RESEARCH ARTICLE

Treatment mechanism of the WHO caregiver skills training intervention for autism delivered in community settings

Michele Settanni[1] | **Katharine Suma**[2] | **Lauren B. Adamson** | **Helen McConachie**[3] | **Chiara Servili**[4] | **Erica Salomone**[4,5]

[1]Department of Psychology, University of Turin, Turin, Italy

[2]Department of Human Development and Family Science, University of Georgia, Athens, Georgia, USA

[3]Population Health Sciences Institute, Newcastle University, Newcastle upon Tyne, UK

[4]Department of Mental Health and Substance Use, World Health Organization, Geneva, Switzerland

[5]Department of Psychology, University of Milano-Bicocca, Milan, Italy

Correspondence
Erica Salomone, Department of Psychology, University of Milano-Bicocca, Piazza dell'Ateneo Nuovo 1, 20126 Milano, Italy.
Email: erica.salomone@unimib.it

Abstract

This study examined the mechanism of effect of the WHO Caregiver Skills Training (CST) through secondary analysis of a pilot RCT conducted in community settings. Participants were 86 caregivers (77% mothers) of children with ASD (78% male, mean age: 44.8 months) randomized to CST ($n = 43$) or treatment as usual ($n = 43$). The primary outcomes, measured at baseline (t1), immediately post-intervention (t2), and 3 months post-intervention (t3), were derived from the coding of caregiver-child free play interactions with the Brief Observation of Social-Communication Change (BOSCC) and the Joint Engagement Rating Inventory scale (JERI). At t3 positive treatment main effects had been observed for caregiver skills supportive of the interaction and for flow of the interaction (JERI), albeit only non-significant changes in the expected direction for child outcomes: autism phenotypic behaviors (BOSCC), joint engagement and availability to interact (JERI). This study tested the theory of change of CST, hypothesizing that the intervention would lead to an improvement on all child and dyad outcomes through an increase in the caregiver skills supportive of the interaction. Serial mediation analyses revealed that the effect of the intervention was significantly influenced by change in caregiver skills. Participation in the intervention led to notable increases in caregiver skills at t2 and t3, which subsequently contributed to improvements at t3 in flow of the interaction, autism phenotypic behavior, joint engagement, and availability to interact. We confirmed our a priori hypothesis showing that change in caregiver skills significantly mediated the effect of treatment on the dyad primary outcome, as well as on the other child outcomes that had shown non-significant changes in the expected direction. Implications for intervention design and policy making in the context of public health services are discussed.

† Deceased.

Lay Summary

Community-implemented caregiver-mediated interventions are commonly used with children with autism spectrum disorder under age 5, but few studies have examined their effective mechanism (i.e., the processes responsible for changes in the clinical outcomes). This study examined the mechanism of a recently developed intervention, the WHO Caregiver Skills Training (CST), within a randomized controlled trial carried out in the community. The trial had shown positive intervention effects on parent skills supportive of the interaction and for fluent interaction between the child and caregiver, but less strong changes in the expected direction for child autism characteristic behaviors, joint engagement and availability to interact. The current study tested the hypothesis that CST works by increasing the parent's skills in support of the interaction, which in turn can lead to improved outcomes. We found that caregivers who received the CST intervention improved significantly more in their interaction skills with the child, and this led to a significant improvement on all joint interaction and child outcomes, including those which did not show a main effect of the intervention. This study shows that an acceptable and feasible open access community-implemented caregiver-mediated intervention can lead to a sustained improvement in the quality of the caregiver–child interaction through enhancing the caregiver's interaction skills.

INTRODUCTION

Despite the tremendous progress in autism intervention research in the past decades, there remain wide unknowns about what kind of treatments should be provided "when, to whom, for how long, with what expected outcomes, and for what cost" (Lord et al., 2021, p. 272). Understanding the "why" and "how" a treatment is efficacious (or is not) is crucial to inform intervention design and, ultimately, in the context of pressure on public health systems globally, essential to support effective health policy decisions. Increasingly, research in child and adolescent mental health has addressed the question of "how" by performing formal tests of the hypothesized mechanism of interventions through mediation models. These allow examination of whether the expected outcomes have been brought forward by the pre-specified intervention active components, and potentially how the treatment effects may continue beyond the intervention period (Charman, 2021). Moreover, mediation studies of treatment mechanism are in themselves fundamentally relevant for developmental science and developmental social neuroscience since they can be conceptualized as analyses of how a given "developmental perturbation" (the intervention) affects the longitudinal course of complex conditions such as neurodevelopmental disorders through enhancing the child-environment fit (Green & Dunn 2008; Dawson, Rieder & Johnson 2023).

