



ORIGINAL ARTICLE

The effects of psychosocial day care program on clinical symptoms and quality of life of persons with depression: a prospective study



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Abstract

Background and objectives: Psychological and psychosocial interventions proved to be effective in treatment of depression. The main objective of this study is to examine the effects of psychosocial day care program on the quality of life and clinical symptoms of persons with depression.

Methods: In a controlled trial, 114 participants aged 20 or older with ICD-10 major depression were recruited after they being discharged from in-patient treatment. The intervention group (n = 59) received a 4-month group psychosocial program consisting of psychoeducation, social skills training and therapeutic community, and the control group (n = 55) received the usual care. Participants were assessed three times: at baseline, at the end-of-treatment and at 6-months follow-up. The outcome measures were the Montgomery-Åsberg Depression Rating Scale and Manchester Short Assessment of Quality of Life.

Results: The intervention group had significantly larger symptom reduction compared to control group ($F(1,98) = 15.11, p < 0.01$), at both second assessment ($-8.31 \pm 0.78, p < 0.01$) and third assessment ($-10.7 \pm 0.69, p < 0.01$). Both groups showed significant reduction in depressive symptoms over study time ($F(1.53, 150.28) = 228.01, p < 0.01$). The psychosocial intervention program had no statistically significant effect on subjective quality of life.

Conclusion: The psychosocial intervention program led to significant reduction of depressive symptoms but had no effect on patients' subjective quality of life.

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Introduction

Depressive disorders are major public health problem causing severe impairments in social functioning and rank among the leading mental health causes of the global burden of disease.¹ Globally, the total number of people with depression was estimated to exceed 300 million, equivalent to 4.4% of the world's population.^{2,3} Studies have shown that majority of people with depression also meet criteria for at least 1 of the other mental disorders, most commonly anxiety disorder and substance use disorders.^{4–6} Depression has also shown to be associated with poorer physical health, increased health care utilisation and higher health care costs.^{7,8} Along with the burden for the health system, severity of depression symptoms have a huge impact on the patients' well-being and quality of life.^{9–11} People suffering from depression manifest significant and pervasive impairments in social functioning, often substantially worse than those experienced by patients with other chronic medical conditions.^{12,13} It has been shown that such impairments can remain present even after a few years of recovery from symptoms of depression.¹⁴ Most depression-related impairments, according to the US National Comorbidity Survey, are in the social role domain (43.4% severe or very severe), followed by the relationship domain (34.3% severe or very severe) and work (28.1% severe or very severe).⁵ Research focusing on particular segments of psychosocial functioning showed depression-related impairments in marital functioning,¹⁵ interpersonal relations¹⁶ and professional productivity.¹⁷ Poor quality of social relations is also a major risk factor for depression. Risk of depression was found to be significantly greater among those with baseline social strain, lack of social support, and poor overall relationship quality.¹⁸

A range of psychological and psychosocial interventions have been shown to reduce symptoms of depression and facilitate recovery in the long term.¹⁹ One of those interventions is psychoeducation and most international clinical guidelines recommend psychoeducational interventions as an important step in the treatment protocol.^{19–21} There is evidence in the literature that psychoeducation has a significant effect on both symptom reduction and relapse extension in patients with major depressive disorder.^{22,23} Psychoeducation is also considered a 'simple' intervention that fits easily into the clinical setting, does not require complex training of highly skilled therapists, can target a range of specific therapeutic goals,²² and can improve clinical outcomes in a short period of time.²⁴ The majority of studies which have assessed the effectiveness of psychoeducation have used "Coping with depression" (CWD) course or a version of it,²⁵ but there are also other psychoeducational formats delivered individually or in groups.^{26–28}

