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Effectiveness of a social cognition remediation intervention for patients with schizophrenia: a randomized-controlled study

Luigi Giuliani[1†], Pasquale Pezzella[1†], Armida Mucci[1*], Davide Palumbo[1], Edoardo Caporusso[1], Giuseppe Piegari[1], Giulia Maria Giordano[1], Pietro Blasio[1], Claudio Mencacci[2], Sara Torriero[2] and Silvana Galderisi[1]

Abstract

This randomized-controlled study evaluates the effectiveness of a newly developed social cognition rehabilitation intervention, the modified Social Cognition Individualized Activity Lab (mSoCIAL), in improving social cognition and clinical and functional outcomes of persons with schizophrenia recruited in two Italian sites: University of Campania "Luigi Vanvitelli" in Naples and ASST Fatebenefratelli-Sacco in Milan. mSoCIAL consists of a social cognitive training module focusing on different domains of social cognition and of a narrative enhancement module. We assessed changes in social cognition, clinical characteristics and functional variables in patients with schizophrenia who participated in 10 weekly sessions of mSoCIAL or received treatment as usual (TAU). A paired-sample t test and a repeated-measures MANOVA were used to investigate respectively within and between-group differences. Twenty people with schizophrenia were blindly assigned to mSoCIAL and 20 to TAU. After 10 weeks, mSoCIAL significantly improved disorganization, emotion recognition, functional capacity and real-life functioning. As compared to TAU, the mSoCIAL group showed a significant improvement in minimal and enriched social inference domain of theory of mind, and in key domains of real-life functioning (interpersonal relationships, everyday life skills, and work skills). mSoCIAL improved social cognition and real-life functioning of people with schizophrenia. These results highlight the importance of social cognition deficit treatment in schizophrenia and the necessity for these interventions to be multifaced and personalized. Such an approach ensures that improvements in social cognition translate into enhanced functional outcomes.

Trial registration NCT05130853, registered on 24 November 2021.

Keywords Metacognition, Narrative enhancement, Real-life functioning, Schizophrenia, Social cognition training

†Luigi Giuliani and Pasquale Pezzella have equally contributed to the manuscript.

*Correspondence:
Armida Mucci
armida.mucci@gmail.com
[1] University of Campania "Luigi Vanvitelli", Piazza Miraglia 2, 80138 Naples, Italy
[2] Department of Psychiatry and Addiction, ASST Fatebenefratelli-Sacco, 20157 Milan, Italy

Introduction

Schizophrenia is a complex and heterogeneous disorder in terms of pathophysiology, clinical presentation, and functional outcome [1–6]. It is one of the leading causes of disability with a significant impact on various aspects of functional outcomes, such as interpersonal relationships, activities of daily living, and work capabilities [7–16]. Negative symptoms and impaired cognition represent important predictors of poor functional outcome [12, 17–23]. Nevertheless, often these aspects are inadequately assessed and treated [14, 18, 19, 24–29].

Among cognitive domains, social cognition (SC) has received interest in clinical research for its direct influence on schizophrenia outcome, but also for its role as a mediator of the impact of other cognitive domains on real-life functioning [30–33]. SC is a complex construct that underlies fundamental skills for social interactions, including perception, interpretation, and generation of responses based on others' intentions, emotions, and behaviors [34, 35]. In persons with schizophrenia (SCZ) an impairment in four domains of SC has been reported: emotion recognition, social perception or knowledge, theory of mind, and attribution style [36]. To apply these social cognitive skills in everyday life, the ability to generate integrated ideas about oneself, others, and the world, i.e., metacognition, is essential. Both SC and metacognition contribute to the construction of a coherent narrative of internal experiences and one's behavior in various interpersonal situations [37–39].

Up to now, pharmacological treatments have had a marginal impact on both neurocognition and social cognition [25, 40–44], while several psychosocial treatments have been developed to achieve significant improvement in various cognitive domains, and consequently in quality of life and real-life functioning [25, 45–49]. Indeed, several cognitive remediation programs have been implemented to improve neurocognitive functions (such as attention, memory, and learning), but only in the last decade SC has become the target of specific intervention programs with promising results [25, 50–52]. There is evidence that SC intervention programs in schizophrenia lead to significant improvements in emotion recognition and, to a lesser extent, theory of mind, contributing to ameliorate patients' functional outcome [52]. Efficacy on psychopathology is uncertain. A meta-analysis by Kurtz et al. reports improvements in PANSS total score but not in negative and positive dimension scores. Improvement in real-life functioning is also controversial, even for integrated cognitive remediation and social cognition training programs [52, 53].

To enhance the impact of SC intervention on real-life functioning we developed an integrated intervention, the Social Cognition Individualized Activities Lab (SoCIAL). To our knowledge, no SC program has included a metacognition module specifically designed to improve real-life functioning of persons with schizophrenia. We found only a previous study that used a metacognitive and social cognition training intervention, demonstrating improvements in social cognition domains, with smaller but positive effects on psychosocial functioning and symptomatology in individuals with schizophrenia [54].

