ORIGINAL ARTICLE

A twelve-week randomized controlled study of the cognitive-behavioral Integrated Psychological Therapy program: positive effect on the social functioning of schizophrenic patients

Estudo controlado randomizado de 12 semanas do programa cognitivo-comportamental IPT (Terapia Psicológica Integrada) com efeito positivo sobre o funcionamento social em pacientes com esquizofrenia

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Abstract

Objectives: *The present study was designed to evaluate the effect of twelve weekly sessions of the cognitive-behavioral program originally known as the* Integriertes Psychologisches Therapieprogramm für Schizophrene Patienten*, designated the Integrated Psychological Therapy (IPT) program in English, on cognition, social adjustment and quality of life in schizophrenic outpatients, comparing it to the effect of treating such patients as usual.* ***Method:*** *Fifty-six adult outpatients (from 18 to 65 years of age) with ICD-10-based diagnoses of schizophrenia were randomly assigned to two different groups: active intervention (IPT group); and treatment as usual (control group). Outcome measures were quality of life (as determined using the WHOQOL-Bref), cognition (Mini-Mental State Examination and Word Recall Test), global functioning (DSM-IV Global Assessment of Functioning Scale), social functioning (Social and Occupational Functioning Assessment Scale) and social adjustment (Social Adjustment Scale).* ***Results:*** *The findings suggest that, in comparison with treatment as usual (control group), the twelve-session IPT program had a positive effect on several outcome measures: cognition in the domains of spatiotemporal orientation (p = 0.051) and memory (p = 0.031); overall social adjustment (p = 0.037), leisure/social life (p = 0.051) and family relations (p = 0.008); overall functioning (p = 0.000); social-occupational functioning (p = 0.000); and quality of life in the psychological domain (p = 0.021).* ***Conclusion:*** *The twelve-session cognitive-behavioral IPT intervention demonstrated superiority over treatment as usual in its effects on cognition, social adjustment and quality of life. Studies involving larger samples, longer follow-up periods and additional outcome measures are needed in order to assess the specific effects on dimensions of social functioning, cognitive functioning and quality of life in patients with schizophrenia.*

Descriptors: *Quality of life; Social adjustment; Cognition; Schizophrenia; Social support*

Resumo

Objetivos: *O presente estudo foi designado para avaliar o efeito de 12 sessões semanais do programa cognitivo-comportamental IPT (*Integrated Psychological Therapy – Integriertes psychologisches Therapieprogramm für schizophrene Patienten – *Terapia Psicológica Integrada), comparado ao tratamento usual sobre o funcionamento cognitivo, ajustamento social e qualidade de vida em pacientes ambulatoriais com esquizofrenia.* ***Método:*** *Cinqüenta e seis pacientes ambulatoriais adultos (idade entre 18 e 65 anos) com diagnóstico de esquizofrenia pela CID-10, foram aleatoriamente designados para dois grupos: intervenção ativa (IPT) e tratamento usual (grupo controle). As diferenças de medidas de resultados foram em qualidade de vida (*WHOQOL-bref*), cognição (*Mini-Mental State Examination *e* word-span*), funcionamento global (*Global Assessment of Functioning-*DMS-IV), funcionamento social (*Social and Occupational Functioning Assessment Scale-*DSM-IV) e ajustamento social (*Social Adjustment Scale*).* ***Resultados:*** *Os achados sugerem que 12 sessões do programa IPT mostraram um efeito positivo sobre várias medidas de resultado comparado ao grupo controle (tratamento usual): cognição nos domínios de orientação no tempo e no espaço (p = 0,045) e memória (p = 0,031); ajustamento social geral (p = 0,037), lazer e vida social (p = 0,051), relações familiares (p = 0,008); funcionamento global (p = 0,000); funcionamento sócio-ocupacional (p = 0,000); e qualidade de vida no domínio psicológico (p = 0,021).* ***Conclusão:*** *A intervenção cognitivo-comportamental de 12 sessões do IPT demonstrou superioridade de efeito sobre cognição, ajustamento social e qualidade de vida comparado ao tratamento usual. Estudos com amostras maiores, maior tempo de seguimento (follow-up) e medidas adicionais de desfechos são necessários para avaliar efeitos específicos sobre dimensões de funcionamento cognitivo, social e qualidade de vida em esquizofrênicos.*

Descritores: *Qualidade de vida; Ajustamento social; Cognição; Esquizofrenia; Impacto psicossocial/reabilitação*