Taking into account the significant impairment in the social functioning of people with depressive disorder, many therapeutic strategies take social skills training as an essential component. It has long been established that social skills training could be related to significant and clinically meaningful changes in depressive symptomatology and social functioning.^{29,30} A meta-analysis conducted in adult psychiatric population showed that patients participating in social skills training programs broadened their repertoire of skills,

continued to demonstrate these skills several months after treatment, and showed diminished psychiatric symptoms related to social dysfunctions.³¹ Social skills training and social activities, among other psychosocial interventions, had a positive effect on quality of life and positive mental health in a population of older adults³² and in a population of youth with comorbid anxiety and depression.³³ Recent meta-analysis revealed that, despite being a well-established treatment modality for depression, social skills training was investigated least often (only 4% of analysed studies) and mostly in small sample studies.³⁴ Prospective control studies of depression treatment outcomes in Croatia are sparse, while the most common and often the only form of treatment is psychopharmacological.³⁵ Also, there is a limited and non-consistent evidence of the efficacy of different outpatient, or day hospital psychosocial programs for patients with depression. The psychosocial program evaluated in this study was developed as an outpatient continuation of depression treatment after acute phase and hospitalization. It is based on the assumption that psychosocial treatment combined with antidepressant therapy is associated with positive long term outcomes in terms of symptom improvement, quality of life and general functionality.^{36–39}

The main objective of this study is to examine the effect of psychosocial day care program on the quality of life and symptom reduction for persons with depression after their discharge from in-patient treatment. The research questions of the study are: (1) Do participants enrolled in the psychosocial intervention group obtain greater reduction in depressive symptoms compared to those who did not receive the psychosocial interventions? (2) Do the participants enrolled in the psychosocial intervention group have greater improvement in quality of life compared to participants in the control group? (3) Can the possible effect of psychosocial interventions be maintained for 6 months after the end of the treatment?

Methods

Study design

The study was designed as a prospective, controlled interventional study without randomisation to intervention or control group. The study used a 3 × 2 between subject design, with repeated measures on two outcome variables: depression severity and quality of life.

Patient eligibility criteria

In total 117 eligible patients were contacted within the period of one month following their discharge from in-patient care at the Department of Social Psychiatry of Clinical Hospital Centre Rijeka. The patient eligibility criteria were: (1) diagnosis of a major depressive disorder (single or recurrent episode: F 32.0-3 and F 33.0-3), according to the International Classification of Disease 10th revision (ICD-10)⁴⁰; (2) age 20 years and older and (3) provision of signed informed consent. The exclusion criteria were: (1) comorbid diagnosis including psychotic disorder, bipolar disorder, substance related disorder, or mental disorder

caused by organic factors; (2) further in-patient care in another psychiatric hospital indicated after discharge; (3) sensory or cognitive disabilities and (4) refusal to provide consent. All the eligible patients after their discharge from in-patient treatment at the Department of Social Psychiatry were contacted by a study team psychiatrist. Participants were recruited over a one-year period. After explaining the purpose and process of the study 114 subjects agreed to participate in the study and signed informed consent forms. All patients who agreed to participate in the study were introduced to the psychosocial program and were offered to participate in it. Those who agreed to join the program were in the experimental (intervention) group (N = 59), while those who did not want to participate in the psychosocial intervention program were in the control group (N = 55) and received the usual treatment. The main reasons for choosing not to participate in the psychosocial program were the distance of the patient's place of residence from the hospital where the program took place. Many patients have stated that it is too expensive for them to pay travel expenses, or that it is complicated to adjust their daily activities with the schedule of the program. Some patients considered the proposed treatment program unnecessary or expressed general distrust of the new approach to treating their illnesses.

Description of the intervention and control condition

The process of developing psychosocial intervention program evaluated in this research was based on contemporary theoretical assumptions and innovative clinical practice. When selecting specific interventions, the authors were guided by several criteria. First, desirable interventions should have addressed both symptom change and functional capacity; second, the interventions should have been easy to implement and third, it was desirable for the interventions to be meaningful and user-friendly, both for patients and professional staff. With all of the above in mind, the authors have created a program including psychoeducation, social skills training and the therapeutic community as essential components.