However, in the autism field, there have been few formal tests of treatment mechanism in caregiver- or teacher-mediated interventions, an intervention type very commonly used for children under 5 years

(Lord et al., 2021) and supported by evidence of changes in proximal outcomes particularly in the social communication domain (Crank et al., 2021). Pickles et al. (2015) showed that "parent synchrony" (proportion of parent communication acts that are a synchronous response to a child communication act) mediated the extent of autism phenotypic behaviors on a separate, examiner-led assessment (the Calibrated Severity Score, CSS, on the ADOS-2; Lord et al., 2012) in the Preschool Autism Communication Trial (PACT). In a trial of the Joint Attention, Symbolic Play, Engagement and Regulation (JASPER) intervention against psychoeducation, "mirrored pacing" (quality and frequency of parent imitation of child play acts) mediated duration of joint engagement in the same parent–child interaction (Gulsrud et al., 2016). Increased parental sense of competence mediated the reduction of child challenging behaviors not only at intervention endpoint but also at a later follow-up in a large cluster randomized trial of "An Individualized Mental Health Intervention for ASD" (AIM HI) training for behaviors that challenge (Brookman-Frazee et al., 2021). Furthermore, secondary analyses of RCTs of the JASPER (Shih et al., 2021) and PACT interventions (Carruthers et al., in press) demonstrated how sustained changes in child skills (joint engagement in JASPER, child initiations in PACT) in turn led to improvements in, respectively, expressive and receptive language on the Mullen Scales of Early Learning and the extent of autism behaviors on the ADOS-2. Taken together, this evidence points to promising pathways to enhancing child skills by improving parent–child interaction outcomes.

Nonetheless, it is important to consider that the effect sizes of child clinical outcomes in caregiver-mediated interventions implemented in community settings are, not surprisingly, considerably smaller than those reported in trials conducted in university-based settings (Nahmias et al., 2019). This reflects a number of challenges, including difficulties maintaining high levels of fidelity across both developmental strategies and behavioral strategies, which are less frequently embedded by early intervention providers in their practice (Pickard et al., 2021). In this perspective, the systematic search for "essential" intervention components can support the progressive optimization of effective treatments implemented in community settings (Williams & Beidas, 2019). Studies of treatment mechanisms of interventions delivered in community settings and formally evaluated for acceptability and feasibility are therefore particularly needed. The accurate reporting of acceptability and feasibility is, in fact, strategic in order to determine whether a lack of (or reduced) intervention effect may fundamentally be due to implementation issues rather than higher-order considerations that pertain to the theory of change underlying the intervention. However, of the few above mentioned autism intervention studies which conducted formal mediation analyses, only two report on trials of interventions implemented in community settings: a teacher-mediated model delivered in public preschools (Shih et al., 2021) and a caregiver-mediated model delivered to parents by community providers trained by trial therapists (Brookman-Frazee et al., 2021); the latter especially stands out from narrower efficacy trials for its complex cascade training model, as previously noted (Charman, 2021). Nonetheless, more evidence is needed on the mechanisms of effect of interventions conducted in the community.

The current study

This study examines the mechanisms of effect of a caregiver-mediated intervention implemented in the community, the "Caregiver Skills Training for families of children with developmental delays or disabilities" (CST). The CST, an open access program developed by WHO for developmental delays or disabilities, including autism (Salomone et al., 2019; WHO, 2022) is based on naturalistic developmental behavioral intervention methodologies (NDBI; Schreibman et al., 2015). CST comprises nine group sessions and three home visits training caregivers through adult-learning methods on the topics of engagement, play and home routines, communication, challenging behavior, daily living skills, parent wellbeing, and problem solving (Salomone et al., 2019); interventionist guides and participant booklets are freely available for download from the WHO website (https://www.who.int/teams/mental-health-and-substance-use/treatment-care/who-caregivers-skills-training-for-families-of-children-with-developmental-delays-and-disorders).

In a pilot RCT of CST provided in public health services in Italy with excellent acceptability to caregivers and feasibility of delivery (Salomone, Ferrante, et al., 2021), some relevant favorable treatment effects were reported on caregiver/child interaction data (Salomone, Settanni, et al., 2021). Specifically, at the 3-months follow-up on the blind-rated primary outcomes positive treatment effects were observed for parent skills supportive of the interaction and for dyadic fluency of the interaction, albeit not for child autism severity, joint engagement, and availability to interact; on these outcomes non-significant changes were observed in the expected direction.

As per registered protocol, the intervention theory of change posits that participation in the intervention is expected to lead to an improvement in the child's availability to interact, in joint engagement and flow of interaction through an increase in the parent's skills in support of the interaction. In this study, we therefore tested the treatment mechanism of CST examining if participation in the intervention would improve parent skills supportive of the interaction at treatment endpoint and at the 3-months follow-up, and if this, in turn, would mediate improvement on all dyad and child outcomes at follow-up, including those which had not shown main treatment effects. According to Hayes (2017), the presence of a significant indirect effect confirms mediation, even without a significant total effect: "A failure to test for indirect effects in the absence of a total effect can lead to you miss some potentially interesting, important, or useful mechanisms by which X exerts some kind of effect on Y" (Hayes, 2009, p. 415). With this study we therefore aimed to identify possible indirect treatment effects to shed light on the intervention mechanism and potentially to identify strategies to boost its effectiveness.

