitive to changes over time). Results of physiological markers of stress reactivity collected in this preliminary RCT (e.g., heart rate variability and salivary cortisol) will be published in a follow-up report.

The secondary hypothesis was partially supported. I-CAT participants showed a reduction in symptoms (i.e., overall, negative, and disorganized) and endorsed higher levels of mindfulness (i.e., attention to the present moment) and well-being (i.e., sense of purpose in life) compared with TAU. TAU was more effective than I-CAT only on aspects of mindfulness self-compassion (i.e., self-kindness at post-treatment and common humanity at mid-treatment). Overall, the pattern of significant results in this preliminary RCT suggest I-CAT demonstrated improvements in targeting the secondary outcomes of symptoms, mindfulness, and well-being.

Findings that I-CAT led to significantly decreased overall symptoms, and maintenance of these gains after treatment, is especially pertinent in the context of early interventions for SSD. Duration of untreated
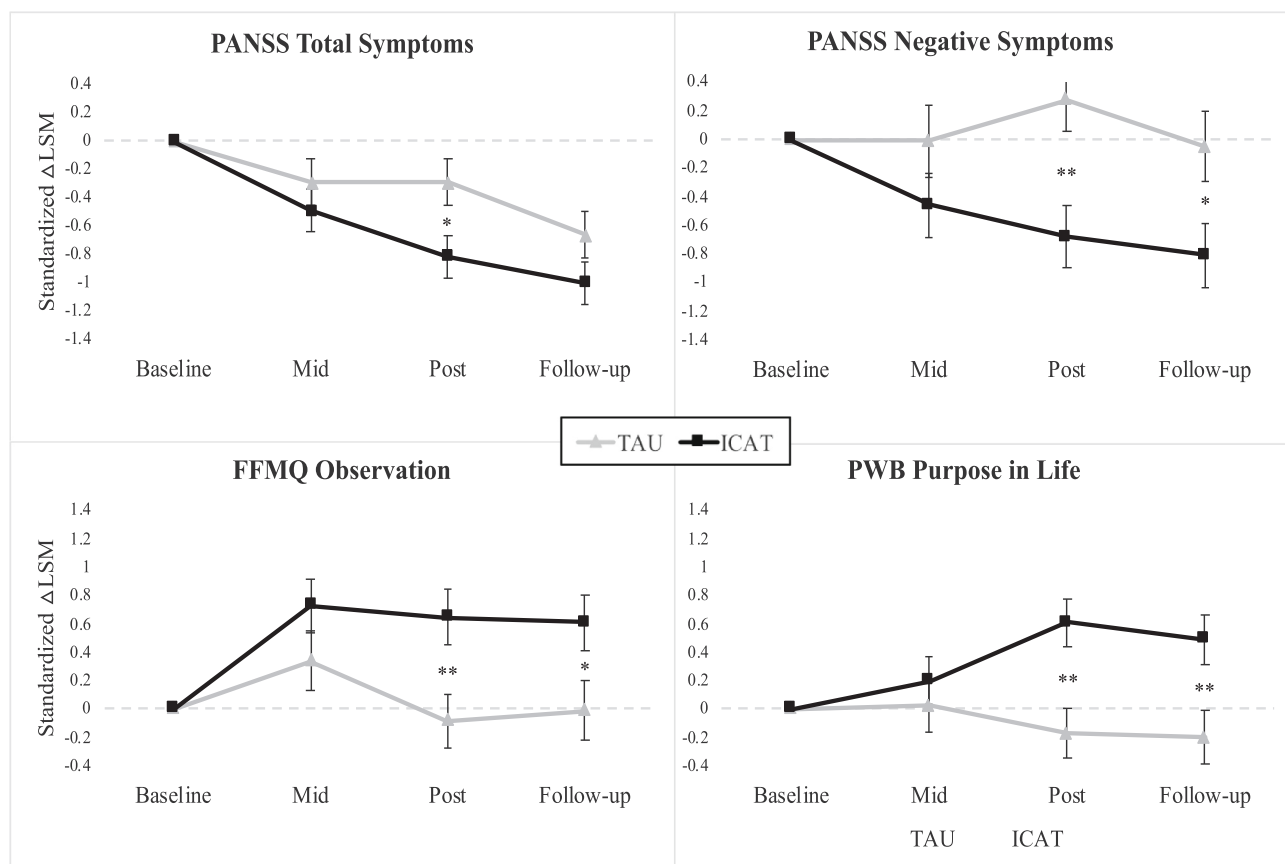
Fig. 2. Significant between-group changes from baseline on secondary outcomes.
Note: *p < .05, **p < .01 indicates significant between-group differences; ΔLSM = Least-squares mean change from baseline, PANSS = Positive and Negative Symptom Scale, FFMQ = Five Facets of Mindfulness Questionnaire, PWB = Perceived Well-Being. FFMQ Observation did not demonstrate significant between-group differences after controlling for employment status.