For the intervention group, the psychosocial program lasted for 4 months and was conducted in two phases: intensive phase and reduced phase. The intensive phase lasted for one month and included 3 sessions per week, while the reduced phase lasted for 3 months and included one session per week. The intensive program consisted of 3 components: (1) a *psycho-education group* led by a psychiatrist; (2) *social skills training group* led by a trained nurse and a social worker and (3) *therapeutic community* where all members of the therapeutic team participated together. Weekly schedule during the intensive phase consisted of one psychoeducational session, one social skills training and one session of the therapeutic community. The reduced phase of the program consisted of one session a week for a three-month period and included social skills training 3 times a month followed by one therapeutic community session at the end of each month. The content of psychoeducational intervention consisted of providing structured information on illness and treatment. The program

provided information about (a) symptoms – how to recognise them on time, how to cope, what to do in case of deterioration, etc.; (b) medication – the way in which certain drug works, the possible side effects and importance of adherence; and (c) how to improve general social functioning. Social skills training program included discussion and practice of different interpersonal relationship skills with the special focus on assertiveness. The purpose and content of the therapeutic community was to discuss the course of the therapeutic process and all the relevant events from the past period, solving problems within the group and getting acquainted with the future activities. Through all three components of the psychosocial program, participants were encouraged to actively engage through questions, suggestions, participation in practical assignments and other activities.

Participants in the control group received treatment as usual which included pharmacotherapy and regular visits to a psychiatrist. The usual visits were scheduled once a month, or more often when needed. During the visits, the patients were asked about their clinical symptoms, general health status, adherence to antidepressant treatment, side effects, social and/or work activities and other segments of their everyday functioning. Each visit lasted from 10 to 20 min. All clinicians involved in the study have undergone a short initial training. Psychiatrists involved in the control arm of the study have been trained in order to ensure that the treatment sessions in the control condition has been delivered in approximately the same way. They were given a written list of instructions to help them keep the structure and the length of the sessions roughly the same. Also, to prevent the potential influence of the personnel from the intervention arm of study on the control clinicians, the professionals involved in the psychosocial program were asked not to share any experiences or information about the program during the study period. Additionally, the psychiatrists involved in the control condition were asked not to change their treatment approach during the study period.

Measures

Sociodemographics

The participants' general characteristics were collected using sociodemographic questionnaire designed for this research. This information included age, gender, marital status, level of education (1- unfinished elementary school, 2- elementary school, 3 – high school, 4 – university degree), employment status (1- employed, 2 – unemployed, 3- retired, 4 - other), financial situation (1 – very bad, 2- bad, 3 – average, 4 – good, 5 – very good), prior psychiatric treatment, and medication. The sociodemographic questionnaire was applied only during the first assessment.

Quality of life (QOL)

Manchester Short Assessment of Quality of Life (MANSA)⁴¹ was used to measure the perceived QOL of the participants and was applied at the first and at the third assessment. The instrument consists of 16 items. Twelve questions are strictly subjective measuring satisfaction with life as a whole, job (or sheltered employment, or training/education, or unemployment/retirement),

financial situation, number and quality of friendships, leisure activities, accommodation, personal safety, people that the patient lives with (or living alone), sex life, relationship with family, physical health, and mental health, using a 7-point rating scale. Four items are termed objective and to be answered with yes or no. These items assess the existence of a close friend, contacts with friends per week, accusation of a crime and victimisation of physical violence. Only subjective QOL items were used. The questionnaire was translated in Croatian and used previously in mental health research demonstrating good metric characteristics.^{42,43}

Depression severity

The Montgomery-Åsberg Depression Rating Scale (MADRS)⁴⁴ was used to measure the levels of depression at the first, second and third assessment. The instrument has 10 items (apparent sadness, reported sadness, inner tension, reduced sleep, reduced appetite, concentration difficulties, lassitude, inability to feel, pessimistic and suicidal thoughts) with score range from 0 to 6, with higher scores indicating more severe depression. Studies showed that MADRS has high internal consistency, inter-rater reliability and high sensitivity in detecting change in depressive symptoms.^{45–47}

