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Functioning Management & Recovery - Resource Group, a psychoeducational intervention to improve empowerment of people with severe mental illness: a 12-month multicenter randomized control study

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Summary. Aim. Functioning Management and Recovery with the Resource Group (FM&R-GR) is a standardized Psychoeducational Intervention elaborated to improve functioning and empowerment of people with Severe Mental Illness (SMI) living in the community. The aim of this study is to prove its efficacy by the primary and secondary outcomes. **Methods.** 60 patients with SMI were recruited in 5 day-centers (North and South Italy) randomly assigned into 2 groups (Experimental vs Control); patients underwent a multicenter follow-up study with a two time-point evaluation (t0, pre-treatment and t1, 12 months). A highly structured FM&R-GR was used in the Experimental Group (EG), whereas a less structured manual was used in the Control Group (CG). At each time point, Social Functioning, Empowerment and Distress, were assessed as primary outcome; furthermore, Psychopathological Status, Cognitive Functioning, and Cognitive Flexibility were assessed as secondary outcome. **Results.** Fifty-nine individuals out of 60 (98.3%) started the study randomly allocated in the EG vs CG. In the EG, 19 people (32.2%) were affected by schizophrenia, 9 (15.2%) by bipolar I disorder with psychotic symptoms and 2 (3.4%) by personality disorders according to DSM-5-TR started the study; in the CG there were respectively 20 (33.9%), 6 (10.2%) and 3 (5.1%). Forty-eight patients, 27 in the EG (56.3%) and 21 in the CG (43.75) completed the study. The total scores of NEL, Distress ($p<0.001$), and PSPS ($p<0.05$) showed a statistically significant improvement. The improvement of the other variables in the EG (BPRS, BANS and MFPT) was not statistically significant. **Conclusions.** After 1 year follow-up these results showed improvement in all variables of primary and secondary outcomes, with great statistically significant difference between the two groups for the empowerment, functioning and distress. Furthermore, the pre-post difference in the Experimental Group was statistically significant for all variables with the exception of cognitive flexibility, while in the CG only for the RBANS. Overall, a remarkable impact of this psychoeducational structured intervention was observed on the primary outcome variables.

Key words. Empowerment, functioning, group intervention, psychoeducation, recovery, salutogenesis.

Functioning Management & Recovery - Resource Group: un intervento psicoeducativo per migliorare l'empowerment delle persone con Disturbo Mentale Grave. Risultati a un anno di uno studio multicentrico controllato randomizzato.

Riassunto. Scopo. Functioning Management and Recovery with the Resource Group (FM&R-GR) è un intervento psicoeducativo standardizzato elaborato per migliorare il funzionamento e l'empowerment delle persone con Disturbo Mentale Grave (DMG) che vivono in comunità. L'obiettivo dello studio è dimostrarne l'efficacia attraverso gli esiti primari e secondari. **Metodi.** Sessanta pazienti con DMG sono stati reclutati in 5 centri diurni (Nord e Sud Italia), assegnati in modo casuale a 2 gruppi (Sperimentale vs Controllo). I pazienti sono stati sottoposti a uno studio di follow-up multicentrico con una valutazione a due tempi (t0, pre-trattamento e t1, 12 mesi). Lo FM&R-GR è stato utilizzato nel Gruppo Sperimentale (GS), mentre un manuale meno strutturato è stato utilizzato nel Gruppo di Controllo (GC). Il Funzionamento Sociale, l'Empowerment e il Distress sono stati valutati come outcome primari. Lo Stato Psicopatologico, il Funzionamento Cognitivo e la Flessibilità Cognitiva sono stati valutati come outcome secondari. **Risultati.** Cinquantanove individui su 60 (98,3%) hanno iniziato lo studio, assegnati in modo casuale al GS vs. GC. Nel GS, 19 persone (32,2%) erano affette da schizofrenia, 9 (15,2%) da disturbo bipolare I con sintomi psicotici e 2 (3,4%) da disturbi di personalità secondo il DSM-5-TR. Nel GC erano rispettivamente 20 (33,9%), 6 (10,2%) e 3 (5,1%). Quarantotto pazienti, 27 nel gruppo sperimentale (56,3%) e 21 nel gruppo sperimentale (43,75), hanno completato lo studio. In questo gruppo punteggi totali di NEL, Distress ($p<0,001$) e PSPS ($p<0,05$) hanno mostrato un miglioramento statisticamente significativo. Il miglioramento delle altre variabili (BPRS, BANS e MFPT) non è stato statisticamente significativo. **Conclusioni.** Dopo un anno di follow-up, questi risultati hanno mostrato un miglioramento in tutte le variabili degli esiti primari e secondari, con una differenza statisticamente significativa tra i due gruppi per l'empowerment, il funzionamento e il distress Inoltre, la differenza pre-post nel gruppo sperimentale era statisticamente significativa per tutte le variabili a eccezione della flessibilità cognitive. Nel complesso, è stato osservato un impatto notevole di questo intervento psicoeducativo strutturato sulle variabili degli esiti primari.