Table 4
Standardized change from baseline for Five-Factor PANSS Symptoms.

PANSS Scale	Timepoint	Within-group						Between-group		
		I-CAT			TAU					
		LSM (SE)	d	p	LSM (SE)	d	p	LSMD	d	p
Total	Mid	**−0.49 (0.15)**	0.78	<.01	−0.29 (0.16)	0.49	.08	0.20	0.19	.39
	Post	**−0.81 (0.15)**	1.31	<.01	−0.29 (0.16)	0.48	.06	**0.52**	0.51	.02
	Follow-up	**−1.00 (0.15)**	1.64	<.01	**−0.66 (0.17)**	1.11	<.01	0.34	0.32	.14
Positive	Mid	0.13 (0.15)	0.20	.42	−0.15 (0.17)	0.26	.35	0.28	0.27	.22
	Post	−0.29 (0.15)	0.45	.07	−0.21 (0.16)	0.34	.20	0.08	0.08	.72
	Follow-up	**−0.52 (0.16)**	0.80	<.01	**−0.56 (0.17)**	0.93	<.01	0.04	0.04	.88
Negative	Mid	**−0.46 (0.22)**	0.52	.04	0.01 (0.25)	0.00	.99	0.47	0.30	.16
	Post	**−0.68 (0.22)**	0.76	<.01	0.28 (0.23)	0.30	.24	**0.96**	0.63	<.01
	Follow-up	**−0.81 (0.22)**	0.92	<.01	−0.05 (0.24)	0.06	.83	**0.76**	0.48	.02
Disorganized	Mid	−0.09 (0.10)	0.23	.35	−0.13 (0.11)	0.32	.25	0.04	0.05	.81
	Post	**−0.43 (0.10)**	1.02	<.01	−0.01 (0.11)	0.00	.99	**0.42**	0.63	<.01
	Follow-up	**−0.38 (0.10)**	0.91	<.01	**−0.31 (0.11)**	0.78	<.01	0.07	0.09	.68
Excited	Mid	−0.05 (0.07)	0.19	.43	**−0.20 (0.07)**	0.77	<.01	0.15	0.35	.13
	Post	−0.08 (0.07)	0.30	.22	**−0.14 (0.07)**	0.54	.04	0.06	0.15	.53
	Follow-up	−0.10 (0.07)	0.39	.12	−0.13 (0.07)	0.51	.07	0.03	0.06	.80
Depressed	Mid	−0.24 (0.23)	0.25	.31	−0.08 (0.24)	0.09	.75	0.16	0.10	.63
	Post	**−0.71 (0.22)**	0.79	<.01	−0.30 (0.23)	0.33	.20	0.41	0.28	.19
	Follow-up	**−0.90 (0.22)**	1.01	<.01	**−0.65 (0.24)**	0.74	<.01	0.25	0.17	.45

Note: d = Cohen's effect size, p = p-value, LSM = least squares means, LSMD = least squares means differences; Bold values indicate significant change from baseline (LSM) or significant treatment condition by time interaction (LSMD), p < .05.

symptoms in the early stages of SSD, specifically negative symptoms, has a detrimental impact on long-term functioning, cognitive abilities, and biological outcomes (Díaz-Caneja et al., 2015). To date, there is limited psychopharmacological efficacy for reducing negative symptoms (e.g.,

Galderisi et al., 2018; Remington et al., 2016). Findings from this preliminary RCT that I-CAT reduces negative symptoms, with maintenance of these improvements beyond treatment, supports I-CAT as a promising early intervention with the potential to improve long-term functioning

Table 5
Standardized change from baseline for secondary outcomes.