Assessments

The assessments were performed 3 times. The first assessment for the intervention group was done on the first day of psychosocial day care programme, while for the control group the same was performed on the last day of inpatient care. The second assessment for the intervention group was performed on the last day of psychosocial day care programme (4 months after the start) and for the control group 4 months after their discharge from the in-patient treatment. The third, follow up assessment for both groups was carried out 6 months after the second one (10 months after the beginning of the study). All assessments were performed in individual data collection sessions. During the intervention period, both groups still received their usual care, including the pharmacotherapy and regular check-ups by a psychiatrist. The study has been approved by the Ethics Committee of the University Hospital Centre Rijeka and the Faculty of Medicine Rijeka.

Data analysis

The sample size calculation was guided by practical restrictions and statistical power estimation. The effect size in this study was considered to be medium using Cohen's criteria. With an accepted alpha risk of 5% and power of 0.8, the minimal sample size needed to detect a relevant difference in the outcome measures was 46 participants in each group. Expected dropout rate was estimated at 15%. All analyses were done on per-protocol basis including only those participants who completed all three assessments.

Baseline differences between intervention and control group on socio-demographic characteristics, QoL, symptom severity were analysed by using independent sample t-test for continuous variables, and Chi-square test for categorical variables.

The general linear model repeated measures was used to examine the effects of psychosocial interventions. The outcome measures included overall subjective quality of life (total MANSA subjective score) and MADRS score. These outcomes were analysed separately with the main effects of intervention condition (psychosocial vs. control), time (1st, 2nd and 3rd assessment) and their interaction. Greenhouse-Geisser correction was applied when data violated the assumption of sphericity and corrected results are shown with Bonferroni adjustments for multiple comparisons. All statistical analyses were done using the SPSS 23.0 for Windows (SPSS Inc., Chicago, IL, USA). The level of significance was set at two tailed with an alpha level of 0.05.

Results

Participants

Out of 117 patients assessed for eligibility 3 declined to participate in the study due to personal reasons. The remaining 114 subjects were assigned either to psychosocial intervention (n=59) or control group (n=55). Six participants from the intervention group and 4 from the control group discontinued their further participation before the second assessment. Between the second and the third assessment 2 participants from the intervention group left the study and 1 participant died, while at the same time one participant left the control group resulting in a total sample of 100 participants - 50 in each group (Fig. 1) The overall dropout rate was 12% (n = 14) and did not differ between groups (9 (15%) in the intervention group vs. 5 (9%) in the control group; $\chi^2 = 0.79$, $p = 0.375$). The most frequently mentioned reasons for the dropout were lack of time, loss of interest, other obligations, transport problems and unwillingness.

The intervention and control groups did not differ in any baseline sociodemographic or clinical characteristic (Table 1). The average age of participants in the intervention group was 51.8 years (SD=7.6, range 28–63) and 50.1 years (SD=9.9, range 25–69) in the control group. Most of the participants in both groups were married women with high-school level of education. About 50% of participants in both groups were employed, while roughly the same percentage of the patients rated their financial situation as 'bad' or 'very bad'. All the participants received some form of pharmacotherapy, mostly antidepressants (100%) and anxiolytics (70% intervention group vs. 64% control group) while other medications were used to a lesser extent.

Effects of psychosocial interventions

There was no difference in baseline level of depressive symptomatology between intervention and control group ($t = 0.19$, $p = 0.853$), while the subjective QoL was significantly higher in the intervention group ($t = 2.15$, $p = 0.035$).

