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Treatment adherence, therapeutic alliance, and clinical outcomes during an exposure-based cognitive-behavioral therapy for pediatric irritability

Reut Naim^{1,2*}, Ramaris E. German³, Jamell White³, Urmi Pandya³, Kelly Dombek³, Michal Clayton³, Samantha Perlstein³, Lauren M. Henry³, Katharina Kircanski³, Lorenzo Lorenzo-Luaces⁴ and Melissa A. Brotman³

Abstract

Background This study explores changes in treatment adherence and alliance during a novel parent- and childpsychotherapy for pediatric irritability. Associations between in-session therapeutic processes and symptom change were examined.

Methods Forty participants (Mean age = 11.23, SD = 1.85; 37.5% female, 77.5% white) with severe irritability, and their parents, received 12 sessions of exposure-based cognitive behavioral therapy (CBT) with parent management training (PMT). Measures included clinician-rated adherence to the manual, alliance scales (Alliance Scale for Children-revised; TASC-r, and Working Alliance Inventory; WAI, respectively), and clinician-, parent- and child-reported irritability scales (Affective Reactivity Index; ARI). Linear mixed models examined session-by-session changes and associations between adherence/alliance and subsequent irritability, and vice versa.

Results First, adherence to standard treatment elements decreased over time ($B \ge -0.03$, $p \le 0.010$), while the focus on specific treatment components increased (i.e., exposure: B = 0.15, p = 0.001; PMT: B = 0.07, p = 0.002). Second, adherence to standard treatment elements were associated with decreased clinician-reported irritability ($Bs \ge -2.23$, $p \le 0.042$). For the alliance measures, parent-reported alliance increased over time ($Bs \ge 0.10$, $p \le 0.01$); child-reported alliance did not change. Bidirectional associations were found between alliance and symptoms; specifically, child-reported alliance predicted clinician-rated irritability at next session ($Bs \ge -0.66$, $p \le 0.053$), and decreases in clinician- ($Bs \ge -0.02$, $ps \le 0.043$) and parent- (B = -0.15, p = 0.024) reported irritability predicted increased alliance at next session.

Conclusions Findings underscore the predictive role of treatment adherence and therapeutic alliance on outcomes, in exposure-based CBT for pediatric irritability.

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Keywords Alliance, Adherence, Youth, Treatment, Pediatric irritability

*Correspondence: Reut Naim reutnaim@tauex.tau.ac.il Full list of author information is available at the end of the article



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Introduction

What are the in-session processes that contribute to improvement in psychotherapy? Decades of research [10, 17, 27, 44, 52] have proposed two factors: treatment adherence to specific in-session behaviors and the therapeutic alliance. Whereas treatment adherence refers to treatment integrity and the extent to which an intervention is being delivered as outlined in the planned protocol [39, 47, 57, 63], the therapeutic alliance can be broadly defined as agreement on treatment tasks, goals, and the patient-therapist bond [5, 23]. In the field of child and adolescent psychotherapy, recent data provide evidence for the important influence of adherence and therapeutic alliance on treatment outcomes [15, 34, 37, 50, 51]. Collyer et al. [7], based on their meta-analytic approach, reported a small but significant relationship between therapist adherence and outcome. In a recent meta-analvsis based on 28 studies, Karver et al. [26] found a significant effect size for the association between alliance and outcome (d=0.39), with stronger alliance ratings being related to weaker posttreatment symptom severity.

Here, we examine in-session therapeutic processes, specifically adherence and alliance, as related to improvement in a novel exposure-based parent- and child-cognitive behavioral therapy for pediatric irritability [45]. Pediatric irritability is an understudied research field, and little is known about evidence-based treatment. Examining treatment process constructs will broaden current understanding on factors influencing treatment outcomes and could help refine our understanding of intervention mechanisms of change in outcomes.

Irritability is defined as an increased proneness to anger that may reach a pathological extent [3]. Notably, while research on irritability has increased exponentially over the past two decades, there are few targeted psychological treatments [19, 21, 56]. In those treatments that have been associated with improvement, including interpersonal psychotherapy, dialectical behavior therapy and parent management therapy [29, 35, 43, 55], the in-session processes of action remain poorly understood.

Based on prior work in behavioral interventions for youth with externalizing problems including oppositional defiant disorder (ODD) and conduct disorder (CD), data suggest small to medium effects for the association between therapeutic alliance and symptom severity [10, 22, 30, 31]. Critically, in studies focusing on parent training components, parent-therapist alliance predicts improvements in child-rearing parenting practices [32]. However, adherence and alliance during treatment of youth with severe irritability has yet to be explored. This is of particular importance as children with irritability tend to exhibit oppositionality [18]. This behavioral characteristic may be expressed as difficulty agreeing on therapeutics tasks and goals, and low compliance with treatment. In turn, this behavior may explicitly influence the therapeutic relationship and pose a challenge to maintaining the treatment.

The current study focuses on two therapeutic processes, adherence and alliance during a novel, exposure-based cognitive behavioral treatment (CBT) that incorporates parent management training (PMT) for youth with severe irritability (for a detailed protocol see: [46]). This exposure-based treatment consists of exposing children with severe irritability and anger difficulties to frustrating situations with the goal of learning to tolerate their anger without having an outburst. Preliminary efficacy of the treatment was supported; irritability improved during the active phase of treatment across several clinician-, parent-, and child-rated irritability metrics [45]. Yet, given the anger-inducing nature of the exposures, it is essential to assess the extent to which children and parents agree with the tasks and goals of treatment, and how well they bond with their therapist.