Parole chiave. Empowerment, funzionamento, intervento di gruppo, psicoeducazione, recupero, salutogenesi.

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Introduction

Empowerment, Functioning and Recovery of people with Severe Mental Illness (SMI) are the three key-words in psychiatric care. In fact, since 2006, thanks to the report of Wallerstein[1] it has become increasingly clear that empowerment can lead to positive health outcomes. It is emphasized that effective empowerment strategies require both individual and community capacity for decision-making building; in addition, they could be considered at the same time a mediator for better long-term mental health and a milestone for recovery oriented mental health care[2]. The more recent paper of Lee et al.[3] well describes the relationships among empowerment, functioning and recovery. A sample of 373 participants to the survey showed that «empowerment fully mediates the association between global function and personal recovery». We are aware that connections between empowerment and functioning of the individual are two-sided[4]. We believe that empowerment can positively influence personal and social functioning but, in turn, it is also the result of improved personal and social functioning, creating a positive loop for recovery[3-6]. However, the study showed that offering empowerment-oriented care is effective for global function improvement in recovery among these patients. Looking to the effective intervention based on this framework we found the work of Tjaden et al.[7] as one of the most interesting. First of all, they rightly underline that one of the essential elements such as the involvement of significant others is not adequately implemented in practice. In their study they showed that creating informal and formal networks to form a Resource Group (RG) to regularly discuss self-formulated recovery by patients is a winning strategy. The results of the randomized clinical trial performed by Tjaden et al.[7] are promising. We agree with this author that the involvement of relatives or caregivers is the best strategy to improve adherence to the care process and better social functioning[8,9]. On these bases we adapted the approach Functioning Management and Recovery (FM&R) – which we found effective for Residential Facilities (RF) – to the community adding an RG formed by relatives or informal/formal caregivers. We specify that FM&R for RF is, in turn, derived from InteGRO[10], another, effective recovery-oriented psychoeducational intervention[11-14] conceived to facilitate functioning, more appropriate for patients living with a minimum support of health and social services. The FM&R-RG is at the same time a psychoeducational and salutogenetic group intervention that reworks the weekly meetings of the FM&R for RF and involves 2-3 caregivers (generally relatives) monthly to share the goals established with the patients. InteGRO, FM&R for RF and FM&R-RG are inspired by the principles of salutogenesis[15,16], in particular by the component of the "meaningfulness" of the Antonovsky's "triade"[15], that is the key element of recovery, as suggested by Jaiswal et al.[17] with the locution "The sense of Meaning". These interventions share the setting of pleasant and personal goals, communication skills, problem solving, emotional literacy with an original work about social cognition and principles of mindfulness. During the several meetings, the participants are guided to give meaning to the stressful events as challenges and, at the same time, to see the experiences in a positive light. This action encourages them to commit and to adhere to the treatment in a satisfactory way. FM&R-RG features a training of 28 sessions (once a week). Many sessions are focused on personal and social functioning with the efforts to prompt life-style changes like diet, physical activity or relaxation self-training; this work is performed by means of a specific schedule with the scores for the evaluation of progress, filled in during the group session. Some sessions are on reshaping negative thoughts and feelings in a positive way, on detection of early warning signs, on relaxation techniques. As we previously stated, the FM&R-RG includes specific sessions with relatives and professionals to support patients to reach their goals and to share the work in progress.