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Introduction

Schizophrenia is a major psychiatric disorder associated with multiple relapses and an alternating pattern of partial or total symptom remission.[1] This pattern is of course associated with considerable damage to and burden on patients and families, encouraging researchers and clinicians to put forth considerable effort to identify better alternatives for treating schizophrenia. The search for more efficient and cost-effective interventions has driven clinicians and researchers over the last decade.[2] Increased understanding of the biology of schizophrenia has provided better biological therapies for the treatment of positive symptoms (hallucinations, deliriums and disorganized thought), which have little effect on negative symptoms[2] (restricted mood, poverty of speech, reduction of interests, lack of objectives, poor social functioning and anhedonia) or on social and interpersonal deficits in schizophrenia.[3] The major goals in the treatment of schizophrenia moved from symptom reduction to family, social and professional improvement.[4] Randomized controlled clinical trials of cognitive-behavioral therapy plus antipsychotics compared with medication alone demonstrated superiority over psychotic symptoms, but small effects over negative symptoms.[5] Systematic reviews of nonpharmacological interventions in schizophrenic patients have provided limited evidence regarding clinically meaningful outcomes such as cognition and social functioning, and few controlled studies have assessed the efficacy of these interventions. In most cases, the interventions were poorly designed and failed to include standardized methods of cognitive-behavioral therapy.[6] A meta-analysis carried out by Mojtabai et al., combining evidence from psychosocial and pharmacological interventions, showed a significant effect of combined intervention.[2] However, a great number of studies were excluded from the analysis due to low standardization and large variability of methods. The psychosocial treatments comprised interventions aimed at different outcomes, such as self-care, social skills, family functioning, involvement in self-help groups, capacity for getting/keeping a job and independent life in the community. Various modalities have been described: psychoeducation; social skills training; family psychoeducation; self-help groups; and vocational intervention.[7-8] Among the most frequently studied interventions is the Social Skills Training Program devised by Liberman et al., which focuses on different aspects affecting social life, such as medication, personal care and symptom management, leisure and entertainment activities.[9] Studies of social skills training have provided evidence of improved personal and social functioning, although there is considerable controversy as to whether these learned skills can be extrapolated to daily life.[8-9] In addition, most studies have focused on specific behavioral measures and have not studied changes in social and community functioning.[10] In the Social Skills Training Program, Liberman et al. introduced social learning through role playing, which addresses improvement in nonverbal communication such as eye contact, verbal fluency, gestures, facial expressions, assertive conversational skills and emotional expression. Structured social skills training has proven superior to various psychological treatments, such as supportive group psychotherapy and occupational therapy.[11] Although the evidence of effectiveness of social skills training demonstrated in clinical settings (inpatient and outpatient facilities), there is evidence of small extension of these effects over daily life in people with cognitive impairment.[8,11]

Roder et al. developed the *Integriertes Psychologisches Therapieprogramm für Schizophrene Patienten* in Germany. Known as the Integrated Psychological Therapy (IPT) program in English, it is a manual-based treatment for schizophrenia that has been shown to be effective in several controlled studies.[11-16] The IPT manual has been translated into more than 10 languages for use in different cultures. The translation to Portuguese was supervised and reviewed by Roder[12] in conjunction with one of the authors of the present study (M. Zimmer). The IPT program was developed to reduce basic cognitive deficits in schizophrenic patients. This program consists of cognitive-behavioral training divided into five subprograms: 1) cognitive differentiation; 2) social perception; 3) verbal communication; 4) social skills; and 5) interpersonal problem solving. Each subprogram consists of steps of increasing complexity. The first subprogram is centered on the development of basic cognitive functions (attention, concentration, perception and motivation). The last two subprograms focus on social skills, social interaction and problem-solving abilities. The IPT techniques include instruction, model learning, role-playing, feedback and positive reinforcement, with the response training on family and social interaction, leisure and relevant social interactions. Various studies have shown that outcomes for IPT-treated patients are superior to those obtained in controls, suggesting that cognitive training reduces damage and improves social competence.[17]

The main goal of this study was to determine the effect of a twelve-session cognitive-behavioral intervention (IPT[6]) compared to that of treatment as usual (TaU), on general functioning, cognition (memory, concentration, and attention), social-occupational functioning, social adequacy, family relationship and quality of life.[18] Previous studies have demonstrated significant effects of an IPT program lasting 17.4 weeks (47.4 hours).[16] In studies performed in various countries, the average frequency/duration of IPT programs was 3 sessions per week/for 6 months to 1 year. Based on two previous studies,[19-20] an abbreviated IPT program was devised, involving minimal application of the manual and the exclusion of some stages (meaning of words, synonyms, antonyms and verbal communication). If this reduced program proves effective, it will facilitate the training professionals and will allow the program to be applied to outpatients served by the Public Health System.