In a pilot study conducted in a group setting without a metacognition-focused module, we compared SoCIAL with a validated program integrating cognitive remediation and social skills training, the Social Skills and Neurocognitive Individualized Training [55–57]. Only those who participated in the SoCIAL program showed an improvement of SC abilities and of the avolition domain of negative symptoms [55]. Changes in positive and disorganization dimensions, neurocognitive functioning, and real-life functioning did not differ between the two treatment groups [55].

We identified two main study limitations: (1) the group setting and (2) the role-play module. The group setting was not accepted by all subjects, and recruitment of participants was challenging. The role-play, a valuable technique for developing social skills, might be less effective in training SC, as individuals with more significant SC impairment may experience frustration during the role-play if others exhibit less compromised SC. Recently, Yanos, Roe and Lysaker implemented the *Narrative Enhancement* intervention, a program that could help persons with schizophrenia to develop their narrative skills [58–62]. Some studies have utilized this intervention in "integrated" rehabilitation programs with encouraging results [61, 62], and found a greater reduction of internalized stigma and an improvement of participants' quality of life in those exposed to this program as compared to other psychological and rehabilitative interventions [62]. Therefore, in the present study we adopted an individual approach and, to increase the impact on real-life functioning, we added the Narrative Enhancement intervention.

The present study aimed to evaluate the effectiveness of the modified SoCIAL (mSoCIAL) by providing the intervention in an individual setting and including a *Narrative Enhancement* intervention [63]. The primary objective was to demonstrate the superiority of the mSoCIAL on various domains of social cognition in SCZ as compared to Treatment As Usual (TAU). The secondary objective was to assess its impact on psychopathology, neurocognition, functional capacity, and real-life functioning.

Materials and methods

The present study is a randomized-controlled trial in which subjects were assigned to two groups: the mSoCIAL treatment group and the Treatment As Usual (TAU) group.

The study was conducted at the Department of Mental Health of the University of Campania "Luigi Vanvitelli" Hospital in Naples and the Department of Mental Health and Addictions ASST, Fatebenefratelli Sacco, Milan. Forty SCZ, regularly attending the outpatient units of the two mental health departments involved in the study, were recruited. Inclusion criteria were: (1) the diagnosis was made according to DSM-5 criteria and confirmed through Structured Clinical Interview (SCID-I-P); (2) age between 18 and 50 years; (3) clinical stability defined as no significant changes in pharmacological treatment or hospitalizations for psychopathological exacerbation in the last 3 months; (4) illness duration < 10 years; (5) at least 5 years of formal education. Exclusion criteria were: (1) medical conditions causing disability; (2) a history of alcohol and/or substance abuse; (3) moderate to severe intellectual disability; (4) current pregnancy or lactation; (5) inability to provide informed consent. Subjects were considered "dropouts" when: (1) did not participate in study sessions for 3 consecutive weeks or withdrew consent to continue the study; (2) interrupted the program for 5 weeks, even if not consecutive; (3) there was a worsening of the psychopathological condition requiring a substantial modification of pharmacological therapy and/or hospitalization. The study protocol was approved by the Ethics Committees of both institutions. All enrolled subjects signed an informed consent form approved by the same Ethics Committees. Participants were randomly assigned to the intervention or control group (TAU) using an ad-hoc Excel spreadsheet [64].

Assessment instruments

Participants were evaluated before starting the program and at the end of the intervention. Psychopathology was assessed by using the Positive and Negative Syndrome Scale (PANSS) [65]. The positive dimension was calculated by summing scores on "delusions" (P1), "hallucinatory behavior" (P3), "grandiosity" (P5), and "unusual thought content" (G9); disorganization was represented by the PANSS item "conceptual disorganization" (P2), to avoid overlaps with cognitive impairment as the PANSS disorganization factor includes "difficulty in abstract thinking" (N5) and "poor attention" (G11) [66]. Since the PANSS negative factor includes items assessing cognitive functions and disorganization, only core negative symptoms were included in the total score (N1-N4 and N6) [18]. Neurocognitive functions were assessed using the Measurement and Treatment Research to Improve Cognition in Schizophrenia (MATRICS) Consensus Cognitive Battery (MCCB) [67]. MCCB has alternate forms for the follow-up assessments of spatial (Brief Visuospatial Memory Test—Revised) and verbal learning (Hopkins Verbal Learning Test) and Reasoning and problem solving (Mazes test). At follow-up we used the alternate forms for these tests [68]. Social cognition (in addition to the social cognition test included in the MCCB) was evaluated by using the Facial Emotional Identification Test (FEIT, [69]), measuring emotion recognition, and The Awareness of Social Inference Test (TASIT [70]), assessing emotion processing and theory of mind. TASIT provides a measure of basic emotion recognition (TASIT-1), and of fundamental (Social Inference-Minimal, TASIT-2) and complex (Social Inference-Enriched, TASIT-3) theory of mind. TASIT has alternate forms which were not used as there is no practice effects even after only one week of interval for the follow-up assessment and the validation in Italian is not available [70]. Functional capacity was assessed by the brief version of the UCSD Performance-based Skills Assessment (UPSA-B), a tool measuring participants' ability to perform, in an experimental context, tasks similar to those encountered in daily life [71, 72]. Subject's real-life functioning was assessed by using the Specific Level of Functioning Scale (SLOF) [73].