We examine three overall questions: (1) how therapeutic alliance (i.e., agreement on tasks, goals, and the bond with the therapist) and adherence change over the course of treatment, (2) whether alliance and adherence levels during a session predict irritability symptomology at the next session, and conversely, (3) whether irritability symptoms at the current session predict alliance at the next session. We hypothesized that adherence and alliance will increase over the course of treatment, and that greater adherence (as measured by the clinician) and greater alliance (as measured by the child and by the parent), will be associated with reduced irritability symptoms. The third question regarding the temporal association between irritability and next session alliance was exploratory.

To address our questions, we first assessed treatment adherence to each component of the treatment manual [46]. We then explored how parent-therapist and childtherapist alliance separately influenced symptom change. As therapeutic alliance consists of an interpersonal aspect of the therapeutic relationship (i.e., the bond), and a collaborative aspect (i.e., agreement on goals and tasks) [5, 25], with previous research suggesting that each of these domains may differ in their impact on treatment outcomes [12, 41, 59, 61], we will examine how different alliance components influence irritability change in the context of the current treatment. Finally, there is a debate in the literature regarding the directionality of the alliance-outcome association, specifically whether it is the influence of prior symptom improvement that improves therapeutic alliance, or vice versa. In other words, whether therapeutic alliance is a cause versus consequence of symptom change [9, 13, 58, 64]. Hence,

a secondary goal of this study was to address this question and examine temporal relations between therapeutic alliance and adherence to symptom improvement of irritability.

Methods

The current study has been approved by the National Institute of Mental Health (NIMH) intramural Institutional Review Board (IRB). Treatment included a novel manualized exposure-based cognitive behavioral therapy for the child combined with parent management training skills for the parent. The full protocol is described in Naim et al. [46] and the findings suggest feasibility and preliminary efficacy of the protocol in reducing pediatric irritability symptoms [45].

Participants

This sample is identical to the sample reported in [45]. Briefly, participants, aged 8–18, resided within a 50-mile radius of the campus location and were recruited via IRB-approved recruitment materials targeting caregivers of children with impairing irritability. Primary inclusion criteria consisted of a diagnosis of Disruptive Mood Dysregulation Disorder (DMDD), or significant levels of temper outbursts or irritable mood as assessed by a licensed clinician using the Kiddie-Schedule for Affective Disorders and Schizophrenia Present and Life-time Version (K-SADS- PL, [28]) including the DMDD module [62]. Exclusion criteria included active suicidality, symptoms of bipolar disorder, meeting full diagnostic criteria for major depressive disorder, schizophrenia, schizophreniform disorder, autism spectrum disorder (ASD), posttraumatic stress disorder, or an estimated IQ below 70 as assessed by the Wechsler Abbreviated Scale of Intelligence (WASI;[60]). ASD symptomatology was assessed using the Development and Well-Being Assessment (DAWBA), the Social Responsiveness Scale (SRS), the Social Communication Questionnaire (SCQ), as well as the K-SADS-PL with a clinical evaluation.

Participant characteristics

Forty youth completed treatment. Table 1 lists the sample's demographic information and the sample characteristics. The study was conducted between 2018 and 2021; during the COVID-19 pandemic, starting in mid-March of 2020 until the end of the study, the team delivered the treatment via telehealth. Nineteen participants completed treatment in-person and 21 completed the treatment via telehealth. Please see [45] for detailed information.

| Table 1 | Demographics and Sample Characteristics for 40 Youth |
|-----------|------------------------------------------------------|
| Treated v | with Exposure-based CBT for Pediatric Irritability |

| Sample Characteristic | n | % | M | SD |
|-------------------------------|----|-------|--------|-------|
| | | | | |
| Age | | | 11.23 | 1.85 |
| IQ | | | 113.43 | 13.70 |
| Sex assigned at birth | | | | |
| Male | 25 | 62.5% | | |
| Female | 15 | 37.5% | | |
| Race | | | | |
| White | 31 | 77.5% | | |
| Black or African American | 4 | 10% | | |
| Asian | 1 | 2.5% | | |
| Multiple Races | 2 | 5% | | |
| Unknown | 2 | 5% | | |
| Ethnicity | | | | |
| Not Latino or Hispanic | 36 | 90% | | |
| Latino or Hispanic | 2 | 5% | | |
| Unknown | 2 | 5% | | |
| Primary DSM-5 Diagnosis | | | | |
| DMDD | 25 | 62.5% | | |
| ODD | 10 | 25% | | |
| ADHD | 5 | 12.5% | | |
| Any Medication | 30 | 75% | | |
| Stimulant | 20 | 50% | | |
| Non-stimulant ADHD medication | 12 | 30% | | |
| Antidepressant | 14 | 35% | | |
| Antipsychotic | 3 | 7.5% | | |
| Anticonvulsant | 1 | 2.5% | | |
| | | | | |

DMDD Disruptive mood dysregulation disorder, ODD Oppositional defiant disorder, ADHD Attention-deficit/hyperactivity disorder

Procedure Treatment

The treatment consisted of twelve, 90-min sessions with the first half of each session being with the child and the second half being with the parent. Earlier sessions focus on psychoeducation, building rapport, and motivational interviewing with the child and parent. The core components of the treatment included exposure to anger-triggering stimuli during child sessions, and parent behavior management skills training during sessions with parents. The final treatment sessions included a summary of the modules taught and lessons learned, a focus on maintenance of treatment gains and skills, and a celebration of the completion of treatment. The specifics of the novel manualized exposure-based CBT are described elsewhere [46]. Six therapists delivered the manualized CBT treatment [Mage=43.83 years old (SD=3.53 years), 100% female, 50% white]. Three therapists were clinical psychologists, one a psychiatrist, and two licensed clinical social workers.