In this contribution we show the results of a multicenter randomized controlled study involving 5 Day-Centers of Southern and Northern Italy after one year of the FM&R-RG intervention, with functioning and empowerment as primary outcomes. Several other variables have been considered, concerning psychopathology, cognitive functions, including flexibility as a specific pattern and level of distress.

Materials and methods

Study design

This is a multicenter randomized controlled study, with a 1-year follow-up, two time-point evaluations (t0= pre-treatment; t1= post-treatment), carried out on empowerment and functioning as the primary outcome; the study was carried out from 2023 to 2024 in individuals with DSM-5-TR[18] schizophrenia, bipolar I disorder with psychotic symptoms, or personality disorder enrolled in 5 day centers (DC). The patients were randomly allocated in two groups per center.

Randomization and blinding

Randomization of the patients to Experimental Group or Control Group (1:1) was performed via an

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interactive web-response system based on a random allocation sequence (Research Randomizer Version 4.0, created by Urbaniak & Plous in 2013). The system sent an email with the randomization to the involved mental health professionals, who notified the participants.

Owing to the nature of the intervention, participants were blinded to allocations, whereas mental health professionals providing the intervention were not. The research staff conducting follow-up assessments at t0 and t1 and the data analysts were blinded. To assess blinding, the research staff conducting follow-up assessments filled in control questionnaires about participants' allocation status after each assessment.

Sample and recruitment

Five Italian Day-Centers (DC), well-known to the Research Lead Unit of Cuneo for professional reasons, were selected and invited to take part in the study. In each of these DCs, people with mental disorders who were clinically stable, without clinical worsening over the past 3 months, were invited to participate if they fulfilled the following inclusion criteria: a) age between 18 and 55; b) diagnosis of Schizophrenia or Bipolar disorder I with psychotic or personality disorders according to the DSM-5-TR criteria[18]; c) a minimum of one year of duration of illness; d) a minimum score on the Social and Personal Performance Scale of 35; e) not Moderate, Severe or Profound Intellectual Developmental Disorder; f) a minimum presence of 3 months in the DC; g) written informed consent to participate in the study and to be evaluated by means of interviews and questionnaires; h) no current severe psychotic symptoms that could interfere with attention; i) absence of use of drugs or intoxication by alcohol.

Individuals with mental disorders who agreed to participate in the study were allocated to the experimental group (EG) or to the control group (CG) on the basis of the process of randomization and blinding. For each group 6 people were admitted. If more than 6 were eligible for the study, they were allocated in a waiting list (up to 3 per center), receiving the intervention at the end of the study in case of positive results. The intervention was discontinued if the recruited individuals: a) were unable to attend more than 4 sessions; or b) were hospitalized for a period superior to one month or had 2 or more relapses during the study; or c) withdrew their consent.

Description of the intervention

The experimental intervention is based on the psychoeducational and salutogenic intervention named FM&R, developed by Veltro et al.[19] in order to improve recovery-oriented functioning in people with severe psychiatric disorders. FM&R was derived from InteGRO, an intervention proved in several studies[11-14] to be effective for individuals with mental disorders who deliberately decide to undertake a recovery journey in the community, asking mental health service professionals to accompany them in this journey. InteGRO is based on four fundamental modules (definition of Pleasant and Life Goals, effective communication, emotional perception and problem-solving), each including different teaching units. For each unit a meeting is scheduled. There are also intermodular educational units to facilitate the acquisition of the skills of single modules. Emotional literacy, emotional perception, social cognition and problem solving are the most used training sessions in this approach. There are usually 36 weekly meetings, each one lasting 90 minutes; some of them are carried out twice a week to facilitate learning on the subject. InteGRO is a proactive and promotional intervention that focuses on the improvement of abilities; there is no reference to symptoms, impairments or deficits. For the Residential Facilities and for the DC we re-elaborated InteGRO in order to intensify the work on personal and social functioning, according to the main aim of promoting Recovery. In this way functioning became the most important aspect of the training. The FM&R intervention for Residential Facilities involves 24 sessions, two per week (whereas InteGRO comprises 36 sessions, 1 per week) and was found to be effective in a multicenter follow-up study[20]. The FM&R – RG involves 28 sessions, including the meetings requiring relatives to share in presence the work in progress together with the users and the professionals, with the aim to support users in reaching personal goals and in modifying life-style behaviors. Training sessions not included in InteGRO are: a) Early Warning Signs; b) Structured Schedule to help individuals with mental disorders to plan Behavioural Changement; c) Problem Solving training to facilitate the work on the Behavioural Changement Schedule (BCS); d) 2 training sessions on the Albert Ellis's ABC model[21] to help individuals reshape their negative thoughts and feelings in a positive way; e) The modified Moritz Model for empathy[22]; f) muscle relaxation training. The BCS represents the fundamental aspect of the work to improve functioning. This schedule contains the basic areas of functioning such as personal self-care, diet, sleep hygiene, motor activity, active mobility, relationships, hobbies and mastery. Each person with mental disorder is asked to specify in two group sessions how he/she intends to work on each area and how he/she intends to plan and evaluate the progress in detail. All sessions of FM&R are illustrated in Appendix. The BCS has already been published[19]. The intervention was carried out by mental health professionals who attended the