Modified social cognition individualized activities lab (mSoCIAL)

The Modified Social Cognition Individualized Activities Lab (mSoCIAL) is an individualized rehabilitation intervention specifically designed to improve social cognition and metacognitive skills in SCZ or schizoaffective disorder. The mSoCIAL intervention was administered once a week for 10 weeks. Each intervention session consisted of two modules.

For each session, the administration time for both modules was 30 min; however, the operator could choose to focus the session on one module over the other, based on the subject's specific needs.

For a detailed description of the intervention modules, please refer to Palumbo et al. [63].

Patients assigned to the mSoCIAL group discontinued any other non-pharmacological interventions they were undergoing prior to randomization.

Module 1: social cognition training

This module focuses on the recognition of emotions and the so-called "social signs" (particularly facial expressions and prosody), as well as the development of strategies belonging to the Theory of Mind (ToM) domain.

The Emotion Recognition training aims to train the subject's ability to discriminate between different emotional states; it consists of two sessions for each basic

emotion (10 sessions in total): fear, anger, surprise, sadness, and joy.

The Theory of Mind (ToM) training helps subjects discriminate between emotional expressions in social contexts and understand others' mental states, assisting the subject in understanding what others think and feel in different social contexts, such as work or interpersonal situations.

Module 2: narrative enhancement

The Narrative Enhancement training consists of storytelling exercises aimed at improving the subject's ability to understand their emotional experience and integrate emotions and behaviors into real-life situations. The operator uses a semi-structured interview procedure. In the first phase, the patient is asked to share a personal story that made him feel bad; in the second phase, the therapist clarifies with the patient the specific emotions the patient experienced during the events narrated and during the recounting; in the third and final phase, the therapist and the patient reflect on the emotions experienced and whether these emotions can influence the patient's actions in the immediate present or the near future.

Treatment as usual (TAU)

Subjects assigned to this group received the treatment they were undergoing before the assignment (TAU) for the entire study duration. TAU encompassed any psychiatric treatments (including pharmacological, psychological, rehabilitative, occupational, etc.) that participants might have initiated before their involvement in the study.

Statistical analysis

Demographic continuous variables were reported as mean ± standard deviation (SD), while categorical variables were reported as frequencies. Comparisons between groups (mSoCIAL vs TAU, and Naples vs Milan) on demographic variables, symptoms severity, cognitive performance and functioning at baseline were performed through independent samples t-tests and χ2 tests. Outcome measures were compared within the two study groups at baseline and follow-up using a paired-sample t-test. A repeated measures MANOVA was used to investigate the differences between study groups (mSoCIAL vs TAU) for changes in psychopathology, cognition and functioning from baseline to follow-up (time x group interaction); the study site was used as covariate.

For all statistical tests, the significance level was set at $p \leq 0.05$. The Bonferroni correction was applied to adjust for multiple testing. All the analyses were performed using IBM SPSS, version 28.0.

Results

Characteristics of the study sample

Forty SCZ participated in the study; 20 were randomly assigned to mSoCIAL and 20 to TAU. In the mSoCIAL group, subjects received only pharmacological treatment, having discontinued all other non-pharmacological interventions, while for 10 subjects TAU consisted of psychiatric follow-up visits only, and for 10 of psychosocial interventions too. Baseline demographic and clinical findings are reported in Table 1. The independent sample t-tests and χ^2 test showed that subjects assigned to mSoCIAL had more severe negative symptoms ($t = 2.781$, $p = 0.008$), and worse interpersonal relationships ($t = 2.035$, $p = 0.049$) as compared to the TAU group (Table 1). Neither of these differences survived correction for multiple testing.

Comparisons on demographic and clinical variables at baseline between subjects recruited at the Naples or Milan study center

The independent samples t-test and χ^2 test results revealed that participants from the two centers differed in demographic characteristics, neurocognition, and social cognition but not in psychopathology and real-life functioning (Table 2). Specifically, subjects from Naples were younger, and showed poorer neurocognition and social cognition (on FEIT and TASIT Enriched social inference). However, none of these differences survived correction for multiple testing.

Outcome variables at baseline and follow-up for intervention groups

Baseline and follow-up characteristics of the two study groups are reported in Table 3. The results of paired-sample t-test are summarized in Table 4.