Method

1. Design

The intervention consisted of a randomized controlled trial involving individuals with ICD-10-diagnosed schizophrenia or schizoaffective disorder treated as outpatients in the Schizophrenia Outpatient Program of the Hospital de Clínicas de Porto Alegre (HCPA). The primary goal was to determine the effect of a twelve-week cognitive-behavioral IPT program on six major outcome measures: 1) global functioning; 2) symptomatology; 3) cognitive functioning (work memory, attention and concentration); 4) social-occupational functioning; 5) social adjustment; and 6) quality of life.

2. Participants

Fifty-six consecutive outpatients treated between August and November of 2003 agreed to participate in the trial and gave written informed consent. The study design and the consent form used were approved by the Ethics Committee of the HCPA.

The inclusion criteria were as follows: being between 18 and 65 years of age; ICD-10-diagnosed schizophrenia or

schizoaffective disorder; presenting no concomitant mental retardation or organic brain disease; having no history of drug use within the preceding year; not being a participant in any other rehabilitation program; not being engaged in regular life activities such as study or work; being a resident of the greater metropolitan area of Porto Alegre; presenting stable symptomatology (no changes in medication, no hospitalizations and no emergency psychiatric consultations) and the absence of acute symptoms (delusion, hallucinations, disorganized speech mannerisms, disorientation and persistent sadness) for the last 6 months; and being in psychiatric (psychopharmacological) follow-up treatment.

The sample size estimation for this study was based on data from previous IPT studies,[6] with differences in active and control treatment estimated at 42%, with a $\beta = 80\%$ and an $\alpha = 0.5\%$. Due to low treatment compliance in schizophrenia, the ratio between samples was 1:2 (1 IPT outpatient for every 2 TaU outpatients). The final sample consisted of 54 (18 IPT and 36 TaU) outpatients. Participants were randomly divided into two IPT groups and two TaU groups, corresponding to two one-year periods. Patient allocation involved the computer generation of random numbers using the PEPI program.

The investigation was approved by the Ethical Committee of the HCPA as on IRB by the Office for Human Research Protections (IRB0000921- project 02-331).

3. Instruments

For all subjects participating in the study, a sociodemographic and clinical history inventory was taken. In addition, various instruments were applied and are described below. All instruments used Brazilian validation criteria and were applied at two time points: at baseline and at the end of treatment. The first four scales were applied by trained raters, whereas the last two were self-administered. The raters were blinded as to the treatment group to which a given patient belonged.

1) Operational criteria checklist for psychotic illness

The Operational Criteria Checklist for Psychotic Illness (OPCRIT) is a semistructured computerized diagnostic interview consisting of 90 items used to evaluate course, outcome, stressors, signs and symptoms of psychiatric disorders, accompanied by a computerized algorithm generating a diagnosis according to 13 classification systems, including the ICD-10. The OPCRIT assesses various dimensions of behavior: appearance and behavior; discourse and formal thought; affection and associated aspects; beliefs and abnormal ideas; and abnormal perceptions. In the present study, diagnoses of schizophrenia were made using OPCRIT/ICD-10 criteria.[21-26]

2) Brief Psychiatric Rating Scale

The Brief Psychiatric Rating Scale (BPRS) consists of an unstructured interview including 18 items: somatic concern; psychic anxiety; emotional withdrawal; conceptual disorganization; feelings of self-depreciation and guilt; somatic anxiety; specific motor disturbances; overly-inflated self-esteem; depressive mood; hostility; suspiciousness; hallucinations; psychomotor retardation; uncooperativeness; unusual thought content; blunted or inappropriate affect; psychomotor agitation; and disorientation/confusion. Each item is scored from 0 to 6 to denote the degree of severity: 0 = absent; 1 = very mild; 2 = mild; 3 = moderate; 4 = moderately severe; 5 = severe and 6 = extremely severe.[27]

3) Mini-Mental State Examination and word-span

The Mini-Mental State Examination (MMSE) contains 11 questions assessing specific cognitive functions (spatiotemporal orientation, language, memory and visual constructive capacity). The total score ranges from 0 to 30 points. In addiction, the word-span consist of words dictated and repeated by the subject.[28-31]

4) Global Assessment of Functioning scale

The Global Assessment of Functioning (GAF) scale is used to assess global functioning using DSM-IV Axis V criteria. The assessment is based on patient behavior in the preceding month and uses a continuous scale ranging from 1 to 100, a score of 1 representing the worst functioning; the higher scores denoting better functioning and fewer symptoms.[32-34]