Clinical assessments

Upon consenting into the study, participants were randomized to an initial baseline waiting period of 2, 4, or 6 weeks and were assigned clinician raters who were unaware of when treatment began. Clinician raters completed the CL-ARI via phone interviews with the parent and child every two weeks after consenting into the study.

Self-report assessments

Before the start of each treatment session, parent and child completed the ARI assessing the child's irritability over the past week. Immediately after each session, parent and child completed the WAI and TASC-r, respectively, each reporting on their alliance with the therapist.

Measures

Adherence

The adherence measure was developed specifically for this treatment protocol (see Appendix A and B for an example of the measures). The measure contained 26 items focused on standard elements of cognitive behavioral therapy (e.g., setting agenda, homework, motivation), treatment-specific elements (e.g., exposure for the child and parent skills training for the parent), and mode of delivery elements (e.g., modeling, rehearsal, coaching). The adherence measure was completed by therapists at the end of each therapy session.

The three phases of treatment were operationalized. Phase 1, rapport-building phase, included sessions 1-3, which we expect based on the protocol to cover standard CBT elements (e.g., rapport, motivation) as well as psychoeducation. Phase 2, the exposure/PMT phase, included sessions 4-10, which we expect to focus on treatment-specific elements more heavily (i.e., exposures for kids and parent skills training for parents). Phase 3, termination phase, included sessions 11-12, which we expect to cover summary of the treatment. Cronbach's α for the Adherence measure in the current sample is 0.768 for the whole questionnaire, 0.731 for the treatment-specific elements, and 0.827 for the standard CBT elements. Internal validity measured via item-rest correlations indicated sufficient validity with correlation coefficients ranging between 0.386-0.575.

Each item assesses the therapist's endorsement of adherence to the task in question. For example, "Therapist encourages child participation in one or more exposure tasks." Therapists rated each item on a 7-point scale including anchors 1 ("Not at all"), 4 ("Considerably"), and 7 ("Extensively"). Our a priori items of interest were the extent to which therapists adhered to child exposure and primary elements of PMT (instrumental learning, praise and acknowledgement, active ignore, dealing with outbursts, commands, and limit setting). We additionally computed average ratings of all the items in the standard CBT section of the child adherence form (i.e., the child standard CBT average), the items in the standard CBT section of the parent adherence form (i.e., the parent standard CBT average), and, averaged across all six PMT items of interest (i.e., the PMT average).

Alliance

The Therapeutic Alliance Scale for Children-revised (TASC-r; [53]) is a 12-item, 4-point Likert-style self-report measure of therapeutic alliance completed by the child after each treatment session. Individual item responses range from 1 ("Not Like You") to 4 ("Very Much Like You"). The TASC-r contains two subscales: the bond and task subscales. The bond subscale assesses the degree that the child feels a bond with the therapist, and the task subscale assesses child's evaluation of whether therapy is a productive, collaborative endeavor [1]. The TASC-r scores have shown adequate reliability and validity [8]. Cronbach's α for the TASC-r in the current sample is 0.91.

The Working Alliance Inventory (WAI; [24]) is a 12-item, 7-point Likert-scale self-report measure of alliance between the parent and therapist completed by the parent after each treatment session. Individual item responses range from 0 ("Never") to 6 ("Always"). The WAI contains three subscales: goal, task, and bond subscales, which assess the degree to which the parent feels they agree with the therapist on the primary goals of therapy, the usefulness of the tasks completed in therapy, and feelings of trust and compatibility with the therapist, respectively. The WAI measure has shown good psychometric properties [41]. Cronbach's α for the WAI in the current sample is 0.89.

Irritability symptoms

The Affective Reactivity Index (ARI; [54]) is a 7-item, 3-point Likert-scale self-report measure assessing the child's irritable mood and behavioral outbursts over the past week, as well as impairment due to irritability. Both parent (ARI-P) and child (ARI-C) assessments were used. Responses range from 0 ("Not true") to 2 ("Certainly true"), and the total score is calculated by summing the first 6 item responses. The seventh item assesses impairment due to irritability and is analyzed separately. ARI has demonstrated excellent internal consistency, reliability and validity [11, 54]. Cronbach's α for the ARI-P and ARI-C in the current sample is 0.87 and 0.91, respectively.

The Clinician Affective Reactivity Index (CL-ARI; [20]) is an adaptation of the parent- and child-report ARI [54]. The CL-ARI is a 12-item inventory conducted by an independent clinician rater to assess irritable mood,

outbursts, and irritability-related impairment over the past week, based on separate interviews with the parent and child. It contains three subscales: temper outburst (the frequency, intensity, and duration of behavioral outbursts), irritable mood (the amount of time the child feels irritable throughout the week), and impairment, which is assessed in three domains: school, home, and peer relationships. Total CL-ARI score is calculated by summing the weighted total for each subscale; scores range from 0–100. Excellent internal consistency and adequate test–retest reliability of the CL-ARI was demonstrated [20]. Cronbach's α for the CL-ARI in the current sample is 0.77. The CL-ARI was completed by a clinician masked as to when the child began treatment, to account for rater expectancy effects.