METHODS

Design

The pilot CST trial was a 6-center, 2-arm assessor-blinded RCT of CST against enhanced treatment as usual (eTAU: one psychoeducation session in addition to TAU) of 86 children with autism aged 24–60 months. This study was performed in line with the principles of the Declaration of Helsinki. The trial was retrospectively registered (trial registry: ISRCTN, registration identification number: ISRCTN11702408, www.isrctn.com), as at the time of drafting of the study protocol the caregiver/child interaction measure that was selected to measure the blind-rated primary outcomes (an adaptation of the JERI scale developed for WHO, Adamson et al., 2020) was not yet available. Ethical approval was granted by the Institutional Review Boards of the University of Turin (#57273) and of all National Health Service study sites: ASL Città di Torino (#0010244 and #0077761),

ASL AL (#AslAL.NPI.16.01), ASL CN1 (#180-16), ASL BI (#CE128/17). Both parents gave written consent. The primary outcome paper (Salomone, Settanni, et al., 2021) followed CONSORT guidelines. Families in the CST intervention group attended 9 weekly group sessions and three home visits (before the first, after the 4th and after the 9th session) over 3 months. Data were collected at baseline (t1), immediately post-intervention (3 months post-baseline, t2), and 3 months post-intervention (t3; Figure 1).

Participants

Participants were caregivers of children ($n = 86$) recruited as per the following inclusion criteria: (a) child age between 24 and 60 months; (b) child local clinical diagnosis of ASD by ICD-10 criteria (obtained with a combination of semi-structured observations, parent interviews and school reports) confirmed by research assessments. The exclusion criteria were: (a) level of spoken Italian in the caregiver not sufficient for a full participation in the intervention; (b) psychiatric conditions in the caregiver as reported in the clinical notes; these criteria were selected to ensure that parents could fully participate in the intervention. Children were not excluded based on level of intellectual disability or any co-occurring condition. Participants were recruited from Child Neuropsychiatry Services of the national public health system in Italy; the sample consisted of mostly male ($n = 67$; 77.9%) preschoolers (age in months: $M = 44.88$; $SD = 9.52$) with moderate levels of autism phenotypic behaviors on the ADOS-2 CSS ($M = 6.94$; $SD = 21.17$) and developmental delay as measured on the Griffiths III (age equivalents scores for the General Development composite: $M = 23.34$; $SD = 6.93$). The two arms did not differ on any demographic or clinical characteristics. The intervention was delivered by local clinicians: one child neuropsychiatrist, eight clinical psychologists and three "psychomotor therapists" (healthcare professionals operating in the neuro-psychomotor, neuropsychology and developmental psychopathology areas). The clinicians received a 5-day training course including presentations, role plays and practice with volunteer families and four post-training supervised practice sessions with families delivered by a WHO CST Team member (ES); all interventionists met post-training CST competency criteria. The interventionists demonstrated faithful and correct
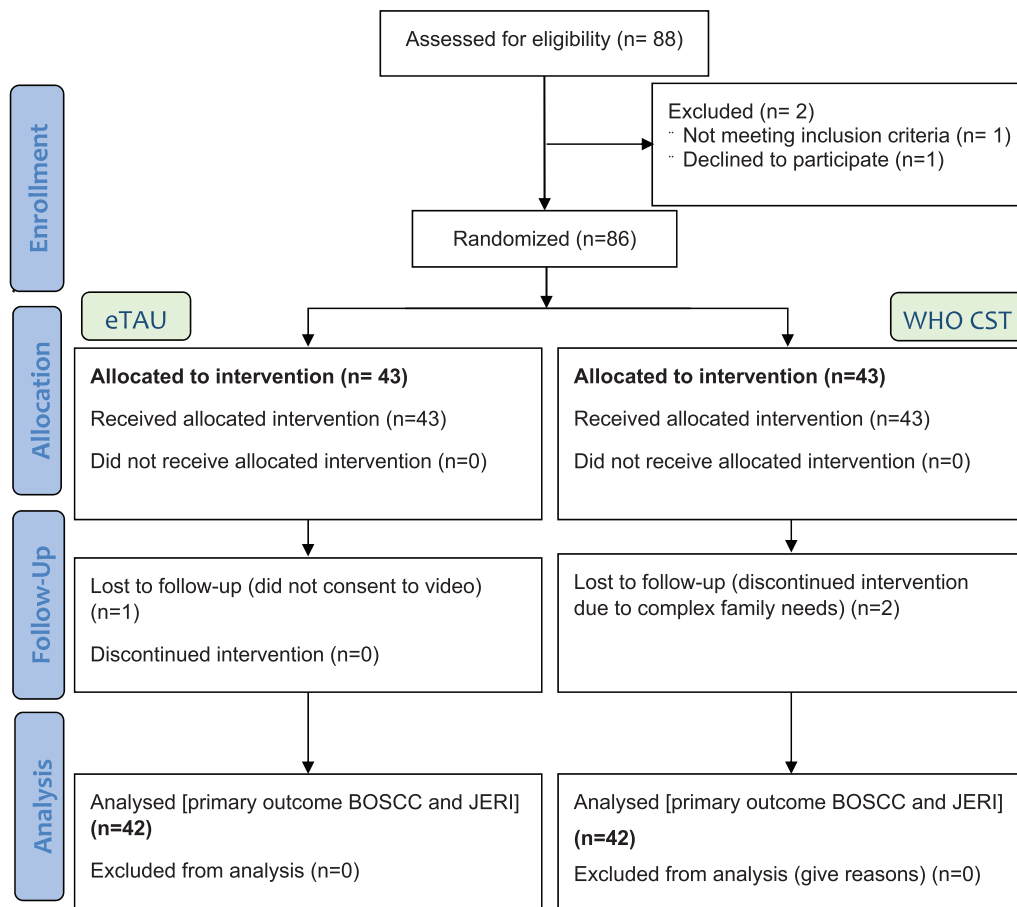