5) Social and Occupational Functioning Assessment Scale

The Social and Occupational Functioning Assessment Scale (SOFAS) quantifies the level of social and occupational functioning of the subject on a continuous scale ranging from 0 to 99, assessing the performance of daily activities, higher scores denoting better functioning. This scale is recommended for identifying changes in social adjustment and interpersonal relations during treatment programs.[32,35-36]

6) World Health Organization Brief Quality of Life Assessment Instrument

The World Health Organization Brief Quality of Life Assessment Instrument (WHOQOL-BREF) is a questionnaire comprising 26 questions, 24 related to four domains (physical, psychological and social relationships, and environment) and 2 regarding quality of life in general.[37]

7) Social Adjustment Scale

The Social Adjustment Scale (SAS) is composed of 54 questions in seven specific subscales: employment; housework; social life and leisure; family relationships (with parents, siblings, in-laws and other members of the extended family); marital relationships; parent-child relationships; and token economy management. In the present study, three of the seven subscales were employed: housework (assessing adaptation to household chores and interest in domestic activities); social life and leisure (assessing friendships, loneliness, leisure activities, social activities, expression of feelings, discomfort, annoyance); and family relationships (assessing the ability to deal with conflicts, disagreements, disappointments, arguments, feelings of guilt and preoccupation with the health of relatives). The other subscales were excluded because they assess specific areas (such as exercise, marital relationships, parent-child relationships and token economy management) that are irrelevant for the patients evaluated.[38-39]

4. The twelve-session IPT Intervention

The twelve-session IPT Intervention was based on two previous studies conducted by the authors of the present study,[19-20] in which it was shown to be more well accepted by schizophrenic patients in the items sentence repetition, social perception, social skills and problem-solving. The manual-based intervention was designed to include one 60-min session per week for a period of 3 months, with a step-by-step description of each IPT[12] stage. The study included one additional psycho-education session, together with exercises designed to improve symptom recognition and treatment compliance. The entire intervention was performed by a clinical psychologist previously trained the IPT author (Roder). The IPT modules employed the following exercises: Cognitive Differentiation (exercise cards); Social Perception (10 slides); Sentence Repetition steps of Verbal Communication; Social Skills Training; and Interpersonal Problem-Solving. Cognitive Differentiation, covered during the first 4 sessions, comprised exercises using special cards

(identification of shapes, colors, numbers and the names of days of the week) and focusing on concentration, attention, working memory, essential-irrelevant differentiation, event categorization and concept building. The second module (Social Perception), applied from the second to the sixth session using 10 slides, trained the ability of scenario description through group discussion and analysis of daily life images. The cognitive complexity and the emotional characteristics in the images were then considered. This module has four objectives: to improve visual perception of social situations; to reduce inappropriate perceptions of social contexts; to establish more appropriate strategies for interpreting social situations; and to achieve better use of previous experiences. The third module, Verbal Communication, was used in the fifth and sixth sessions and only applied to the literal repetition of IPT verbal sentences related to the daily lives of the patient (e.g., *"It's raining a lot today"; "When I got to the bus stop, the bus had already left"*). The goals of this module were to improve patient capacity to listen, understand and memorize. The Social Skills Training module, applied from the seventh to ninth sessions, employed role-playing methodology, selecting daily life activities according to patient needs, and cognitive exercises of increasing complexity. This module had three major objectives: to reduce social anxiety; to interrupt negative self-reinforcement; and to increase social performance. The Interpersonal Problem-Solving module, employed in the eighth, ninth, eleventh and twelfth sessions, dealt with problem identification, cause-effect reasoning and effective social behavior. An additional psychoeducation session was included in the tenth session, working on the identification of symptoms, relapses and needs, as well as on the use of medication, treatment compliance and the management of drug side effects. The principal goals of this module were to increase patient knowledge regarding the illness (schizophrenia) and to improve treatment compliance. The program sequence is described in Table 1.

5. Treatment as usual

The TaU intervention consisted of individual outpatient consultations, conducted once every two weeks with psychiatry residents, according to the usual standard of care. All cases were individually reviewed and discussed, and the patients were monitored weekly in clinical rounds with the staff.