In the mSoCIAL group disorganization, emotion recognition measured by the TASIT-1, functional capacity, interpersonal relationships, everyday life skills and work skills significantly improved from baseline to follow-up (Tables 3 and 4). In the TAU group disorganization improved, while deficit in enriched social inference domain of theory of mind worsened from baseline to follow-up (Tables 3 and 4).

Only changes in interpersonal relationships in the mSoCIAL group survived after correction for multiple tests (Table 4).

Differences between study groups for changes in psychopathology, cognition, and real-life functioning after treatment

The results of repeated measures MANOVA are summarized in Table 5. The analyses showed no significant

Table 1 Characterization of the study sample and group comparisons on demographic and clinical variables at baseline

	SoCIAL (n = 20)	TAU (n = 20)	t- χ^2/p- value
Age	37.15 ± 9.96	36.70 ± 9.44	0.147/0.884
Gender (M/F)	15/5	13/7	0.476/0.490
Education (years)	11.8 ± 2.46	12.10 ± 2.00	0.423/0.675
Diagnosis (Schizophrenia/Schizoaffective)	20/0	20/0	–
PANSS positive	8.00 ± 2.77	8.25 ± 2.61	0.293/0.771
PANSS negative	13.30 ± 4.85	9.30 ± 4.23	2.781/0.008*
PANSS disorganization	2.50 ± 1.05	2.50 ± 1.19	0.000/1.000
MCCB neurocognitive composite score	30.00 ± 13.04	28.15 ± 14.64	0.395/0.695
FEIT total score	35.00 ± 8.96	35.25 ± 10.22	0.082/0.935
TASIT—emotion evaluation test	22.30 ± 4.63	22.10 ± 6.14	0.116/0.908
TASIT—minimal social inference	37.90 ± 11.27	39.05 ± 13.07	0.298/0.767
TASIT enriched social inference	36.40 ± 11.17	37.15 ± 13.12	0.195/0.847
UPSA total score	64.05 ± 22.83	65.35 ± 18.64	0.197/0.845
SLOF interpersonal relationships	21.80 ± 4.95	25.00 ± 4.99	2.035/0.049*
SLOF everyday life skills	45.30 ± 5.34	47.65 ± 5.40	1.383/0.175
SLOF work skills	19.60 ± 4.10	21.45 ± 5.17	1.250/0.219

Mean ± Standard Deviation for age, years of education, and the scores of PANSS, SLOF, UPSA, MCCB, FEIT and TASIT; frequency for gender

SoCIAL Social Cognition Individualized Activity Lab, *TAU* Treatment As Usual, *PANSS* Positive And Negative Symptom Scale, *MCCB* MATRICS Consensus Cognitive Battery, *FEIT* Facial Emotion Identification Test, *TASIT* The Awareness of Social Inference Test, *UPSA* UCSD Performance-based Skills Assessment, *SLOF* Specific Levels Of Functioning

* *The difference does not remain significant after controlling for multiple tests*

** *Statistically significant difference between groups after Bonferroni correction for multiple tests (p < 0.003)*

Table 2 Comparisons on demographic and clinical variables at baseline between subjects recruited at Naples and Milan

	Naples (n = 27)	Milan (n = 13)	t- χ^2/p- value
Age	34.07 ± 8.48	42.85 ± 9.29	2.972/0.005*
Gender (M/F)	18/9	10/3	0.440/0.507
Education (years)	11.59 ± 2.24	12.69 ± 2.06	1.491/0.144
PANSS positive	8.56 ± 2.55	7.23 ± 2.77	1.497/0.143
PANSS negative	12.11 ± 5.12	9.62 ± 4.17	1.526/0.135
PANSS disorganization	2.52 ± 1.25	2.46 ± 0.78	0.150/0.881
MCCB neurocognitive composite score	24.13 ± 13.28	37.54 ± 10.33	3.137/0.004*
FEIT total score	32.11 ± 9.77	41.38 ± 5.12	3.202/0.003*
TASIT—emotion evaluation test	21.63 ± 6.09	23.38 ± 3.33	0.967/0.339
TASIT—minimal social inference	35.93 ± 12.12	43.77 ± 10.45	1.999/0.053
TASIT enriched social inference	33.59 ± 12.66	43.38 ± 7.30	2.579/0.014*
UPSA total score	64.07 ± 22.71	66.00 ± 16.03	0.274/0.786
SLOF interpersonal relationships	22.70 ± 4.78	24.85 ± 5.83	1.236/0.224
SLOF everyday life skills	46.85 ± 4.90	45.69 ± 6.56	0.627/0.534
SLOF work skills	20.93 ± 4.49	19.69 ± 5.23	0.771/0.445

Mean ± Standard Deviation for age, years of education, and the scores of PANSS, SLOF, UPSA, MCCB, FEIT and TASIT; frequency for gender