The results of the repeated measures ANOVA are shown in Table 2. Participants in the intervention group had significantly larger symptom reduction compared to control group ($F(1,98) = 15.11$, $p < 0.01$), at both second assessment (-8.31 ± 0.78 , $p < 0.01$) and third assessment (-10.7 ± 0.69 , $p < 0.01$). Both groups showed significant reduction in depressive symptoms over study time

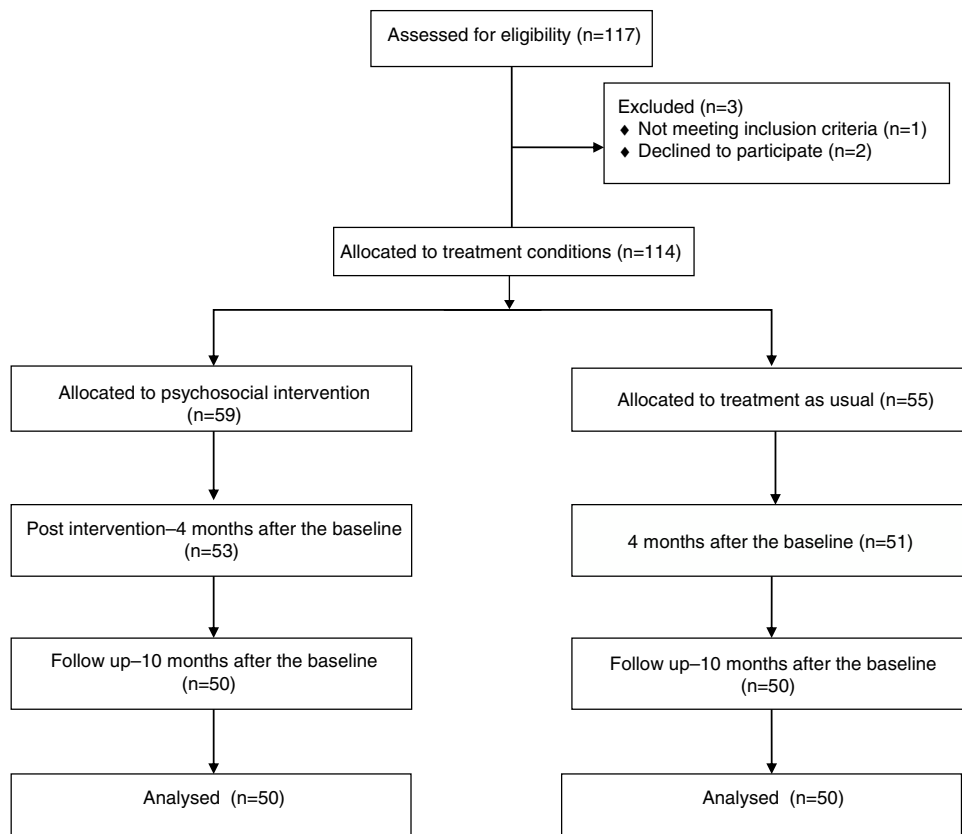


Fig. 1 CONSORT flow chart of participants.

($F(1.53, 150.28) = 228.01, p < 0.01$). Levels of depression were lower comparing baseline and second assessment ($-7.73 \pm 0.71, p < 0.01$), baseline and third assessment ($-14.01 \pm 0.77, p < 0.01$) and second compared to third assessment ($-6.28 \pm 0.45, p < 0.01$).

The intervention condition did not show statistically significant effect on subjective QOL. Although the overall result did not reach statistical significance, the item analysis of QOL revealed that at the final assessment participants in the intervention group were more satisfied with their friendships compared to controls ($4.47(1.54)$ vs. $3.82(1.75)$, $p < 0.05$). Both groups showed significant improvement in subjective QOL at third assessment compared to baseline ($F(1,98) = 19.11, p < 0.01$).

Discussion

The main objective of this study was to examine the effects of psychosocial interventions implemented within the day care program on symptom reduction and quality of life of individuals with depression. The results showed that the intervention program was effective in reducing levels of depressive symptoms registered immediately after the end of the program and that these effects are maintained for at least 6 months after. At the end of the program psychosocial interventions group showed 12 points reduction in the MADRS score, compared to 3,5 points reduction in the control group. Six months after the end of the psychosocial program, the differences in symptoms reduction were

even more pronounced. For the quality of life, the pattern of change was different. Although, the quality of life at the end of the study was significantly higher compared to the baseline, the subjects who participated in the psychosocial interventions group did not significantly improve their subjective QOL compared to the control group, so this increase cannot be associated with the effect of psychosocial interventions.