6. Procedures

The Schizophrenia Outpatient Program database identified 272 outpatients as being eligible for inclusion in the study. In the first selection phase, 80 consecutive outpatients were interviewed, of which 50 were excluded (30 failed to meet the inclusion criteria; 18 declined to participate; and 2 dropped out for unspecified reasons). Of the 30 patients that initially accepted to participate in the study, 4 refused to give written informed consent at randomization. In the second selection phase, 90 patients were interviewed, and 54 of those were excluded (43 failed to meet the inclusion criteria; 9 declined to participate; and 2 dropped out for unspecified reasons). Of the 36 patients that were ramdomized in the second selection phase, 6 refused to give participate in the study after immediately randomization. Therefore, the total final sample comprised 56 patients receiving intervention in two periods. In the first period, 10 IPT outpatients and 16 TaU outpatients were treated; and, in the second period, 10 IPT outpatients and 20 TaU outpatients (Figure 1). After giving written informed consent, each participating patient received a numerical code and completed a Personal Information Protocol form. Randomization was achieved through the use of a random table generated using the PEPI package. There were 4 patients who dropped out: 1 due to becoming employed; 1 due to enrolling in an academic program; and 2 due to changing their minds. Outpatients selected for the IPT group were submitted to weekly group sessions and had consultations with an attending physician every two weeks. Outpatients in the TaU group followed the original treatment protocol and had consultations with an attending physician every two weeks.

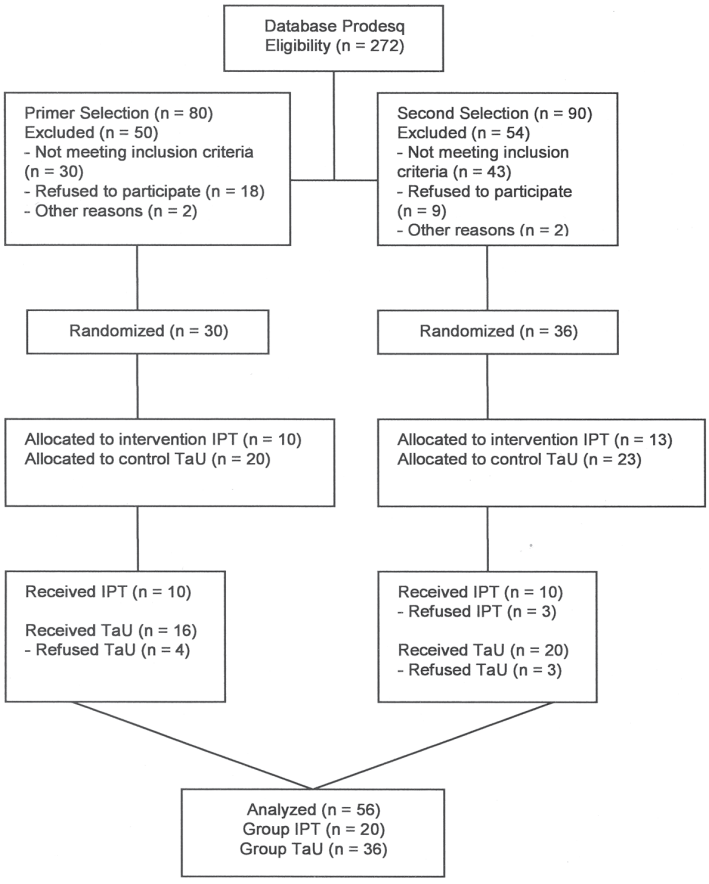

Figure 1 – Flow chart of progress throughout the phases of the randomized trial

Fluxogram according to CONSORT, JAMA, 2001.

Table 1 - Distribution of stages over the course of the twelve sessions of the IPT intervention

Subprogram	Cognitive differentiation	Social perception	Verbal communication	Social skills	Problem solving	Psychoeducation
Selection stages	Exercises with cards	10 slides	Literal repetition of verbal sentences (6 sentences)	All proposed stages 4 practice situations	All proposed stages 6 practice situations	General information on schizophrenia
Session	1st 2nd 3rd	2nd 3rd 4th 5th	5th 6th	7th 9th	8th 11th 12th	10th

7. Statistical analysis

The analyses of frequencies and associations were made using the Statistical Package for the Social Sciences (SPSS), version 11.0. The Student's *t*-test for independent samples and chi-square test were used for group comparisons of baseline data. The Mann-Whitney test was used for group comparisons of symptomatology, as measured using the BPRS. The ANOVA was used for repeated measures for parametric comparisons, analyzing differences regarding the interaction test hypothesis in GAF scale, SOFAS, MMSE, Word Recall Test, WHOQOL-BREF and SAS scores.