PANSS Positive And Negative Symptom Scale, *MCCB* MATRICS Consensus Cognitive Battery, *FEIT* Facial Emotion Identification Test, *TASIT* The Awareness of Social Inference Test, *UPSA* UCSD Performance-based Skills Assessment, *SLOF* Specific Levels Of Functioning

* *The difference does not remain significant after controlling for multiple tests*

** *Statistically significant difference between groups after Bonferroni correction for multiple tests (p < 0.003)*

Table 3 Psychopathology, cognition, and real-life functioning of the two study groups at baseline and follow-up

	SoCIAL		TAU	
	T0	T1	T0	T1
PANSS positive	8.00 ± 2.77	7.30 ± 2.34	8.25 ± 2.61	7.79 ± 2.90
PANSS negative	13.30 ± 4.85	11.90 ± 3.66	9.30 ± 4.23	9.68 ± 3.93
PANSS disorganization	2.50 ± 1.05	2.15 ± 0.88	2.50 ± 1.19	2.00 ± 1.00
MCCB neurocognitive composite score	30.00 ± 13.04	30.94 ± 11.32	28.15 ± 14.64	30.00 ± 15.25
FEIT total score	35.00 ± 8.96	37.50 ± 6.37	35.47 ± 10.56	35.32 ± 9.85
TASIT—emotion evaluation test	22.30 ± 4.63	24.80 ± 5.33	22.11 ± 6.31	22.53 ± 5.52
TASIT—minimal social inference	37.90 ± 11.27	41.00 ± 9.73	39.26 ± 13.40	35.47 ± 11.16
TASIT enriched social inference	36.40 ± 11.17	38.90 ± 10.57	36.95 ± 13.45	33.89 ± 10.29
UPSA total score	64.05 ± 22.83	74.13 ± 15.76	66.00 ± 18.92	68.05 ± 19.23
SLOF interpersonal relationships	21.89 ± 5.06	24.89 ± 5.47	25.00 ± 5.13	24.63 ± 4.80
SLOF everyday life skills	45.47 ± 5.43	47.53 ± 5.74	47.37 ± 5.40	46.68 ± 6.32
SLOF work skills	19.84 ± 4.06	20.95 ± 3.41	21.53 ± 5.33	20.58 ± 5.037

SoCIAL Social Cognition Individualized Activity Lab, *TAU* Treatment As Usual, *PANSS* Positive And Negative Symptom Scale, *MCCB* MATRICS Consensus Cognitive Battery, *FEIT* Facial Emotion Identification Test, *TASIT* The Awareness of Social Inference Test, *UPSA* UCSD Performance-based Skills Assessment, *SLOF* Specific Levels Of Functioning

Table 4 Changes in the outcome variables from baseline to follow-up

	mSoCIAL (N = 20)					TAU (N = 20)				
	t	p-value	Cohen's d	Lower CI	Upper CI	t	p-value	Cohen's d	Lower CI	Upper CI
PANSS positive	1.926	0.069	− 0.431	− 0.921	0.060	1.083	0.292	− 0.242	− 0.717	0.233
PANSS negative	1.837	0.082	− 0.411	− 0.899	0.078	− 0.728	0.476	0.163	− 0.309	0.634
PANSS disorganization	2.666	**0.015***	− 0.596	− 1.106	− 0.086	2.364	**0.029***	− 0.529	− 1.030	− 0.027
MCCB neurocognitive composite score	− 1.651	0.115	0.369	− 0.115	0.854	− 1.822	0.084	0.407	− 0.081	0.895
FEIT total score	− 1.862	0.078	0.416	− 0.073	0.905	− 0.312	0.758	0.070	− 0.399	0.538
TASIT—emotion evaluation test	− 2.173	**0.043***	0.486	− 0.010	0.982	− 0.665	0.514	0.149	− 0.322	0.619
TASIT—minimal social inference	− 1.629	0.120	0.364	− 0.120	0.848	2.026	0.057	− 0.453	− 0.946	0.040
TASIT—Enriched social inference	− 2.084	0.051	0.466	− 0.028	0.960	2.545	**0.020***	− 0.569	− 1.075	− 0.063
UPSA total score	− 3.078	**0.006***	0.688	0.165	1.211	− 1.404	0.177	0.314	− 0.166	0.794
SLOF interpersonal relationships	− 3.886	**0.001****	0.869	0.316	1.422	0.535	0.599	− 0.120	− 0.589	0.350
SLOF everyday life skills	− 2.965	**0.008***	0.663	0.144	1.182	1.545	0.139	− 0.345	− 0.828	0.137
SLOF work skills	− 2.531	**0.020***	0.566	0.060	1.072	1.665	0.112	− 0.372	− 0.857	0.112

Mean ± Standard Deviation for age, years of education, and the scores of PANSS, SLOF, UPSA, MCCB, FEIT and TASIT; frequency for gender

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In bold statistically significant difference

* *The difference does not remain significant after controlling for multiple tests*

** *Statistically significant difference between groups after Bonferroni correction for multiple tests (p < 0.003)*

Time x Group interaction on psychopathology and neurocognition. We observed a significant Time x Group effect on social cognition and functioning. Post-hoc analyses showed that, as compared to TAU, the mSoCIAL intervention significantly improved minimal and enriched social inference among social cognitive domains (Table 6), and interpersonal relationships, everyday life skills, and work skills among real-life functioning domains (Table 7).