Data analysis

Adherence measures

Multilevel mixed-effects regression models with robust standard errors were used to analyze nested withinsubject data using Hierarchical Linear Modeling (HLM software, version 7.0, [48]). Within-person measures of treatment process (i.e., alliance and adherence) and irritability scores were entered into the model at level 1. For models with clinical ratings (i.e., CL-ARI), we entered the number of days between ratings and alliance measure completion as a covariate at level 1. All variables were grand-mean centered.

Change in adherence throughout treatment

To examine linear change in adherence throughout treatment, multilevel modeling was conducted with CBT session number (1-12) entered as the predictor, uncentered, and adherence elements (i.e., adherence to standard CBT elements and treatment-specific elements for both child and parent) were entered as the outcome variable at level 1. To more specifically investigate how standard CBT and treatment-specific adherence components changed across different treatment phases, we applied a threephase piecewise model with the break points between the three treatment phases. Time was coded independently for each phase by weeks, where the reference timepoint (intercept) reflects the average score at session 4, the breakpoint between first phase (i.e., rapport-building) and second phase (i.e., exposure/PMT) of the treatment. The breakpoint between the second and third phase (i.e., termination) of treatment was session 11. Level 1 outcome measures included within-subject repeated adherence data.

Associations between irritability and adherence scores

To examine temporal associations between pediatric irritability and adherence, we conducted lagged analyses

to predict session-by-session associations between the standard and treatment-specific elements in each session, and child irritability in the following session (as measured by the clinician-, child-, and parent-reported ARI). Adherence scores for each standard and treatment-specific elements were entered separately as group-centered predictors, and each of the irritability measures were entered separately as outcome variables at level 1. Previous session ARI scores were also entered as predictors to control for irritability autocorrelation. For the analyses involving the clinician ARI, number of days between treatment session and clinical ratings was included as a covariate. We also used piecewise modeling, as described above, to explore whether the adherence-irritability association differs across treatment phases.

Alliance measures

Change in alliance over the course of treatment

To examine change in alliance over treatment sessions, separate models were run for parent-reported and child-reported alliance measures. Alliance total score (e.g., WAI or TASC-r) for sessions 1–12 was entered as the dependent variable with session number as the predictor of change at level 1. No variables were entered at level 2.

Associations between irritability and alliance scores

To examine the relations between alliance and irritability ratings, a lagged approach was used. In the level 1 model, alliance scores were paired with irritability scores in the following session to test whether alliance scores at a given session predicted irritability levels reported at the beginning of the following session. In all models where selfreport irritability measures were used, child-reported ARI was predicted by TASC-r, and parent-reported ARI was predicted by the WAI. To test for potential bidirectional effects, separate lagged analyses were conducted with self- and parent- reported ARI predicting self- and parent- alliance at the following session. Previous session ARI scores were entered as predictors to control for irritability autocorrelation.

Lastly, we tested whether change in clinician-reported irritability (CL-ARI) over treatment is associated with alliance. At level 1, alliance scores were paired with the closest subsequent CL-ARI rating occurring after the current session and before the next session. The first set of analyses tested whether parent- or child-reported alliance score at a given session predicted clinician-reported irritability at the next clinical rating. To test the potential bidirectional relationship of clinician-reported irritability and alliance, a second set of analyses was conducted by pairing CL-ARI ratings, beginning at pre-treatment assessment, to the closest subsequent session's alliance scores. For all the models that involved the CL-ARI, the number of days between the session and clinical ratings was added as a covariate.

For each set of analyses, and across each of the child and parent models, we applied false discovery rate (FDR) correction, using Benjamini–Hochberg procedure. The expected proportion of false positives was set to q = 0.05. Adjusted p values based on FDR correction are reported in the results below.

Between-therapist analyses

To test for potential between-therapist differences in irritability and alliance ratings, each therapist was entered as a dichotomous variable at level 2, with one therapist set up as the reference to test the contrast for each of the six therapists. At level 1, parent- and child-reported alliance and irritability were modeled separately as the dependent variable.

The datasets analyzed during the current study are available in the OSF repository, https://osf.io/f7gma/? view_only=071cb5b0d5ea4ef49b614ed2c9e3731d.

Results

See Table 1 for demographic data and characteristics on the sample, and Table 2 for average scores for adherence, alliance, and irritability measures at sessions 1, 6, and 12. No associations were found between each of the irritability, adherence, or alliance measures with either age (all *ps* > 0.065) or sex (*ps* > 0.511), except for one significant association between child-reported irritability and sex (B = -3.53, SE = 1.00, t(31) = -3.53, p = 0.001), indicating higher self-reported irritability scores for females versus males.

Adherence measures

Change in child sessions adherence throughout treatment

Adherence to standard CBT elements significantly decreased over the child's 12 treatment sessions (B = -0.07, SE = 0.01, t(39) = -6.23, adjusted p = 0.001). Adherence to the child exposure item significantly increased over the 12 sessions (B = 0.15, SE = 0.03, t(39) = 5.46, adjusted p = 0.001). Examining within the three treatment phases, we found that adherence to child standard CBT elements did not significantly change during the rapport-building phase (B = 0.05, SE = 0.04, t(39) = 1.16, p = 0.252), and significantly decreased in the exposure phase (B = -0.10, SE = 0.02, t(39) = -4.70, p < 0.001) when the focus of treatment shifts to practicing exposures. Level of adherence to child standard CBT elements was maintained during the termination phase (B = -0.03, SE = 0.02, t(39) = -1.63, p = 0.111).