Results

1. Sociodemographic data

The final sample consisted of 56 patients (42 males and 14 females). As can be seen in Table 2, 17 males and 3 females composed the IPT group (n = 20), whereas the TaU group consisted of 25 males and 11 females (n = 36). Patients were maintained on the same drug regimen throughout the study period, during which there was no evidence of illness decompensation, and there were no losses. The great majority (95%) of the patients were diagnosed with schizophrenia. Mean age at the onset of the illness in the IPT group was 20.8 years, with a standard deviation (SD) of ± 5.2 years, compared with 22.17 ± 6.56 years in the TaU group. The duration of the illness was 15.25 ± 8.2 years in the IPT group and 17.14 ± 8.48 years in the TaU group.

Sociodemographic characteristics, as well as baseline GAF scale, SOFAS, MMSE, Word Recall Test, SAS and WHOQOL-BREF scores, were similar between the two groups. Global functioning, as determined using the GAF scale, improved significantly in the IPT group after the twelve weeks of treatment (p = 0.000). The GAF scale assesses the level of functioning, which is directly influenced by symptom severity. It differs from the SOFAS, which assesses the level of social and occupational functioning not directly influenced by symptoms.[32] The BPRS assessment of symptomology revealed a significant difference between the groups in terms of mean suspiciousness score at baseline (0.84 in the IPT group and 1.80 in the TaU group; p = 0.046, Mann-Whitney test), although this difference was not significant at the study endpoint. There was also a significant difference between the groups (favoring the IPT group) in BPRS emotional withdrawal score at the study endpoint (p = 0.017, Mann-Whitney test). As shown in Table 3, significant differences between the groups (again favoring the IPT group) were observed in MMSE cognitive scores at the study endpoint: spatiotemporal orientation; memory; and capacity for visual reproduction (p = 0.045). Patients in the IPT group also presented significantly greater improvement in verbal memory (p = 0.031, ANOVA for repeated measurements), as assessed using the word-span Word Recall Test (10 words dictated and repeated by the subject). In addition, social-occupational functioning, as measured using the SOFAS, increased significantly in the IPT group, from a pre-intervention score of 34.20 ± 5.31 to a post-intervention score of 43.25 ± 6.54 (p = 0.000). On the SOFAS, a score between 31 and 40 described in the DSM-IV[32] as significant damage in *several* areas, such as work, school and family relationships". Although this difference was found to be significant (magnitude of effect, d = 1.447, which is considered large according to Cohen[40]), the improvement in social-occupational functioning failed to reach the next level (41 on a scale of 1 to 100), described in the DSM-IV[32] as "serious damage to social functioning *either* occupationally *or* academically". In other words, the post-intervention difference in SOFAS scores reflects patient improvement, as reported by patients and relatives, in specific areas, mainly in social-occupational functioning, such as increased involvement in household tasks and in family relationships. Social adjustment, as assessed using the SAS, displayed a magnitude of effect of d = 0.887, although greater improvements in general social adjustment (p = 0.037) and family relationships (p = 0.008) were seen in the IPT group. Leisure and social life also showed a strong trend toward improvement, favoring the IPT group (p = 0.051) over the TaU group. The effect on the psychological domain as measured using the WHOQOL-BREF, was also found to be significantly greater in the IPT group (p = 0.021). The overall quality of life, measured by two questions by WHOQOL-BREF, scores were low in both groups, although there was a significant difference between the groups (p = 0.000).

Table 2 – Demographic characteristics of the sample (n = 56)

	IPT (n = 20)	TaU (n = 36)	p	
			t-test	χ^2 test
Gender			0.205	
Male	17	25		
Female	3	11		
Mean age in years ± SD (range)	36.05 ± 7.09 (22-45)	39.31 ± 8.85 (22-64)	0.164	
ICD-10 diagnosis			0.731	
Schizophrenia	19	34		
Schizoaffective disorder	1	2		
Age of onset in years ± SD (range)	20.80 ± 5.19	22.17 ± 6.55	0.266	
Illness duration in years ± SD (range)	15.25 ± 8.18	17.14 ± 8.47	0.422	
Years of education				0.287
Up to 5 years, n (%)	5 (25%)	18 (50%)		
5 to 8 years, n (%)	5 (25%)	8 (22.2%)		
9 to 11 years, n (%)	8 (40%)	8 (22.2%)		
Over 11 years, n (%)	2 (10%)	2 (5.6%)		
Marital status			0.367	
Single, n (%)	14 (70%)	28 (77.77%)		
Married, n (%)	2 (10%)	5 (13.89%)		
Separated, n (%)	4 (20%)	3 (8.33%)		
Course (OPCRIT)				0.198
Multiple episodes, good recovery, n (%)	1 (5%)	4 (11%)		
Multiple episodes, partial recovery, n (%)	7 (35%)	6 (16.7%)		
Continuous chronic disorder, n (%)	9 (45%)	13 (36.1%)		
Chronic disorder with impairment, n (%)	3 (15%)	13 (36.1%)		