Secondary outcome measure	Timepoint	Within-group						Between-group		
		I-CAT			TAU					
		LSM (SE)	d	p	LSM (SE)	d	p	LSMD	d	p
Mindfulness										
Five Facets of Mindfulness Questionnaire										
Total	Mid	0.18 (0.14)	0.32	.19	**0.51 (0.15)**	0.96	<.01	0.33	0.36	.11
	Post	**0.35 (0.14)**	0.62	.01	0.26 (0.14)	0.48	.07	0.09	0.11	.64
	Follow-up	0.26 (0.14)	0.47	.07	**0.13 (0.15)**	0.60	.04	0.13	0.06	.80
Observation	Mid	**0.73 (0.19)**	0.92	<.01	0.34 (0.21)	0.46	.10	0.39	0.30	.18
	Post	**0.65 (0.19)**	0.84	<.01	−0.08 (0.19)	0.10	.70	**0.73**	0.61	<.01
	Follow-up	**0.61 (0.20)**	0.81	<.01	−0.01 (0.21)	0.02	.95	**0.62**	0.49	.03
Description	Mid	0.17 (0.18)	0.08	.34	0.32 (0.20)	0.45	.11	0.15	0.13	.57
	Post	**0.39 (0.17)**	0.01	.03	0.05 (0.18)	0.07	.79	0.34	0.30	.18
	Follow-up	0.31 (0.18)	0.02	.09	0.13 (0.20)	0.19	.52	0.18	0.15	.50
Aware of actions	Mid	−0.05 (0.15)	0.08	.73	0.18 (0.16)	0.29	.29	0.23	0.22	.31
	Post	0.13 (0.15)	0.10	.39	0.20 (0.16)	0.32	.22	0.07	0.07	.75
	Follow-up	0.01 (0.15)	0.25	.98	−0.01 (0.17)	0.01	.98	0.02	0.01	.97
Non-judgmental inner experience	Mid	0.04 (0.16)	0.06	.79	0.27 (0.17)	0.43	.13	0.23	0.21	.34
	Post	0.12 (0.16)	0.18	.47	0.21 (0.16)	0.35	.18	0.09	0.10	.66
	Follow-up	0.11 (0.16)	0.18	.50	0.27 (0.17)	0.45	.13	0.16	0.14	.52
Non-reactivity	Mid	**0.56 (0.22)**	0.63	.01	**0.64 (0.24)**	0.74	<.01	0.08	0.05	.81
	Post	**0.60 (0.22)**	0.67	<.01	0.22 (0.23)	0.25	.34	0.38	0.26	.24
	Follow-up	**0.52 (0.23)**	0.58	.03	**0.58 (0.26)**	0.65	.03	0.06	0.04	.85
Self-Compassion Scale										
Total	Mid	−0.06 (0.18)	0.08	.74	0.30 (0.20)	0.42	.13	0.36	0.29	.19
	Post	0.11 (0.18)	0.15	.54	0.27 (0.19)	0.37	.15	0.16	0.13	.54
	Follow-up	0.04 (0.19)	0.06	.83	0.13 (0.20)	0.19	.52	0.09	0.07	.74
Self-kindness	Mid	−0.10 (0.21)	0.12	.63	0.22 (0.23)	0.26	.35	0.32	0.22	.32
	Post	−0.12 (0.22)	0.13	.60	0.35 (0.22)	0.41	.12	0.47	0.32	.14
	Follow-up	−0.36 (0.23)	0.41	.12	0.39 (0.24)	0.47	.11	**0.75**	0.49	.03
Self-judgment	Mid	−0.19 (0.21)	0.22	.37	−0.19 (0.24)	0.22	.43	0.00	0.00	.99
	Post	**−0.48 (0.21)**	0.55	.03	−0.41 (0.24)	0.45	.09	0.07	0.05	.83
	Follow-up	−0.12 (0.22)	0.14	.58	−0.29 (0.25)	0.34	.25	0.17	0.11	.62
Common humanity	Mid	−0.08 (0.18)	0.10	.67	**0.72 (0.19)**	1.04	<.01	**0.80**	0.66	<.01
	Post	0.28 (0.18)	0.38	.12	**0.43 (0.19)**	0.59	.02	0.15	0.13	.56