For child treatment-specific element of exposure, we found that adherence to the child exposure item

| Table 2 | Descriptive Statistics | for Adherence, | Alliance, and |
|-----------|------------------------|----------------|---------------|
| Pediatric | Irritability Measures | | |

| Measure | Session 1 <i>M (SD)</i> | Session 6 <i>M (SD)</i> | Session 12 <i>M (SD)</i> |
|---------------------------------|----------------------------|----------------------------|-----------------------------|
| Exposure treatment adherenc | e (child session | s) | |
| Exposures administered | 1.21 (0.82) | 4.49 (2.11) | 1.26 (0.85) |
| PMT adherence (parent sessio | ns) | | |
| Instrumental learning | 1.33 (0.85) | 2.91 (1.70) | 1.65 (1.18) |
| Praise and acknowledge- ment | 1.30 (0.77) | 4.01 (1.63) | 2.00 (1.50) |
| Active ignore | 1.81 (0.88) | 3.55 (1.99) | 1.74 (1.16) |
| Dealing with outbursts | 1.00 (0.01) | 2.68 (2.25) | 1.53 (1.08) |
| Commands | 1.06 (0.35) | 1.73 (1.52) | 1.38 (0.98) |
| Limit setting | 1.16 (0.38) | 1.42 (1.13) | 1.35 (0.97) |
| Alliance | | | |
| TASC-r Total Score | 37.55 (7.28) | 39.03 (7.44) | 40.45 (6.65) |
| TASC-r Bond Score | 18.71 (3.59) | 19.17 (3.63) | 20.26 (3.48) |
| TASC-r Task Score | 19.32 (3.86) | 20.61 (3.92) | 20.74 (3.45) |
| WAI Total Score | 63.55 (9.06) | 67.30 (6.69) | 69.00 (5.23) |
| WAI Goal Score | 20.16 (3.81) | 22.05 (2.77) | 22.58 (2.20) |
| WAI Task Score | 21.47 (3.97) | 22.63 (2.26) | 23.50 (2.10) |
| WAI Bond Score | 21.92 (3.13) | 22.68 (2.35) | 23.37 (1.65) |
| Irritability | | | |
| ARI Parent Report | 7.13 (2.73) | 6.10 (2.51) | 4.82 (3.03) |
| ARI Child Report | 4.73 (3.70) | 4.50 (3.28) | 3.90 (3.36) |
| Clinician ARI | 43.63 (17.43) | 39.31 (16.08) | 36.11 (19.94) |

PMT Parent Management Training, *TASC-r* Therapeutic Alliance Scale for Children-revised, *WAI* Working Alliance Inventory, *ARI* Affective Reactivity Inventory

significantly increased in the rapport-building phase (*B*=1.14, *SE*=0.12, *t*(39)=9.42, *p*<0.001), remained high and consistent during the exposure phase (*B*=0.06, *SE*=0.06, *t*(39)=1.02, *p*=0.316), and significantly decreased in the termination phase (*B*=-0.23, *SE*=0.03, *t*(39)=-6.39, *p*<0.001).

Change in parent sessions adherence throughout treatment

Similar to the child sessions, adherence to parent standard CBT elements significantly decreased over the parent 12 treatment sessions (B = -0.03, SE = 0.01, t(39) = -2.93, adjusted p = 0.010). Examining by phases, adherence to parent standard CBT elements significantly increased during the rapport-building phase (B = 0.16, SE = 0.05, t(39) = 3.41, adjusted p = 0.002), and significantly decreased in the PMT phase (B = -0.06, SE = 0.02, t(39) = -2.79, adjusted p = 0.008) and the termination phase (B = -0.04, SE = 0.01, t(39) = -2.67, adjusted p = 0.011).

For specific PMT treatment items, we found a significant increase over the 12 sessions (B=0.07, SE=0.02, t(39)=3.80, adjusted p=0.002). Four of the six PMT

items significantly increased over the 12 sessions as well, including active ignore (B=0.07, SE=0.028, t(39)=2.31, adjusted p=0.035), commands (B=0.13, SE=0.02, t(39)=6.16, adjusted p=0.002), dealing with outbursts (B=0.13, SE=0.02, t(39)=6.29, adjusted p=0.002), and limit setting (B=0.13, SE=0.02, t(39)=6.29, adjusted p=0.002). Levels of praise, acknowledge, and instrumental learning showed non-linear change throughout treatment; these three items increased from the rapportbuilding phase to the PMT phase, and then decreased towards the termination phase.

Examining adherence by treatment phase, adherence to the PMT average significantly increased during the rapport-building phase (B=0.42, SE=0.06, t(39)=7.33, p < 0.001), remained consistently high during the PMT phase (B=0.06, SE=0.03, t(39)=1.81, p=0.078), and significantly decreased during the termination phase (B=-0.09, SE=0.02, t(39)=-5.27, p < 0.001). Similar patterns were observed across all the six PMT treatment specific items, indicating high adherence scores towards and during the PMT phase, followed by an increase during the termination phase. See Table 3 for item-level statistics.

Associations between pediatric irritability and adherence scores

Overall associations

Therapist adherence to standard CBT elements in both child and parent sessions was associated with decreased CL-ARI scores (child adherence: B = -3.15, SE = 1.41, t(38) = -2.23, p = 0.031; parent adherence: B = -2.82, SE = 1.28, t(38) = -2.20, p = 0.034). No other significant findings survived FDR correction.