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training course (see below). A less structured manual was used for the Control Group, featuring the same topics for each session, including key-questions for each unit to prompt a free discussion on the topics; in this group there was not a Resource Group.

Training of mental health professionals in the intervention

The training course consisted of one residential meeting lasting 2 days, 8 hours a day; it took place in the Residential Facility of Gambatesa, near Campobasso, in Southern Italy in order to: a) inform professionals on the study purposes and methodology; b) train 2 professionals from each DC in FM&R-GR; c) train 1 researcher from each DC on the assessment tools and test inter-rater reliability. In addition, we had 3 online supervision meetings, each lasting 3 hours; moreover, a regular supervision via phone and e-mail was carried out. The mental health professionals who participated in the residential training were psychiatrists (10%), psychologists (20%), psycho-social rehabilitation technicians (40%), psychiatric nurses (10%), social workers (20%). All psychologists had a cognitive behavioral therapy expertise. All other professionals had Social Skills Training and psychoeducational intervention expertise. All professionals had previously been fully trained in InteGRO.

Assessment instruments

The primary outcome of the study was the improvement of personal and social functioning and empowerment after 12 months. We would like to pinpoint that the intervention lasts 6 months plus 6 meeting of booster sessions.

Functioning was assessed by the Personal and Social Performance Scale (PSPS)[23]. PSPS was derived from the DSM-IV version of the Social and Occupational Functioning Assessment Scale (SOFAS); compared to the SOFAS, the PSPS has better face validity and psychometric properties. The PSPS evaluates personal and social functioning through a semi-structured interview and the information available from acquaintances and health workers. Four main areas are considered: 1) socially useful activities (including working and studying); 2) personal and social relationships; 3) taking care of appearance and hygiene; 4) disturbing and aggressive behaviors. The total score ranges from 0 (worst possible functioning) to 100 (excellent functioning).

Empowerment was assessed by the Netherland Empowerment Scale (NEL)[24], a 40-item scale developed to measure empowerment, particularly for individuals with SMI. It assesses empowerment across six domains: self-management, social support, caring community, connectedness, confidence and purpose, professional help. Items are typically rated on a 5-point Likert-type scale, from "completely disagree" to "completely agree". The internal consistency was good: Cronbach's alpha was 0.94 (for one sample) and 0.95 (for another sample) for the total scale. The repeated measures of NEL in the treatment group were available for 57 individuals. The NEL intraclass correlation coefficient in this group was 0.79.

The Stress Scale[25], made up of 9 items taken from the well-known and widespread Goldberg tool for investigations in routine conditions, with a dichotomous yes-no (yes is scored 1, no is scored 2). The Cronbach's alpha was evaluated >.70 in all studies in which it was used. The test-retest reliability was assessed and met the criterion of >.70 in all cases. A two factor models best describes the scale: Perceived helplessness and Lack of self-efficacy.