Psychosocial interventions in this study consisted of three components: psychoeducation, social skills training and therapeutic community, and each of these components in most previous studies has shown a significant effect on reducing the symptoms of depression.^{18,22,26,31,32,34,48} The mean effect size (Cohen's d) for psychoeducational interventions compared control condition was found to be between 0.07 and 0.61⁴⁹ and for social skills training between 0.62 (compared to waitlist condition) and 0.30 (compared to usual care).³⁴ The combination of these interventions within the unique psychosocial program in our study resulted in a relatively large reduction of depression symptoms, both post intervention and in a six month follow up period. The effects of multicomponent intervention programs on depression symptoms may involve different mechanisms and pathways. For example, patients are given the opportunity to analyse their usual ways of dealing with stress and to practice change of their usual patterns of thinking and reacting. Also, improving social and communication skills within the program can help depressed individuals expand their network of friends and acquaintances and reduce general isolation and loneliness, which is one of the most important

Table 1 Sample characteristics at baseline for the psychosocial intervention and control group.

	Psychosocial intervention (n = 50) n (%)	Control group (n = 50) n (%)	χ^2	p
Gender				
Male	7 (14.0)	11 (22.0)	1.08	0.436
Female	43 (86.0)	39 (78.0)		
Marital status				
Married/cohabitation	32 (64.0)	32 (64.0)	6.44	0.266
Single	8 (16.0)	12 (24.0)		
Divorced	8 (16.0)	5 (10.0)		
Other	2 (4.0)	1 (2.0)		
Housing conditions				
Own house	36 (72.0)	38 (76.0)	6.95	0.225
At parent's house	8 (16.0)	9 (18.0)		
Temporary accommodation	6 (12.0)	1 (2.0)		
Other	0 (0.0)	2 (4.0)		
Education				
Elementary school	9 (18.0)	4 (8.0)	6.34	0.175
High school	30 (60.0)	37 (74.0)		
University	11 (21.0)	9 (18.0)		
Employment status				
Employed	27 (54.0)	25 (50.0)	1.19	0.756
Unemployed	12 (24.0)	12 (24.0)		
Retired	11 (22.0)	13 (26.0)		
Financial situation				
Very bad	11 (22.0)	10 (20.0)	5.13	0.401
Bad	18 (36.0)	14 (28.0)		
Average	12 (24.0)	13 (26.0)		
Good	7 (14.0)	13 (26.0)		
Very good	2 (4.0)	0 (0.0)		
Medication				
Antidepressant	50 (100)	50 (100)	/	/
Antipsychotic	15 (30)	13 (26)		
Anxiolytic	35 (70)	32 (64)		
Hypnotic	5 (10)	6 (12)		
	Mean (SD)	Mean (SD)	t	p
Age (year)	51.76 (7.64)	50.10 (9.96)	1.03	0.307
Symptom severity MADRS	27.18 (8.69)	26.86 (8.58)	0.19	0.853
Subjective QOL (MANSA)	3.83 (1.16)	3.39 (0.87)	2.15	0.034

Table 2 Changes in symptom severity and subjective quality of life between the psychosocial intervention group and control group across the three assessment points.

	Estimated mean change between assessments (SE)			Estimated mean differences between groups (SE)		
	Baseline vs. Assessment 2	Baseline vs. Assessment 3	Assessment 2 vs. Assessment 3	Int. vs. Cont Baseline	Int. vs. Cont Assessment 2	Int. vs. Cont Assessment 3
Symptom severity (MADRS)	−7.73 (0.71)**	−14.01 (0.77)**	−6.28 (0.45)**	−0.32 (0.02)	−8.31 (0.78)**	−10.7 (0.69)**
Subjective QOL (MANSA)	/	0.37 (0.09)**	/	0.45 (0.07)*	/	0.08 (0.001)

* p < 0.05.