Lagged analyses

Higher PMT adherence average was associated with decreased levels of clinician-reported irritability in the

following session (B = -2.36, SE = 1.13, t(39) = -2.10, p = 0.042). Additionally, both higher levels of dealing with outbursts (B = -1.23, SE = 0.41, t(39) = -2.97, adjusted p = 0.040) and active ignore (B = -1.50, SE = 0.56, t(39) = -2.68, adjusted p = 0.044) were associated with decreased levels of the clinician-reported ARI in the following session. No other significant findings survived FDR correction.

Alliance measures

Change in alliance over the course of treatment

Hierarchical linear models (HLMs) examining change in parent-reported alliance by treatment sessions revealed significant associations, indicating that WAI total and all subscales scores increased during the treatment (WAI total: B=0.38, SE=0.10, t(39)=3.48, adjusted p=0.004; WAI bond: B=0.10, SE=0.04, t(39)=2.70, adjusted p=0.010; WAI goal: B=0.18, SE=0.05, t(39)=4.09, adjusted p=0.002; WAI task: B=0.10, SE=0.04, t(39)=3.05, adjusted p=0.005). Change in the child-reported TASC-r throughout treatment sessions yielded non-significant effects (all $p \ge 0.90$).

Lagged analyses of alliance scores predicting self-, parentand clinician-reported irritability

A negative association at a trend level was found between the parent-reported WAI total score (B = -0.08, SE = 0.03, t(39) = -2.51, adjusted p = 0.064) and the goal subscale (B = -0.12, SE = 0.05, t(39) = -2.43, adjusted p = 0.053) at the current session predicting parent-reported irritability at the following session. No associations were found between the task (adjusted p = 0.088) and bond subscales (adjusted p = 0.431) at the current session and parent-reported irritability at the following session.

Models examining the association between childreported measures of alliance (i.e., TASC-r and its

| Table 3 Beta Coefficients for PMT Adherence Items Acros | ss Phases of Treatment |
|---------------------------------------------------------|------------------------|
|---------------------------------------------------------|------------------------|

| PMT item | All 12 sessions | | Rapport-building phase (sessions 1–3) | | PMT-focused phase (sessions 4–10) | | Termination phase (sessions 11–12) | |
|----------------------------|-----------------|------|------------------------------------------|------|--------------------------------------|------|------------------------------------|------|
| | В | SE | В | SE | В | SE | В | SE |
| Instrumental learning | -0.02 | 0.03 | 0.52** | 0.11 | -0.19** | 0.05 | -0.02 | 0.02 |
| Praise and acknowledgement | 0.01 | 0.03 | 0.87** | 0.09 | -0.20** | 0.05 | -0.05 | 0.03 |
| Active ignore | 0.07* | 0.03 | 0.67** | 0.12 | -0.01 | 0.06 | -0.12** | 0.02 |
| Dealing with outbursts | 0.13** | 0.02 | 0.19** | 0.07 | 0.23** | 0.05 | -0.13** | 0.04 |
| Commands | 0.13** | 0.02 | 0.19** | 0.06 | 0.24** | 0.05 | -0.14** | 0.03 |
| Limit setting | 0.13** | 0.02 | 0.01 | 0.03 | 0.26** | 0.05 | -0.11** | 0.03 |
| PMT Average | 0.07** | 0.02 | 0.42** | 0.06 | 0.06 | 0.03 | -0.09** | 0.02 |

* Adjusted p < .05

** Adjusted p < .01</p>

subscales) and child-reported irritability at the following session did not yield significant associations (all ps > 0.567, all adjusted ps > 0.567).

After adjusting for days in between the treatment session and the clinician rating, no significant effects were found for parent-reported WAI scores predicting the next CL-ARI rating (all *ps* > 0.122, adjusted *ps* > 0.139). However, the child-reported TASC-r bond alliance measure was significantly associated with the next CL-ARI rating following the session (B = -1.41, SE = 0.58, t(39) = -2.45, adjusted p = 0.038). There were marginally significant associations between TASC-r total score (B = -0.66, SE = 0.27, t(39) = -2.48, adjusted p = 0.053) and TASC-r task subscale score (B = -1.04, SE = 0.38, t(39) = -2.76, adjusted p = 0.053) predicting decreased CL-ARI in the next rating.

Crosses lagged analyses of pediatric irritability predicting alliance

Decreases in parent-reported irritability at the current session significantly predicted increases in alliance at the next session as measured by the WAI total score (B = -0.31, SE = 0.13, t(39) = -2.34, adjusted p = 0.040). Similar patterns were found for specific subscales, with significant associations for the goal subscale (B = -0.15, SE = 0.05, t(39) = -2.92, adjusted p = 0.024) and at a trending level for the task subscale (B = -0.07, SE = 0.04, t(39) = -2.02, adjusted p = 0.057). The effect for the bond subscale was not significant (adjusted p = 0.156). No effects emerged for the association between self-reported irritability and TASC total score or subscales (all adjusted p > 0.451).

CL-ARI was found to significantly predict both child and parent alliance at the next session. Specifically, decreased clinician-reported irritability was associated with increased alliance at the next session (TASCr total: B = -0.06, SE = 0.02, t(39) = -2.97, adjusted p = 0.015; TASC-r task: B = -0.33, SE = 0.01, t(39) =-3.28, adjusted p = 0.012; WAI total: B = -0.06, SE = 0.02, t(39) = -3.42, adjusted p = 0.008; WAI task: B = -0.02, SE = 0.01, t(39) = -2.45, adjusted p = 0.038; WAI goal: B = -0.03, SE = 0.01, t(39) = -2.23, adjusted p = 0.043; WAI bond: B = -0.02, SE = 0.01, t(39) =-2.53, adjusted p = 0.039). The association of CL-ARI rating predicting TASC-r bond at the next session was not significant after correcting for multiple comparisons (adjusted p = 0.074).