Discussion

The primary objective of the present study was to evaluate the effectiveness of the mSoCIAL intervention in ameliorating social cognition of people with

Table 5 Changes from baseline to follow-up in psychopathology, cognition, and real-life functioning: MANOVA results

Psychopathology	**Lambda di Wilks**	**F**	**p**
Group	0.799	2.844	0.052
Time	0.835	2.239	0.102
Time x Site	0.829	2.339	0.091
Time x Group	0.853	1.956	0.139
Neurocognition	**Lambda di Wilks**	**F**	**p**
Group	0.991	0.250	0.620
Time	0.971	0.946	0.338
Time x Site	0.993	0.225	0.639
Time x Group	0.996	0.142	0.709
Social cognition	**Lambda di Wilks**	**F**	**p**
Group	0.975	0.215	0.928
Time	0.486	8.472	**< 0.001**
Time x Site	0.488	8.652	**< 0.001**
Time x Group	0.714	3.306	**0.022**
Real-life functioning	**Lambda di Wilks**	**F**	**p**
Group	0.960	0.335	0.853
Time	0.802	1.981	0.121
Time x Site	0.827	1.673	0.181
Time x Group	0.679	3.785	**0.012**

Bold indicates a statistically significant difference

Table 6 Changes in social cognition from baseline to follow-up: Post-hoc analyses

		Estimate	**SE**	**tStat**	**DF**	**pValue**	**Lower CI**	**Upper CI**
FEIT	(Intercept)	24.559	4.072	6.032	74			
	Time	− 0.077	1.079	− 0.071	74	0.943	− 2.227	2.073
	Group	0.895	2.555	0.350	74	0.727	− 4.196	5.987
	Site	7.636	2.614	2.921	74	**0.004**	2.428	12.845
	Time x Group	2.577	1.508	1.709	74	0.092	− 0.428	5.582
TASIT—emotion evaluation test	(Intercept)	22.597	2.600	8.692	74			
	Time	0.419	0.977	0.429	74	0.669	− 1.527	2.365
	Group	0.147	1.686	0.087	74	0.931	− 3.213	3.506
	Site	− 0.355	1.655	− 0.215	74	0.831	− 3.652	2.942
	Time x Group	2.081	1.367	1.523	74	0.132	− 0.642	4.804
TASIT—minimal social inference	(Intercept)	34.945	5.501	6.353	74			
	Time	− 3.713	1.770	− 2.098	74	**0.039**	− 7.240	− 0.186
	Group	− 0.710	3.507	− 0.203	74	0.840	− 7.697	6.277
	Site	2.932	3.517	0.834	74	0.407	− 4.077	9.941
	Time x Group	6.813	2.475	2.752	74	**0.007**	1.881	11.746
TASIT—enriched social inference	(Intercept)	27.038	5.412	4.996	74			
	Time	− 3.049	1.201	− 2.539	74	**0.013**	− 5.443	− 0.656
	Group	0.333	3.362	0.099	74	0.921	− 6.365	7.032
	Site	7.223	3.483	2.074	74	**0.042**	0.284	14.162
	Time x Group	5.549	1.678	3.306	74	**0.001**	2.205	8.894

SoCIAL Social Cognition Individualized Activity Lab, *TAU* Treatment As Usual, *UPSA* UCSD Performance-based Skills Assessment, *SLOF* Specific Levels Of Functioning
Bold indicates a statistically significant difference

Table 7 Changes in Functional capacity and Real-life functioning from baseline to follow-up: Post-hoc analyses

		Estimate	SE	tStat	DF	pValue	Lower CI	Upper CI
UPSA total score	(Intercept)	62.336	9.499	6.563	74			
	Time	2.194	2.692	0.815	74	0.418	− 3.170	7.558
	Group	− 0.977	5.989	− 0.163	74	0.871	− 12.911	10.957
	Site	2.153	6.091	0.353	74	0.725	− 9.983	14.289
	Time x Group	7.889	3.764	2.096	74	**0.039**	0.390	15.388
SLOF interpersonal relationships	(Intercept)	23.765	2.467	9.632	74			
	Time	− 0.362	0.741	− 0.489	74	0.626	− 1.839	1.114
	Group	− 3.068	1.559	− 1.968	74	0.053	− 6.174	0.039
	Site	0.882	1.581	0.558	74	0.579	− 2.269	4.033
	Time x Group	3.391	1.048	3.237	74	**0.002**	1.303	5.479
SLOF everyday life skills	(Intercept)	49.789	2.829	17.599	74			
	Time	− 0.729	0.657	− 1.110	74	0.271	− 2.039	0.580
	Group	− 2.579	1.758	− 1.467	74	0.147	− 6.084	0.925
	Site	− 1.528	1.820	− 0.839	74	0.404	− 5.156	2.100
	Time x Group	2.797	0.929	3.010	74	**0.004**	0.945	4.649
SLOF work skills	(Intercept)	24.698	2.181	11.325	74			
	Time	− 0.947	0.510	− 1.858	74	0.067	− 1.963	0.069
	Group	− 2.198	1.356	− 1.621	74	0.109	− 4.900	0.504
	Site	− 2.320	1.403	− 1.653	74	0.103	− 5.117	0.476
	Time x Group	2.073	0.721	2.876	74	**0.005**	0.636	3.510