	Follow-up	−0.31 (0.19)	0.42	.11	0.01 (0.20)	0.01	.96	0.32	0.25	.25
Isolation	Mid	−0.20 (0.20)	0.23	.34	0.05 (0.23)	0.06	.84	0.25	0.17	.43
	Post	−0.17 (0.20)	0.20	.40	0.13 (0.22)	0.14	.58	0.30	0.21	.33
	Follow-up	−0.08 (0.21)	0.18	.69	−0.01 (0.24)	0.01	.92	0.07	0.05	.82
Mindfulness	Mid	0.33 (0.23)	0.34	.16	0.45 (0.25)	0.50	.08	0.12	0.08	.71
	Post	0.09 (0.23)	0.09	.70	0.23 (0.24)	0.25	.34	0.14	0.09	.68
	Follow-up	0.21 (0.25)	0.21	.42	0.19 (0.26)	0.21	.46	0.02	0.01	.97
Over-identified	Mid	0.18 (0.18)	0.24	.33	0.19 (0.19)	0.27	.33	0.01	0.01	.96
	Post	−0.22 (0.18)	0.30	.22	0.01 (0.19)	0.01	.98	0.23	0.19	.40
	Follow-up	0.03 (0.19)	0.04	.86	−0.01 (0.21)	0.02	.95	0.04	0.04	.87
Well-being										
Ryff Scales of Psychological Well-Being										
Total	Mid	0.21 (0.14)	0.37	.13	0.17 (0.15)	0.31	.27	0.04	0.04	.85
	Post	**0.36 (0.14)**	0.62	.01	−0.01 (0.15)	0.01	.96	0.37	0.40	.08
	Follow-up	**0.29 (0.14)**	0.53	.04	0.12 (0.16)	0.21	.46	0.17	0.18	.41
Autonomy	Mid	0.15 (0.18)	0.20	.41	**0.46 (0.20)**	0.65	.02	0.31	0.26	.23
	Post	0.34 (0.17)	0.47	.06	0.26 (0.18)	0.37	.15	0.08	0.07	.77
	Follow-up	0.26 (0.18)	0.37	.15	0.17 (0.20)	0.23	.42	0.09	0.08	.35
Environmental mastery	Mid	0.26 (0.18)	0.36	.14	0.30 (0.19)	0.44	.12	0.04	0.03	.89
	Post	0.30 (0.18)	0.41	.09	0.31 (0.18)	0.45	.09	0.01	0.01	.96
	Follow-up	0.17 (0.18)	0.24	.35	0.25 (0.20)	0.38	.20	0.08	0.07	.77
Personal growth	Mid	**0.32 (0.16)**	0.49	.04	0.25 (0.16)	0.37	.18	0.07	0.07	.75
	Post	**0.56 (0.16)**	0.84	<.01	0.10 (0.17)	0.15	.57	0.46	0.43	.06
	Follow-up	**0.39 (0.17)**	0.57	.03	−0.08 (0.18)	0.12	.68	0.47	0.40	.07
Positive relations with others	Mid	−0.15 (0.14)	0.26	.30	0.02 (0.16)	0.03	.91	0.17	0.17	.43
	Post	−0.01 (0.14)	0.02	.94	−0.06 (0.15)	0.10	.71	0.05	0.05	.83
	Follow-up	−0.11 (0.15)	0.19	.48	0.16 (0.16)	0.28	.33	0.27	0.27	.23
Purpose in life	Mid	0.20 (0.17)	0.30	.23	0.02 (0.18)	0.03	.92	0.18	0.17	.45
	Post	**0.61 (0.17)**	0.88	<.01	−0.17 (0.18)	0.25	.34	**0.78**	0.70	<.01
	Follow-up	**0.49 (0.17)**	0.72	<.01	−0.20 (0.19)	0.32	.28	**0.69**	0.59	<.01
Self-acceptance	Mid	**0.38 (0.16)**	0.58	.02	0.07 (0.18)	0.10	.71	0.31	0.29	.19
	Post	**0.38 (0.16)**	0.57	.02	−0.04 (0.17)	0.05	.83	0.42	0.39	.08
	Follow-up	**0.43 (0.17)**	0.68	.01	0.20 (0.18)	0.32	.27	0.23	0.21	.35