Between-therapist analyses

No significant differences across therapists were found for the change in alliance during treatment, using the WAI and TASC-r (ps > 0.194).

Discussion

The current study explored treatment process during a novel, exposure-based CBT and PMT intervention for youth with severe irritability, which demonstrated preliminary feasibility and efficacy [45]. The primary goal was to examine clinician-reported adherence to treatment protocol, and how parent-therapist and childtherapist therapeutic alliance and its components (i.e., agreement on tasks, on goals, and the bond between therapist and informant) change over the course of treatment. We also examined the session-by-session temporal relations between treatment adherence, therapeutic alliance, and pediatric irritability symptoms.

First, we found that clinicians delivered the treatment as outlined in the planned protocol. As expected, clinicians focused on standard CBT elements early in treatment, and focused on treatment-specific components during the core of the intervention. Overall, higher therapist adherence to CBT elements was associated with decreased irritability symptoms. At the sessionby-session level, we found that adherence to parent treatment-specific components, particularly dealing with outbursts and active ignore, were associated with decreased clinician-reported irritability in the following session. This suggests that the active ingredients that are specific to this PMT treatment are influencing child irritability, therefore supporting the importance of adhering to PMT modules. An important piece to note regarding the sequence of PMT modules by phase of treatment is that PMT modules tend to build on each other. For example, instrumental learning builds on active ignore, which further builds on dealing with outbursts. As such, while therapists have the flexibility to introduce modules in any order, it is likely that therapists tended to follow a certain flow of order due to the sequential logic of some modules. We did not find session-by-session changes in exposure adherence, which, alongside descriptive data showing that levels of exposure adherence were consistently high across sessions 3-11, indicates an overall high adherence to the exposure protocol throughout treatment. This is expected, given that exposure is the main technique of the treatment protocol.

Regarding therapeutic alliance, we found that both total score and subscales of parent-therapist alliance increased over the course of the treatment. It is possible that as parents engage more with treatment, and the anger exposures become more potent while parent learn and practice more management training components, there is an increase in agreement with therapeutic goals, tasks, and emotional bond within the parent-therapist dyad. We did not find significant change in levels of child-reported alliance across treatment. One potential explanation for the current discrepancy in the findings between child and parent could be due to the specific nature of the child intervention (i.e., the in-vivo exposure to anger/frustration). In this treatment, the therapist challenges the child by confronting them with anger-inducing triggers, which can shift the focus away from the therapist providing support and praise; in turn, this may limit increases in the child's alliance as exposure becomes the focus of treatment. Fjermestad and colleagues [15] showed that specific alliance-building behaviors can be differentially correlated with outcomes: they found that behaviors such as exploring motivation, praise, and support correlated positively with outcomes, while behaviors such as expressing positive expectations or exploring cognitions were negatively associated with outcomes. Alternatively, children might be less nuanced when repeatedly reporting on their levels of alliance. This assumption is in line with previous research demonstrating low to modest correlation between parent- and child- alliance [49]. Notably, alliance levels at baseline in the current study were relatively high for both parents and children, which might create a ceiling effect lessening the ability to reveal significant changes over time and further increases in alliance.

From a clinical perspective, the observed high alliance at baseline (see: Table 1) implies that the child may be trusting the parents' and/or community provider's endorsement of the study from the beginning. The current treatment protocol may reinforce this trust as the clinicians spend a lot of time explaining the rationale for the exposures, as well as emphasizing the autonomy of the child in deciding whether they want to participate and providing continuous assent during treatment. Thus, the child may feel a greater sense of control and increased trust in the therapeutic relationship, such that alliance is developed before the first exposure session.

When we explored the temporal sequence of the relations between alliance and pediatric irritability, we found that increased child-therapist alliance, particularly bond, was associated with reduced clinician-rated irritability at the next clinical rating. Additionally, increased parenttherapist alliance, particularly agreement on goals in the session, led to a trend-level decrease in parent-reported irritability at the following session. Similar modest findings between alliance and outcomes were also reported for other psychological conditions, such as depression in adults (for review see: [6]). Studies in youth indicate mixed results which vary across samples, clinical diagnoses, and tools used to assess alliance [14, 16].

The current study adds to the existing adherence- and alliance-outcome literature in youth by focusing on pediatric irritability and examining the bidirectionality of the association between alliance and irritability on a session-by-session basis. Lagged analyses utilizing multi-informant ratings sets this study apart from those which are unable to test directional hypotheses or examine treatment processes at a more detailed level. For example, Labouliere and colleagues [35] (2017) conducted a CBT study for youth with depression and found that first-session therapeutic alliance was a strong, significant predictor of session 4 depression symptoms, but pretreatment depression scores were not significantly predictive of subsequent therapeutic alliance. By utilizing reports from all twelve treatment sessions, we were able to assess for temporal associations between adherence, alliance, and symptom levels at different stages of treatment.

Current findings indicate that clinician-reported irritability predicts parent-reported and child-reported alliance. A similar pattern is found for parent-reported irritability predicting parent-reported alliance. Our findings provide stronger support for the directionality of symptom improvement predicting increases in therapeutic alliance, compared to the inverse direction (i.e., alliance predicting irritability). In the context of the debate in the CBT literature regarding the directionality of this association [40, 42, 50, 64], the current study aligns with some previous research in the field of anxiety and depression showing that higher ratings in alliance predicted greater subsequent symptom reduction (e.g., [4, 36, 59]).