SoCIAL Social Cognition Individualized Activity Lab, *TAU* Treatment As Usual, *UPSA* UCSD Performance-based Skills Assessment, *SLOF* Specific Levels Of Functioning
Bold indicates a statistically significant difference

schizophrenia. According to describedfindings, the mSoCIAL intervention significantly improved key aspects of social cognition. This improvement was not observed in SCZ who continued their usual treatment (TAU) during the same period, despite the two groups were comparable for demographic and clinical features at baseline. According to the within-group comparisons (Table 4), the mSoCIAL program had a significant impact on emotion recognition as assessed by TASIT part 1, despite it did not survive correction for multiple tests. The mSOCIAL also improved patients' theory of mind scores, but this effect did not reach statistical significance. While the mSoCIAL intervention showed promising effects on social cognition, these did not reach statistical significance or withstand correction for multiple comparisons. This outcome may reflect the subtle nature of change achievable within a brief, ten-session program, especially given the stability of cognitive impairments in schizophrenia. These findings highlight the potential need for more intensive or prolonged interventions to drive substantial improvements in social cognition. Moreover, according to the MANOVA analysis (Table 6), as compared to TAU, the experimental intervention significantly improved the theory of mind of subjects with schizophrenia, particularly their ability to make both fundamental (TASIT part 2) and complex (TASIT part 3) social inferences. On the contrary, there was no significant time x group interaction as regard emotion recognition, although the effect of the intervention was greater on TASIT part 1 scores. Indeed, when examining theory of mind, patients in the TAU group experienced worsening over time, while those in the mSoCIAL group showed improvement (Table 3). This suggests that the significant Time x Group effect observed for theory of mind is likely due not only to the improvement seen in the mSoCIAL group but also to the worsening in the TAU group, which together contributed to the statistical significance. In contrast, for emotion recognition, although the impact of mSoCIAL was significant, there were no differences with TAU because the improvement occurred in the mSoCIAL group, did not correspond to an opposite change in the TAU group (Table 3).

It is important to note that our study was conducted during the COVID-19 pandemic, a period marked by social isolation and the widespread use of face masks. These contextual factors may have influenced the observed differences in social cognition outcomes between the mSoCIAL and TAU groups [74, 75]. Indeed, recent studies [74, 75] found that pandemic worsened impairments in social cognition due to social distancing and mask use. Specifically, mask-wearing may have hindered emotion recognition and reading social cues, as

patients missed out on facial expressions. Social distancing further limited opportunities for in-person interactions, which are crucial for practicing and maintaining learned social skills. These combined factors may have worsened existing impairments, reducing patients' ability to maintain social cognitive skills. Pandemic-related restrictions may have had a less adverse impact on the mSoCIAL group, where structured training and interaction within the intervention could have limited the negative effects of social isolation and mask-wearing. Thus, it is possible that the mSoCIAL intervention not only prevented further decline but also facilitated improvements in social cognition, despite the adverse conditions imposed by the pandemic.

Overall, the results of the present study suggest that the mSoCIAL intervention could offer protective benefits against external factors that exacerbate theory of mind impairment in schizophrenia, and might improve different domains of social cognition, in particular emotion recognition. This finding aligns with recent meta-analyses showing that integrated social cognition training interventions have a statistically significant impact on emotion recognition and the theory of mind in patients with schizophrenia [76, 77].

Moreover, the mSoCIAL program turned out to be specific for social cognition. Indeed, the improvement across various domains of social cognition was not accompanied by an enhancement in neurocognitive impairment. In fact, no statistically significant differences were observed between mSoCIAL and TAU in terms of changes in neurocognitive scores. While the neurocognitive impairment of patients in the mSoCIAL group remained largely unchanged, patients in the TAU group exhibited slight, but not significant, improvements. This could be attributed to the fact that the treatment for some of these patients included cognitive remediation interventions.

The secondary objective of the study was to evaluate the impact of the mSoCIAL intervention on the functional outcome of people with schizophrenia. Our findings demonstrated that various aspects of real-life functioning, particularly interpersonal relationships, activities of daily living, and work-related skills, significantly improved in subjects who participated in the mSoCIAL intervention, as compared to TAU. The relevant literature reports conflicting results about the effectiveness of social cognition training programs in improving functional outcomes of SCZ [78, 79].