SD: standard deviation

Discussion

The results of the present study demonstrate that the effect of the twelve-session IPT program was superior to that of TaU among outpatients diagnosed with schizophrenia or schizoaffective disorder. Although previous studies conducted in other countries have shown that IPT has positive effects, a recent meta-analysis,[16] published in December of 2005, demonstrated that there have been no systematic studies of this technique in Brazil, probably due to the complexity of and the time involved in performing a complete intervention. However, many authors[11-17] have applied shortened versions of the IPT program and have obtained favorable results.

Table 3 – Mean differences before and after 12-weeks comparing 20 subjects on IPT group and 36 in TaU group (ANOVA for repeated measures)

Scales	IPT (n = 20)		TaU (n = 36)		ANOVA Repeated measures (p)
	Before	After	Before	After	
GAF[1]	34.70 (4.27)	39.50(5.36)	35.25(5.46)	33.81(5.12)	0.000
SOFAS[2]	34.20(5.31)	43.25(6.54)	35.81(5.56)	34.14(4.53)	0.000
MMSE[3]	26.65(2.37)	27.15(2.64)	25.06(3.70)	24.22(3.92)	0.045
Word-Span[4]	4.35(1.72)	4.95(1.82)	4.11(1.47)	4.42(1.81)	0.031
WHOQOL-bref[5]					
Physical	36.59(26.64)	36.83(27.14)	35.45(24.53)	32.95(21.86)	0.384
Psychological	38.70(25.07)	40.08(26.84)	40.30(25.74)	34.44(23.17)	0.021
Pers. Accomplishment	35.75(28.00)	36.35(29.59)	35.84(26.49)	32.25(20.52)	0.414
Environment	36.16(22.66)	37.63(26.38)	38.30(25.53)	34.92(23.11)	0.215
Overall	71.82(18.09)	39.15(27.82)	61.81(21.33)	35.63(24.89)	0.000
SAS[6]					
Housework	1.54(0.44)	1.61(0.61)	1.84(0.71)	1.92(0.72)	0.955
Leisure/social life	2.56(0.43)	2.28(0.61)	2.68(0.69)	2.78(0.88)	0.051
Family relationships	1.94(0.54)	1.68(0.53)	1.99(0.50)	2.20(0.68)	0.008
Overall	2.02(0.33)	1.86(0.47)	2.15(0.46)	2.27(0.61)	0.037

1- GAF – Global Assessment of Functioning
2- SOFAS – Social and Ocupational Functioning Assessment Scale
3- MMSE – Mini-Mental State Examination
4- Word-Span – Repetion ten words
5- WHOQOL-Bref – Word Health Organization Quality of Life
6- SAS – Social Adjustment Scale

Therefore, our main goal was to determine whether a twelve-week, manual-based IPT program would improve social functioning in outpatients with schizophrenia. If such an improvement could be demonstrated, it would support the recommendation of the use of IPT in patients served by the Public Health System. Our results provide evidence that a twelve-session cognitive-behavioral IPT program has a positive effect.

The positive results can be attributed to the focus on specific activities throughout the various stages of treatment. The major daily-life problems reported by patients before the IPT intervention were related to poor concentration, faulty memory, deficient communication with the family, lack of motivation for household tasks, insecurity, shopping/token economy management, and shyness/inhibition (in asking for information and holding conversations with others). Problems of attention, concentration and memory were addressed during the training through card exercises, slide presentations and discussion of daily-life scenarios, sentence repetition and modeling of group interaction. The sentence repetition stage focused on the importance of concentrated attention, as well as on interest in activities and group interaction. Among the IPT outpatients, there was a significant improvement in memory, concentration and spatiotemporal orientation, as assessed using the MMSE ($p = 0.045$; magnitude of effect, $d = 0.854$). None of the patients were employed or had regularly scheduled activities at the study outset. However, by the study endpoint, there was increased interest in seeking activities outside the home. Quality of life, as measured using the WHOQOL-BREF, decreased to a similar degree in both groups. This could be attributed to increased patient insight into and awareness regarding personal difficulties. This domain is assessed through two questions regarding individual general self evaluation of quality of life ("*How would you evaluate your quality of life?"; "How satisfied are you with your health?*"). The IPT program probably favored increased personal awareness regarding objective behavior and limitations. However, the reason for the worsening in TaU group outpatients is unknown. Further studies, involving larger samples, would be necessary in order to investigate these factors.