FIGURE 1 CONSORT 2010 flow diagram (adapted from http://www.consort-statement.org/).

implementation both of the group sessions component (range of integrity ratings: 82%–97%), and of the home visits component (range of fidelity of use of intervention strategies in interaction with children: 73%–80%; Salomone, Settanni, et al., 2021). Access to treatment as usual was not restricted for either arm and the two groups did not differ on hours of child-directed services, school support, parenting programs or psychoeducational counseling received during the trial. In the treatment arm, participation in the program was open to 1–2 caregivers per family; for both groups data were collected on a target caregiver/child dyad designated by the family at baseline. For more details on the methodology of the trial, see previous reports (Salomone, Ferrante, et al., 2021; Salomone, Settanni, et al., 2021).

Outcomes

The child and dyad primary outcome measures were derived from the coding of 10 consecutive minutes of an approximately 12-min free play caregiver-child interaction videorecorded at the child's home ($n = 256$ interactions). Parents were given a standard toy kit suitable for a range of developmental play levels and instructed to play as they would usually do; coding began as soon as either partner had referenced or touched a toy. The recordings were rated for autism severity and dyadic engagement respectively with the Brief Observation of Social Communication Change (BOSCC, Version July 27, 2017; Grzadzinski et al., 2016) and the Joint Engagement Rating Inventory (JERI; Adamson et al., 2012; 2020) by two observers blind to the study hypotheses, group allocation and time point of the assessment. The BOSCC rates child social-communication skills (9 items), restricted and repetitive behaviors (3 items) and other co-occurring behaviors (3 items) on 6-point scales; as per the manual, averaged Total scores were obtained for two 5-minutes segments that were scored separately. The JERI characterizes child joint engagement (1 item), child availability to interact (3 items), parent support of interaction (3 items) and flow of interaction (1 item) on 7-point rating scales. The inter-rater reliability on the double-coded videos (22% of the corpus) was excellent both for the BOSCC on the Total score (intraclass correlation coefficients, ICC = 0.92) and for the JERI items (range of weighted Cohen Kappas: 0.89–1.0). The following primary outcomes were obtained in the main trial analysis: for the caregiver's outcome, *Parent support of interaction* measured with the JERI; for the child's outcomes, *Child autism phenotypic behaviors*, measured with the BOSCC, as well as *Child joint engagement* and *Child availability to interact* measured with the JERI; for the dyad's outcome, *Flow of interaction* measured with the JERI. For additional information on rating procedures and measures, see Salomone, Settanni, et al. (2021).

Statistical analyses

Statistical analyses were conducted as follows: first, descriptive statistics and bivariate correlations between study variables were obtained. Next, after having computed standardized effect sizes for each outcome, sequential mediation models were tested, using Hayes SPSS Process macro. These models were used to test the theoretically expected indirect effect of the intervention, as mediated by changes in parent skills supportive of the interaction (*JERI Parent support of interaction*). Specifically, the indirect effects of the intervention on the following outcomes were tested: *BOSCC Child autism phenotypic behaviors*, *JERI Child joint engagement*, *JERI Child availability to interact*, *JERI Flow of interaction*. For each outcome, we included in the model change scores at follow-up. Analyses were performed using change scores to measure changes in parent skills supportive of the interaction (also referred to as "parent skills"). These scores were taken at the endpoint (PSK_endpoint) and at the 3-month post-intervention follow-up (PSK_followup). The use of change scores is supported by literature, such as Gottman and Rushe (1993) and Rogosa and Willett (1983), which highlights their reliability and validity in capturing change over time. These scores serve as intermediate links between participation in the intervention and the study outcomes (see Figure 2). For each model, the indirect effect going only through the first mediator (change in parent skills at endpoint), the indirect effect going only through the second mediator (change in parent skills at follow-up, and the sequential indirect effect of intervention on outcome going through both mediators were calculated (Hayes, 2017; Taylor et al., 2008). Hence, for each model tested, one direct path (Intervention → Outcome) and three indirect paths (Intevention → PSK_endpoint → Outcome; Intervention → PSK_followup → Outcome; and Intervention → PSK_endpoint → PSK_followup → Outcome) were estimated. Following Hayes et al. (2011), mediation analyses were conducted irrespective of whether a significant association, that is, a total effect, was observed between the intervention and outcome variables. In each model tested, two covariates were included: the first one, common to all models, is the measure of parent skills at baseline, the second is the outcome measure obtained at baseline. We chose to covary the pre-test outcome variable to account for potential baseline differences and to provide a clearer picture of change over time. This approach is consistent with what proposed by Castro-Schilo and Grimm (2018) and with the recommendations of researchers who advocate for controlling for baseline values to obtain a more accurate representation of change (e.g., Mara et al., 2011). Mediation analyses were carried out using Mplus ver. 8. Given the non-normality of the outcomes, we used a MLR estimator to test the model. In addition to the estimates of
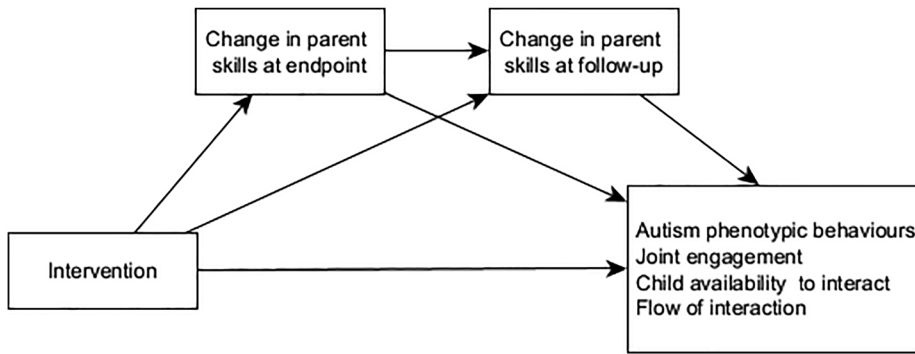
FIGURE 2 Conceptual model of the effects of the intervention on study outcomes, mediated by changes in parent skills at endpoint and follow-up. Model outcomes are change scores at follow-up.