Note: *d* = Cohen's effect size, *p* = *p*-value, LSM = least squares means, LSMD = least squares means differences; Bold values indicate significant change from baseline (LSM) or significant treatment condition by time interaction (LSMD), *p* < .05.

in SSD.

Alleviation of negative symptoms and improved well-being through a mindfulness and positive psychotherapy intervention replicates findings of smaller-scale studies and extends previous work with I-CAT as a novel intervention *integrating* these approaches in the early stages of SSD (e.g., Johnson et al., 2011; Louise et al., 2018; Meyer et al., 2012). Alleviation of negative symptoms, along with promising occupational and well-being outcomes, may also suggest I-CAT directly addresses recovery with increased engagement in life activities and well-being. The addition of an effective psychosocial intervention option within CSC is especially relevant for individuals in the early stages of SSD where collaborative decision-making and client autonomy are important aspects of the recovery model (e.g., Mueser et al., 2015; Treichler & Spaulding, 2017).

There are limitations in the present study to consider. This is a preliminary RCT meant to replicate and extend results from an initial nonrandomized pilot study. Although I-CAT demonstrated significant improvements across primary and secondary domains (e.g., decreased negative symptoms) compared with TAU, it should be noted that I-CAT improvements from baseline were comparable (i.e., no significant group differences) to TAU improvements across other domains (e.g., quality of life). Although, the study sample was adequate to reliably detect medium treatment effects, there is limited power to detect moderator effects (Kreidler et al., 2013). Employment status was entered as a covariate in all significant models with the pattern of results unchanged (i.e., all treatment differences remained significant), however baseline differences in employment status between treatment groups may have impacted work ability and school social functioning outcomes. When number of treatment sessions was entered as a covariate, I-CAT no longer demonstrated significant treatment effects on observational mindfulness suggesting this effect may be partially due to treatment duration. Furthermore, corrections for multiple comparisons were not applied since this was an initial feasibility RCT. Therefore, significant outcomes should be interpreted as domains of interest for future large-scale RCTs.

Another potential limitation is the assessment of negative symptoms using the PANSS, a global measure of symptoms, rather than a specific assessment of negative symptoms, such as the Clinical Assessment for Negative Symptoms (Kring et al., 2011). Specific measures offer more comprehensive understanding of negative symptoms, specifically motivation, which was not measured in the present study. Finally, since most of the participants in TAU were enrolled in CSC, there might have been an underestimate of I-CAT treatment effects when generalized to more standard outpatient settings. CSC delivered in first-episode specialty clinics is an especially effective mode of treatment for early SSD compared with typical outpatient community care (Correll et al., 2018; Kane et al., 2016).

4.1. Future directions

I-CAT, a manualized intervention for early psychosis integrating mindfulness and positive psychology, demonstrated excellent feasibility with preliminary results suggesting I-CAT led to greater reduction in symptoms (i.e., overall, negative, and disorganized symptoms), increased observational mindfulness, increased endorsement of a sense of purpose in life, and preservation of work abilities and school social functioning compared with TAU. Future directions should focus on the mechanisms of I-CAT that lead to improvements in negative symptoms as well as aspects of psychosocial functioning. The surprising outcome that I-CAT was more effective at changing secondary outcomes may highlight domains of interest for larger-scale RCTs examining the long-term and broad-based effects of teaching mindfulness and positive psychology strategies in SSD. I-CAT may also be amenable to a group format (e.g., Meyer et al., 2012) or telehealth delivery with a manualized structure, worksheets, and skills-based approach. Additionally, integration of mindfulness and positive psychology approaches may be

effective in individuals who have experienced multiple episodes of SSD and larger-scale RCTs should be expanded to include individuals in both early and later stages of SSD.

Contributors

TFH wrote the first draft of the manuscript, assisted with data collection, and completed all analyses and certifies the accuracy of the results. PMK was a principal investigator, assisted with study design, assisted with intervention design, and supervised study therapists. DOP was a principal investigator and assisted with study design. SAG assisted with intervention design and supervised study therapists. OSP assisted with study design. LNN assisted with data collection. SBA assisted with intervention design. KMG assisted with study design. DLP served as a principal investigator, supervised study implementation, assisted with study design, assisted with intervention design, and supervised study therapists. All authors contributed to and approved the final manuscript.

Role of the funding source

Declaration of competing interest

Piper S. Meyer, David L. Penn, Susan Gaylord, and Diana O. Perkins are authors of the Integrated-Coping Awareness Therapy Treatment Manual. Tate F. Halverson, Olafur S. Palsson, Lana Nye, Sara B. Algoe, and Karen Grewen have no known conflicts of interest to disclose.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.schres.2021.07.022.

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