Another unusual aspect of this study was the incorporation of a psychoeducation session on schizophrenia (symptom definition; identification of signs of relapse; importance of treatment compliance; continued need for medication; strategies for dealing with side-effects; and the benefits of practical activities). Nevertheless, various studies have also included or excluded different IPT modules. In the study conducted by Lemos et al., a psychoeducational module for patients and families was included, and the cognitive differentiation subprogram was excluded.[14] This program was excluded due to concerns regarding the possibility of generalizing those exercises to daily life activities, and because those exercises were more indicated for the treatment of primary deficits related to schizophrenia vulnerability. The authors questioned whether or not the cognitive intervention has a significant impact on outpatient behavior and did not consider it important for social training. In a recent meta-analysis of 28 IPT studies[16] published between 1980 and 2003 (14 from Germany; 6 from Switzerland; 3 from Spain; 1 from the Netherlands; 1 from Japan; 1 from the USA; 1 from England; and 1 from Canada). Of the 28 studies, only 9 employed the full program. Of the 19 remaining studies, only 5 included the verbal communication subprogram. Of those 5 studies, only 2 used IPT subprograms accompanied by other approaches. Another important finding of that meta-analysis is that only 5 of the 28 studies involved outpatients exclusively, 2 involving patients in mixed models of care (inpatient and outpatient) and 21 involving inpatients only. The 9 studies employing the complete program were conducted in Germany, Switzerland or Japan, and 12 of the 28 used the cognitive differentiation and social perception modules, suggesting the importance of cognitive training for improving social functioning and rehabilitation.[17] Among prior IPT studies, there was no uniformity in selection criteria for subprograms, and different criteria were used to quantify changes.[13,17] This lack of uniformity increases the difficulty involved in treatment implementation, in the possibility of implementation and in determining the extent of changes in daily life achieved with the IPT program.[14,19] Müller et al. investigated the effect of IPT in different samples and institutions, as well as under different conditions.[16] However, the authors state that, among

heterogeneous groups, without nonspecific deficits in different areas of functioning, the complete IPT application produced a more robust effect.

Our primary goal was to compare the effects of a twelve-session (one session per week) cognitive-behavioral program, in comparison with those achieved through the use of TaU, on cognition (memory, attention and concentration), global functioning, social-occupational functioning, social adjustment and quality of life in patients with schizophrenia. A secondary goal was the creation of an IPT manual. The twelve-week IPT program resulted in improvements in various areas when compared to TaU. Therefore, we can argue that the IPT technique should be recommended for the treatment of patients served by the Mental Health Public System. This could be accomplished by groups trained using the manual cited above, and the rehabilitation process could be accelerated through the involvement of mental health professionals. The current models of psychosocial rehabilitation in schizophrenia recommend application of specific rehabilitation techniques (in general more complex than those typically employed by psychosocial teams). Based on the findings of the present study, we suggest that rehabilitation programs include cognitive-behavioral approaches, such as IPT, that have been shown to have an effect on basic cognitive and motor functions. It seems that group approaches present better results in patients with schizophrenia and are also feasible due to the low cost of their implementation.

The present study has several strengths: being a randomized controlled clinical trial with diagnoses made through the use of standardized assessment instruments; blinded raters used in the treatment allocation; the use of a step-by-step treatment manual; employing reinforcement strategies to increase compliance; selection of a therapist trained by the author (Roder); and twelve years of experience (on the part of the authors) with the cognitive-behavioral approach in schizophrenic patients.

Finally, we suggest that further studies, involving larger samples and longer follow-up periods, be conducted in order to confirm our findings regarding the effects of IPT effects on specific dimensions of the life of patients with schizophrenia or schizoaffective disorder. Such studies should also compare efficacy in different psychosocial environments. If we follow this line of reasoning, it seems evident that additional studies, employing different treatment strategies for the assessment of predictive characteristics associated with good responses also be conducted. In addition, we should concentrate on the study and dissemination among different categories of antipsychotic drugs (first-generation, second-generation, typical and atypical) and psychosocial treatment.[8]

Limitations of the study

The major limitation of the study was the small sample size. In addition, the evaluation of the symptoms was limited by varying intervals between pre-intervention and post-intervention applications of standardized scales. Furthermore, the daily use of drugs was not monitored.

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