the model parameters and their respective significance levels, we also calculated indirect-to-direct and indirect-to-total effects ratios for each of the study outcomes. The indirect-to-direct effects ratio shows the proportion of the total effect that is due to the indirect effect, compared to the direct effect. This ratio is useful for determining the relative importance of the indirect effect in mediating the relationship between the predictor and outcome variables. If the indirect-to-direct effects ratio is greater than 1, it suggests that the indirect effect is more important than the direct effect in explaining the relationship between the predictor and outcome variables. However, if the indirect-to-direct effects ratio is less than 1, it suggests that the direct effect is more important than the indirect effect in explaining the relationship. On the other hand, the indirect-to-total effects ratio shows the proportion of the total effect that is due to the indirect effect, compared to the total effect. This ratio is useful for determining the strength of the indirect effect relative to the overall effect.

Results

Descriptive statistics and correlations among study variables are shown in Table 1. As expected, we report strong negative correlations between child autism phenotypic behaviors and child joint engagement ratings at baseline. Change in parent skills supportive of interaction at endpoint was moderately positively correlated with change in dyad and child outcomes at follow-up, whereas there was no significant association between change in parent skills supportive of interaction at follow-up and outcomes at follow-up.

Before testing the mediation models, we calculated standardized effect sizes (Cohen's d) for each outcome. Intervention effect sizes were small for JERI scores, ranging from $d = 0.21$ for child availability to interact to $d = 0.37$ for flow of interaction. Change in child joint engagement had a value of $d = 0.26$. As regards autism phenotypic behaviors the effect size was absent, $d = 0.03$.

To assess indirect links between intervention participation and the four outcomes considered (i.e., child autism phenotypic behaviors, child joint engagement, child availability to interact, and flow of interaction) sequential mediation analyses were conducted. Results reported in Table 2 show that the effect of intervention is consistently mediated by the change in parent skills supportive of interaction. In fact, a homogeneous pattern emerges with respect to how the intervention shows to act on the considered outcomes.

In particular, it is noteworthy that the indirect effects Intervention → PSK_endpoint → Outcome and Intervention → PSK_followup → Outcome are always significant and in the expected direction for all outcomes considered. It is interesting to note that the indirect effect Intervention → PSK_endpoint → PSK_followup → Outcome is also always significant and has the opposite effect to the indirect effects commented above. Inspection of Table 2 indicates that the sign of these indirect effects is explained by the presence of a significant negative relationship between PSK_endpoint and PSK_followup, that indicates that individuals who report more marked changes in parent skills supportive of interaction at baseline tend to experience a less strong change between endpoint and follow-up, and vice versa. Overall, the indirect effects for each of the outcomes considered are in line with theoretical expectations, so that participants in the intervention tend to see their parent skills supportive of interaction improve at both endpoint and follow-up more than individuals in the control group, and this improvement is reflected in an overall improvement of the outcomes of the study: the total indirect effects of the intervention are always significant and are equal to -0.12 (SE = 0.05), 0.14 (SE = 0.06), 0.12 (SE = 0.05), 0.13 (SE = 0.05) respectively for change scores in BOSCC *Child autism phenotypic behaviors*, JERI *Child joint engagement*, JERI *Child availability to interact*, and JERI *Flow of the interaction*. It is noteworthy that for all four outcomes, the direct effect is not significant. This suggests that changes in parent skills related to the intervention play a significant role in influencing the observed outcomes. Table 2 also shows the indirect-to-direct and indirect-to-total effects ratios for each outcome. Inspection of these ratios indicates that indirect effects always predominate over direct effects and account for most of the total effect of the intervention for each outcome, with minimum values of 0.59 and 0.74 respectively for JERI *Flow of the*

TABLE 1 Spearman's correlations and descriptive statistics for study variables (N = 86).