** p < 0.01.

component of depression. In addition, patients involved in the program receive information on symptoms and treatment of depression, including the importance of adherence to medications. Because they target multiple segments of the patient's life and the relationship with the disease, combined psychosocial interventions may have more pronounced long-term effect on symptom reduction compared to the usual treatment.

Changes in subjective quality of life, on the other hand, could not be related to the effect of psychosocial interventions in this study and there are several potential explanations for such a result. Participants assigned to the intervention group at the beginning of the study had a significantly higher level of quality of life compared to the control group. This baseline difference possibly reflects a selection bias. Patients who agreed to participate in the psychosocial program were probably more motivated and had greater capacity and resources to improve their mental health. Despite an equal baseline level of symptoms compared to the control group, intervention group at the beginning generally had a more positive view of life as a whole, had more social contacts, were more satisfied with their work, financial situation and other aspects of functioning. Ten months after there were no differences in subjective quality of life between groups. Participants in the control group who received usual treatment improved their QoL to much greater extent and reached the level of intervention group. The psychosocial intervention program seems to be ineffective in terms of improving subjective QoL in patients who are already perceiving the quality of their life relatively high. The only exception is in the friendships domain where participants from the intervention group are significantly more satisfied 6 months after the end of the program compared to controls. The results suggest that patients with depression can benefit from the psychosocial program in terms of symptom reduction but not in quality of life area. To target certain segments in quality of life, this psychosocial program should probably be revised through the addition of individualized psychotherapeutic interventions or domain specific skills training. Additionally, the duration of psychosocial program provided may not be long enough, especially for social skills acquisition, environmental adjustment, and social /environmental QoL enhancement.^{50,51} Certainly, more research is needed to confirm this assumption.

Limitations of the study and further research

The main limitation of this study was a non-random design: the participants were assigned to the intervention or control group according to their willingness to participate in the psychosocial program after their discharge from the inpatient treatment. Although the patients from the intervention and control group did not differ on basic sociodemographic characteristics and pre-treatment level of symptoms it is possible that the study groups were not balanced on other relevant factors. For instance, patients who agreed to participate in the psychosocial program were probably more motivated and had greater capacity and resources to improve their mental health. They also scored higher on subjective QoL scale prior to their engagement in

psychosocial treatment compared to controls, suggesting that their social functionality and general well-being were better. These and other variables associated with selection bias could have influenced the effects of psychosocial treatment on the outcomes of the study. Secondly, the sample size of 50 participants per-condition was relatively small with the drop-out rate between 9% (control group) and 15% (intervention group). Although the drop-out rate did not significantly differ between the groups, the loss of participants could have an impact on the results. Additionally, the study included only two outcome measures, MADRS and MANSA, using only subjective, self-rated measures of symptom severity and quality of life, respectively. Finally, a longer follow-up period with more assessments points would allow for a more accurate examination of the long-term effects of psychosocial interventions.

Despite described limitations, this study has several advantages. It is the first study to assess the effectiveness of this multicomponent psychosocial outpatient program developed at Psychiatric Clinic, Clinical Hospital Centre Rijeka. It is a naturalistic study aiming to evaluate the psychosocial intervention programme while staying as close as possible to the usual practice of the Psychiatric Clinic. As far as the authors know it is a first prospective, controlled study in Croatia examining structured psychosocial program as an adjuvant component to the usual outpatient treatment (pharmacotherapy + regular psychiatrist controls) for depression. Bearing in mind the exploratory nature of this research following the development of a psychosocial intervention program, future research should focus on evaluation of the program through a study with a more rigorous methodology. Ideally, the psychosocial intervention program should be tested using a randomized controlled trial by an independent research team. The study should use a mixed-method approach, including data from both patients and clinicians, in order to establish causal effects of the interventions and to clarify the mechanisms of action.

Conflict of interest

We certify that no party having a direct interest in the results of the research supporting this article has or will confer a benefit on us or on any organization with which we are associated.

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