Indeed, although many studies have identified significant correlations between impairment in social cognition and in psychosocial functioning of SCZ [7], interventions specifically targeting social cognition have not consistently led improvements in real-life functioning [78]. This inconsistency in literature may reflect the complexity of the social cognition construct, which includes different abilities, i.e., perception, interpretation, and generation of responses based on others' intentions, emotions and behaviors. Each of these abilities can differently impact real-life functioning of the subjects, and as a result, interventions that focus only on specific social cognitive skills may have limited impact on real-life functioning. For instance, emotion recognition may help improve simple social interactions, whereas theory of mind is crucial for understanding complex social cues and maintaining relationships. Indeed, theory of mind is the domain for which a strong association with real-life functioning has been reported more consistently [7, 80–83], probably due to its relevance to everyday social interactions, communication, social reasoning, and pragmatism. Consequently, interventions that target one or more of these specific skills may enhance certain aspects of social functioning but may not necessarily lead to broader improvements in real-life functioning. This variability is likely to contribute to the inconsistent outcomes seen across studies of social cognition training. The mSoCIAL intervention is designed to address these complexities by incorporating a multifaceted approach that specifically targets various domains of social cognition. In fact, it influences different domains of social cognition with an important effect on emotion recognition and theory of mind, both for fundamental and complex social inferences. This may have contributed to the significant improvement in real-life functioning in subjects assigned to the experimental treatment as compared to those who continued the TAU. In addition, mSoCIAL is a flexible program as the time dedicated to each specific skill training is tailored to the patient's needs, resulting in personalization of the treatment [63, 84], which represents another important factor in ameliorating the functional outcome of study participants. Furthermore, the presence within mSoCIAL of the narrative enhancement module might have favored the transfer of therapeutic benefits of the intervention into real-life. However, as no outcome variable assessed changes in the narrative skills after the training, this remains a hypothesis to be tested in further studies. To our knowledge, this is the first study investigating the effectiveness of a social cognition remediation treatment including a narrative enhancement program in SCZ.

Our study has some limitations. First, the sample size, although larger than in other similar studies, may limit the generalizability of the results and may have reduced the statistical power needed to detect significant effects after the Bonferroni correction. Second, the mSoCIAL intervention was compared with TAU and no other social cognition remediation interventions. However, for ten subjects (50% of the sample) TAU included psychosocial interventions. In future studies, an active arm,

aimed at comparing mSoCIAL with other integrated interventions, should be included. Third, a limitation of this study is the absence of specific measures to directly assess improvements in narrative skills within the Narrative Enhancement Module. Future research should consider incorporating targeted assessments for narrative abilities to better evaluate the efficacy of this component within the mSoCIAL intervention. Finally, the lack of information regarding illness duration limits our ability to assess the potential influence of illness chronicity on the outcomes. Including this variable in future studies could provide a more nuanced understanding of how the duration of illness impacts the efficacy of the mSoCIAL intervention.

In conclusion, the mSoCIAL program demonstrated effectiveness in improving social cognition and real-life functioning of subjects with schizophrenia. The key factors underlying its impact on patients' real-life functioning are not entirely clear, but we hypothesize that the flexibility (allowing for personalization) and the multifaced nature of mSoCIAL, with the presence of a metacognitive training, contribute to its efficacy.

Author contributions

SG, DP, AM and GP contributed to study conceptualization and intervention implementation. DP designed the experimental procedures; LG and PP analysed the data and drafted the manuscript. All Authors contributed to the interpretation of findings, critically reviewed the content and approved the final manuscript.

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Availability of data and materials

The data that support the findings of this study are available on reasonable request from the corresponding author. No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The protocol has been approved by the Ethics Committee of the Università degli Studi della Campania "Luigi Vanvitelli"—A.O.U. "Luigi Vanvitelli", A.O.R.N. "Ospedale dei Colli" and by the Ethics Committee of ASST Fatebenefratelli-Sacco of Milan.

Consent for publication

Not applicable.

Competing interests

This study received funding from Otsuka Pharmaceutical Italy s.r.l. The funder was not involved in the study design, collection, analysis, interpretation of data, the writing of this article or the decision to submit it for publication. AM has been a consultant and/or advisor to or has received honoraria from Angelini, Gedeon. Richter Bulgaria, Janssen Pharmaceuticals, Lundbeck, Otsuka Pharmaceutical, Pfizer, Pierre Fabre, Rovi. Pharma and Boehringer Ingelheim. GG has been a consultant for Angelini. SG has been a consultant and/or advisor to or has received honoraria from Angelini, Boehringer Ingelheim, Gedeon Richter-Recordati, Janssen, Lundbeck, Otsuka, ROVI.

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