	M (SD)	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.
1. Age	45.21 (9.69)	—										
2. JERI Parent skills (baseline)	11.30 (4.26)	−0.10	—									
3. BOSSC Total score (baseline)	29.42 (11.26)	−0.12	−0.55**	—								
4. JERI Child Joint engagement (baseline)	3.23 (2.11)	0.09	0.65**	−0.84**	—							
5. JERI Child Availability to interact (baseline)	12.30 (4.57)	0.11	0.56**	−0.90**	0.90**	—						
6. JERI Flow (baseline)	3.72 (1.64)	0.04	0.67**	−0.80**	0.91**	0.88**	—					
7. JERI Parent skills (change T1-T2)	1.58 (4.27)	0.12	−0.41**	0.23*	−0.28*	−0.31**	−0.34**	—				
8. JERI Parent skills (change T1-T3)	0.36 (4.27)	−0.12	0.14	−0.29**	0.22*	0.31**	0.28*	−0.59**	—			
9. BOSSC Total score (change T1-T3)	−1.89 (6.50)	0.13	0.16	−0.20	0.14	0.15	0.12	−0.21	−0.10	—		
10. JERI Child Joint engagement (change T1-T3)	0.70 (1.58)	−0.08	−0.19	0.12	−0.39**	−0.27*	−0.35**	0.21	0.21	−0.49**	—	
11. JERI Child Availability to interact (change T1-T3)	0.54 (2.77)	−0.19	−0.05	0.04	−0.18	−0.24*	−0.17	0.34**	−0.01	−0.53***	0.55**	—
12. JERI Flow (change T1-T3)	0.58 (1.22)	−0.13	−0.22*	0.10	−0.37*	−0.26*	−0.43**	0.35**	0.14	−0.45***	0.78**	0.68**

*p < 0.05; **p < 0.01.

TABLE 2   Results of sequential mediation models.

Outcome (change scores at follow-up)	Intervention effects	Estimate	SE	Est./SE	p-Value	Indirect-to-direct effect ratio	Indirect-to-total effect ratio
BOSCC—Total Score	Total	−0.122	0.093	−1.307	0.191		
	Direct	0.001	0.101	−0.005	0.996		
	Total indirect*	−0.121	0.052	−2.330	0.020	−121.000	0.991
	Specific indirect effects (mediated by)						
	PSK_endpoint	−0.088	0.046	−1.897	0.058		
	PSK_followup	−0.118	0.040	−2.940	0.003		
	PSK_endpoint→PSK_followup	0.084	0.034	2.484	0.013		
JERI—Child Joint engagement	Total*	0.183	0.087	2.098	0.036		
	Direct	0.049	0.085	0.568	0.570		
	Total indirect*	0.135	0.061	2.224	0.026	2.755	0.738
	Specific indirect effects (mediated by)						
	PSK_endpoint	0.091	0.042	2.160	0.031		
	PSK_followup	0.153	0.055	2.772	0.006		
	PSK_endpoint→ PSK_followup	−0.109	0.037	−2.943	0.003		
JERI—Child Availability to Interact	Total	0.139	0.092	1.517	0.129		
	Direct	0.021	0.092	0.228	0.819		
	Total indirect*	0.118	0.045	2.609	0.009	5.619	0.849
	Specific indirect effects (mediated by)						
	PSK_endpoint	0.091	0.044	2.076	0.038		
	PSK_followup	0.096	0.039	2.467	0.014		
	PSK_endpoint→ PSK_followup	−0.069	0.027	−2.582	0.010		
JERI—Flow of the interaction	Total*	0.227	0.083	2.739	0.006		
	Direct	0.093	0.081	1.156	0.248		
	Total indirect*	0.133	0.052	2.556	0.011	1.430	0.586
	Specific indirect effects (mediated by)						
	PSK_endpoint	0.094	0.043	2.206	0.027		
	PSK_followup	0.136	0.047	2.918	0.004		
	PSK_endpoint→ PSK_followup	−0.097	0.036	−2.733	0.006		

Note: PSK_endpoint, change in JERI Parent skills at endpoint; PSK_followup, change in JERI Parent skills at follow-up; JERI, Joint Engagement Rating Inventory; BOSCC, Brief Observation of Social Communication Change.
*$p < 0.05$.

interaction and JERI *Child joint engagement*. It should also be noted that with respect to JERI *Child availability to interact* and BOSCC *Child autism phenotypic behaviors*, the total effect of the intervention was not significant.