Interestingly, and consistent with previous published research (e.g., [59]), our findings reveal more consistent and robust effects for the therapist and client agreement on the goal and the task of the treatment compared to the bond. Specifically, we found that improvement in symptoms is more strongly related to increases in client-therapist dyad agreement on goal and task, rather than increases in bond. It seems that once the client sees that the therapy is having an effect in decreasing youth irritability, then the client is more in agreement with what is being done (the tasks) and the main goals of the treatment. These changes in symptoms may have a less direct effect on the bond or the warmth the client feels towards the therapist. This all suggests that it is particularly important to focus on interventions that can have early effects on symptom improvement in order to increase client agreement with treatment goals. Of note, our treatment modality is active, didactic, and skills-focused, and the goal of the tasks involved in the sessions are to develop new skills. Specifically, exposures challenge children to confront their anger triggers, and parent management skills training challenge parents to manage and cope with their child's irritability. Hence, one might expect a stronger association between agreement on tasks and treatment goals to symptom change, compared to the bond. The current findings can further elucidate the process by which therapy helps patients recover, and given the time-limited nature of therapy, inform therapists on which therapeutic factors to prioritize in order to optimize outcomes.

This current study has substantial strengths: it is the first to assess treatment adherence and therapeutic alliance-outcome relations in the context of a novel treatment of exposure-based CBT and PMT for children with clinically impairing irritability. Adherence and alliance measures, as well as clinical outcomes, were assessed at multiple time points, allowing us to examine the temporal precedence and the direct influence of adherence and alliance at one session on clinical symptom reports at the next session, and vice-versa. We used multiple reporters for both alliance and symptom change.

While our results are informative, several limitations should be noted. First, adherence measures were created specifically for this study and therapists rated their own adherence to the manual, which introduces potential confounds. Future work is needed with objective observers coding recordings of sessions. Second, the self-report measures for both alliance and outcome may have been influenced by reporter bias. This is especially relevant for the youth report, as some youth may underreport their symptoms relative to their parents. This cross-informant discrepancy is well-known in youth with psychopathology [2], and irritability specifically [56], and may have limited our ability to detect associations related to childreport. Similar to the current findings, some previous research has failed to find that child-therapist alliance predicts child outcome [38]. Some of the associations detected may have also been influenced by common reporter variance, since statistical models used the same reporter for alliance and symptom change (i.e., parent alliance predicting parent symptom change; see [33]). Third, the current study did not include other potentially relevant information on participants, such as treatment outcome expectancies, a variable found to be relevant in previous studies [58], to investigate third variables which could influence alliance and outcome. Fourth, we did not conduct a separate a priori power analyses for the current research question; rather, we relied on our primary power analyses conducted for the initial study as reported in the published protocol [46].

This study is a first step in examining therapeutic processes in a novel exposure-based CBT plus PMT treatment for youth with severe irritability. Preliminary data show efficacy of the treatment [45] and the current findings provide preliminary evidence for high adherence and therapeutic alliance in the sample, which were associated with clinical improvement. Future investigations, also in the context of a full RCT design, could shed further light on these treatment processes, their interactions, and their potential roles as mechanisms of change.

Abbreviations

| Attention-deficit/hyperactivity disorder |
|----------------------------------------------------------------|
| Affective Reactivity Inventory |
| Autism Spectrum Disorder |
| Cognitive Behavioral Therapy |
| Conduct disorder |
| Clinical-rated ARI |
| Development and Well-Being Assessment |
| Disruptive mood dysregulation disorder |
| False Discovery Rate |
| Hierarchical linear models |
| Institutional Review Board |
| Kiddie-Schedule for Affective Disorders and Schizophrenia Pre- |
| sent and Life-time |
| National Institute of Mental Health |
| Oppositional defiant disorder |
| Parent Management Training |
| Randomized Controlled Trail |
| Social Responsiveness Scale |
| Social Communication Questionnaire |
| Therapeutic Alliance Scale for Children-revised |
| Working Alliance Inventory |
| Wechsler Abbreviated Scale of Intelligence |
| |

Supplementary Information

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Additional file 1.

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Authors' contributions

RN conducted the analyses and wrote the original draft. RN, REG, KK, MB, KD, UP were involved in the conceptualization and in the statistical modelling and analyses, JM, REM, MC, SP, KD, UP contributed to data collection and project administration. All authors reviewed and edited the manuscript, and all authors approved the final version.

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Data availability

The datasets analyzed during the current study are available in the OSF repository, https://osf.io/f7gma/?view_only=071cb5b0d5ea4ef49b614ed2c9e3731d.

Declarations

Ethics approval and consent to participate

All procedures were approved by the National Institute of Mental Health (NIMH) Institutional Review Board (IRB). Participants and parents/guardians gave informed assent and consent, respectively. Children and caregivers were informed that participation was voluntary, and that assent/consent could be withdrawn at any time.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Author details

¹School of Psychological Sciences, Tel-Aviv University, Tel-Aviv, Ramat Aviv 6139001, Israel. ²Sagol School of Neuroscience, Tel-Aviv University, Tel-Aviv, Israel. ³Emotion and Development Branch, National Institute of Mental Health, Bethesda, MD, USA. ⁴Department of Psychological and Brain Sciences, Indiana University Bloomington, Bloomington, IN, USA.

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