DISCUSSION

In this study, we tested the theory of change of, CST, a novel caregiver-mediated intervention, expecting that it

would lead to an improvement in the child and dyad outcomes through an increase in the caregiver's skills in supporting the interaction. We confirmed our a priori hypothesis showing that change in caregiver's skills supportive of interaction significantly mediated the effect of treatment on the dyad primary outcome (JERI *Flow of the interaction*), as well as on other child outcomes that had shown non-significant changes in the expected direction in the main trial report (Salomone, Settanni, et al., 2021): JERI child joint engagement and availability to interact, and BOSCC child autism phenotypic

behaviors. In line with theoretical expectations, we showed that parents in the CST group demonstrated greater improvements in skills in interaction with the child than those in the control group both immediately post-intervention and at the 3-months follow-up; and that this improvement was reflected in a positive change on all dyad and child outcomes at follow-up. For all outcomes, the intervention effect was significantly mediated by changes in parent skills supportive of interaction. However, it should be noted that while the indirect effect of the intervention via changes in caregiver skills at endpoint and follow-up was significant for all the studied outcomes, and the direct effect was not significant for any of them (indicating that the effect of the intervention was significantly driven by change in caregiver skills), the total effect of the intervention was significant only for flow of the dyad and child joint engagement, but not for child availability to interact and autism phenotypic behaviors. This finding may appear to contrast with our main trial analyses (Salomone, Settanni, et al., 2021), which were conducted under an ITT approach and found a significant intervention effect solely for flow of the dyad. However, the divergence in one additional outcome reaching significance is attributable to the different analytical approaches and estimators used in the two studies, each designed to answer distinct research questions.

This pattern of results distinguishes our study from the existing literature on the mechanisms underlying caregiver-mediated interventions for children with autism. Specifically, previous studies have primarily reported indirect effects on child outcomes in conjunction with significant main effects of the intervention (Brookman-Frazee et al., 2021; Carruthers et al., in press; Gulsrud et al., 2016; Pickles et al., 2015; Shih et al., 2021). This is not entirely surprising as most of these intervention models were delivered in controlled university settings (with the notable exception of Shih et al., 2021 and Brookman-Frazee et al., 2021), and all of them are more intensive than CST, a low-intensity intervention designed to be feasible even in low-resource contexts. Arguably, our mediation analysis is of particular relevance specifically *because of* the lack of main effects on child-level outcomes, which indicates that CST was detectably effective on the more proximal outcomes (change of caregiver's behavior, and change in the overall quality of the dyadic interaction) but not on the ultimate target, child's behavior, despite there being positive changes in the expected direction.

Formal tests of process of treatment are essential to understand treatment mechanisms and in turn to refine intervention strategies and methodologies; identifying indirect treatment effect in absence of direct or total effects is not only statistically viable and advisable (Hayes, 2017) but also clinically useful. This study suggests that the effectiveness of CST can be attributed, in part, to its focus on enhancing parent skills, which is a

key component of the intervention. This is indeed both a useful clinical information specific to CST, and a generalizable critical element of reflection for planning and design of other caregiver-mediated interventions similarly targeting early pivotal social communication behaviors. Our findings mirror indeed those of two other mechanistic studies of parent-mediated interventions, the NDBI model Improving Parents as Communication Teachers (ImPACT; Yoder et al., 2021) and the developmental intervention Adaptive Responsive Training (ART; Watson et al., 2017). Despite the trial design differences with our and previously considered mediation studies — both Yoder et al. (2021) and Watson et al. (2017) are pre-emptive trials targeting toddlers at increased familial risk for autism, rather than diagnosed children — their pattern of results is consistent with our findings. Both studies did not find significant treatment effects on child outcomes but report moderately large intervention effects on parent skills (responsiveness in the ART trial, and overall use of a set of strategies to elicit communication and engagement in ImPACT) which in turn promoted most of the measured child outcomes (primarily communication and motor imitation). This shared pattern of findings, since it is aligned with the hypothesized theory of change, not only shows that the intervention is effective on the proximal target, caregiver's behavior, which in turn operates as catalyst of change in the ultimate target, child skills, but is also signals that there is *potential* for the intervention to produce detectable effects on these more distant targets. The question therefore becomes that of identifying and addressing the factors responsible for the attenuated treatment response.

There are indeed several reasons that may underlie a positive direct treatment effect on parent, but not child outcomes, accompanied by indirect treatment effects through the former on the latter. These are particularly worthy of examination when sample sizes are relatively small, and therefore a "full" mediation may mask other potential, unmeasured, mediators. First and foremost, it is important to acknowledge that there is substantial heterogeneity not only in the characteristics of children with autism, but also, as similarly noted by Yoder et al. (2021), in those of their parents. Several parental characteristics, such as stress, mental health concerns, education, demographic characteristics and certain cognitive profiles, are indeed likely to play a role in determining the effectiveness of caregiver-mediated interventions (Shalev et al., 2020). Gaining insight into the relationship between these important parental factors and the use of specific intervention strategies (domain-specific treatment fidelity) would help understand the complex process of acquisition of the more global "caregiver interaction skills" that ultimately impact children's outcomes. As even early intervention providers in the community tend to implement NDBI strategies unevenly (Pickard et al., 2021), it is likely also that different caregivers will find some strategies easier to incorporate in their

interaction style than others. This could be a result of the interplay among personal factors (such as parental self-efficacy; Russell & Ingersoll, 2021), perceived relevance of strategies for family functioning (Stahmer & Pellecchia, 2015), degree of complexity of implementation (e.g., use of teaching strategies is rarer prior to instruction compared to responsive strategies (Maye et al., 2020) and even cultural factors (such as *respeto* in Latino parenting; Adamson et al., 2021). It also remains to be explored how the rate and extent of caregiver skills acquisition is associated with relevant child characteristics, such as cognitive level, autism severity, language ability and availability to interact, which are likely candidates as moderators of treatment efficacy (Trembath et al., 2019). In light of the above-described complex dynamic of mediating components (e.g., specific intervention strategies) or moderating elements (e.g., characteristics of the parent or child) components, a second factor potentially responsible for indirect intervention effects in the absence of direct effects could be time. As Yoder et al. (2021) and Watson et al. (2017) point out, children may need more time to benefit from the mediating effects of improved parent skills, and it therefore may be necessary to implement longer follow-up assessments to detect smaller effects. Thirdly and finally, these findings could instead indicate the need to improve the intervention, either *qualitatively*, by refining the skills training techniques and/or modifying contents, or *quantitatively*, by increasing the dosage.

In sum, while our findings show that caregiver skills supportive of the interaction led the improvement in the dyad and child outcomes, learning how best to accommodate and support each caregiver's progress would improve the overall effectiveness of the intervention with the ultimate goal of ensuring progress for every dyad. This could be achieved by using the knowledge on how the ability of the parent to learn intervention strategies interacts with the child's specific needs, abilities and challenges in order to guide the design of modifications to the treatment protocol. For example, identifying which specific intervention strategies may be more difficult to learn may inform the contents and methodology of additional "booster" facilitator-led sessions or parents-only meetings, which were proposed as desirable modifications in pilot studies of CST (Salomone, Ferrante, et al., 2021; Sengupta et al., 2021). Identifying essential and desirable intervention components can also inform more cost-effective use of resources, and has implications for methods of training of trainers and for planning how to best support caregivers in maintaining use of intervention strategies beyond the therapy period (Carruthers et al., 2022).

Strengths and limitations

There are several methodological strengths to the present study, which examined the treatment mechanism of one of the first community-implemented caregiver mediated interventions evaluated through a randomized controlled design. We combined rigorous clinical characterization of participants through standardized assessments with assessment of primary outcomes that were blind rated, to a high level of reliability, at multiple timepoints, allowing a rigorous test of treatment mediation that rules out "reverse causality."

Nevertheless, the results should be interpreted in the context of some design features that may limit the interpretation of findings. The non-significance of the direct effect of the intervention on the child outcomes warrants caution in the interpretation of the findings, as outlined above. Second, even though we examined intervention effects on "flow of the dyad" that can be considered a small, and therefore potentially clinically relevant, effect as per the benchmarks generated by Chow et al. (2022), the use of primary outcome measures derived from caregiver-child interaction makes these proximal, context-bound, direct measures of social communication outcomes prone to correlated measurement error (Crank et al., 2021). Nevertheless, these measures are common in the field, and also have the strengths of objectivity through blind rating while being clinically meaningful and acceptable to caregivers. Finally, while this is among the largest RCTs conducted in a public community setting, a larger sample size would have had the necessary power to conduct subgroup analyses, for example, by autism phenotypic behaviors at baseline.

Conclusions and implications

Findings from the study demonstrate that an acceptable, feasible, open access caregiver-mediated intervention implemented in the community can lead to a sustained improvement in the quality of the caregiver–child dyadic interaction through enhancing caregiver's skills supportive of such interaction. The WHO CST has been shown to be feasible and acceptable across both low-and-middle-income countries (Montiel-Nava et al., 2022; Sengupta et al., 2021; Tekola et al., 2020) and high-income countries (Ferrante et al., 2022; Lau et al., 2022; Salomone, Ferrante, et al., 2021; Seng et al., 2022), with evidence of treatment effects on caregiver skills and overall quality of the dyadic interaction (Salomone, Settanni, et al., 2021). The current study shows that it is precisely this improvement of caregiver skills that in turn can promote social communication outcomes in the child. Further research is needed to identify and subsequently target specific caregiver characteristics and skills corresponding to intervention strategies, in order to design caregiver interventions with larger impact on children's outcomes.

AUTHOR CONTRIBUTIONS
Erica Salomone conceived and designed the study, part of the WHO field-testing initiative coordinated by

Chiara Servili, and led the research team. Helen McConachie, Katharine Suma, and Lauren B. Adamson provided training and methodological support for the coding of video-recorded data. Michele Settanni analyzed the data. Erica Salomone and Michele Settanni led the interpretation and writing of the paper with input from all authors.

CONFLICT OF INTEREST STATEMENT
The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT
The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT
This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Institutional Review Boards of the University of Turin (#57273) and of all National Health Service study sites: ASL Città di Torino (#0010244 and #0077761), ASL AL (#AslAL.NPI.16.01), ASL CN1 (#180–16), ASL BI (#CE128/17).

INFORMED CONSENT STATEMENT
Informed written consent was obtained from parents/legal guardians and professionals participating in the study.

ORCID
Lauren B. Adamson https://orcid.org/0000-0002-6601-8874
Chiara Servili https://orcid.org/0000-0002-1885-822X

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