Other outcome measures were evaluated by means of:

- The Italian version of Brief Psychiatric Rating Scale (BPRS)[26-28], a psychopathological hetero-evaluation scale consisting of 24 items. Each item is assessed on a Likert scale with 7 coding levels ranging from 1 (absent) to 7 (very severe). From a factorial analysis, five symptomatic clusters were identified: "disorganization" (range 4-28); "negative affectivity" (range 6-42); "positive symptoms" (range 4-28); "expanded affectivity" "negative symptoms" (range 3-21).
- The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS)[29]: a brief, individually administered test measuring attention, language, visuospatial/constructional abilities, immediate and delayed memory. It consists of 12 subtests, which yield five Index scores and a Total Scale score. Stimuli are contained in a wire-bound, easel-type booklet, making the test easily portable. Clinical validity study of the RBANS suggests that it is sensitive both in terms of detecting and characterizing cognitive deficits.
- The Modified Five-Point Test (M-FPT)[30] is a test for measuring non-verbal fluency (figurative) of executive functioning, linked to cognitive flexibility. The main aspects assessed are: cognitive flexibility, presence or absence of perseveration and strategic performance. Consequently, scores are of 3 types: 1) Unique Drawings (UDs), i.e. number of valid drawings not produced before. 2) Cumulative strategies (CSs) i.e. number of UDs produced with a particular strategy that can be either enumerating (CSse) or rotative (CSsr). 3) Error index (ErrI), i.e. percentage of perseverative drawings or breaking of rules (errors) on the total number of drawings. The aim of the Italian validation study was to collect normative data

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for a version of the Five-Point Test (M-FPT); its psychometric properties were well known from the original validation studies, administered to a sample of Italian healthy adults aged 16-60. The availability of these normative data allows one to assess individual's performance with reference to cut-off scores.

Statistical analysis

For variables with parametric distribution the average ± sd was calculated; for variables with non-parametric distribution the median and range were calculated.

For parametric variables: the Student's t-test was used to compare scores between groups (experimental, EG versus control, CG) at t0 (pre-treatment) and t1 (12months); the Paired Samples t Test was used to compare scores obtained at t0 versus t1 for each group (EG and CG).

For non-parametric distribution variables: The Mann-Whitney U-Test was used to compare scores between groups (EG versus CG) at t0 and t1; The Wilcoxon signed-rank test for paired samples was used to compare scores obtained at t0 versus t1 for each group (EG and CG).

Effect size estimates were calculated and reported for the principal outcomes. Subjects who dropped out of the study did not just drop out of the treatment, they also refused subsequent analyses, therefore an ITT analysis is not feasible.

The SPSS version 30.0.0.0 software for macOS (IBM SPSS Statistics, IBM Corp. 2024) was used for statistical analysis. All methods were carried out in accordance with relevant guidelines and regulations.

Human ethics and consent to participation declarations

Ethical approval of the experimental protocols

The study was conducted according to the Declaration of Helsinki. The protocol was submitted to and approved by the relevant ethical and review boards Comitato Etico Interaziendale AO "Santa Croce e Carle" di Cuneo AASSLL Cuneo 1, Cuneo 2, Asti, reference "ASL CN1/PSICH. 4" (Determina 00000576 del 24/03/2023). Prior to their participation in the study, all individuals were fully informed about the study scope, objectives, methodology and components, and they provided written informed consent. They were also informed that their participation was voluntary and they could withdraw from the study at any time. Written informed consent of the participants was obtained before the study.

Results

Recruitment process and drop-out

All 5 centers agreed to participate to the study; all of them ran the intervention after the training of mental health professionals. Each center was expected to recruit up to 6 individuals with mental disorders according to the criteria illustrated in the methodology. In all Centers the goal of 6 individuals was achieved. The sample starting the study consisted of 60 individuals, but on the first day one patient of the CG decided not to participate anylonger. In the same group other 8 individuals left the study during the fourth and the fifth month. In the EG three patients dropped out during the six months. At the end of the study, the total number of the sample was 48 (27 in the EG).

The socio-demographic characteristics and diagnoses of the sample

59 individuals started the study. 30 (51%) were allocated in the EG, 29 (49%) were allocated in the CG. 39 (66%) were male (19 of them in the CG), 20 (34%) were female (11 of them in the CG). 53 (90%) patients were single (27 of them in the CG), 5 (8%) were engaged (1 of them in the CG), 1 (2%) was married and in the CG. 55 (93%) patients were unemployed (26 of them in the CG), 4 (7%) were employed (3 of them in the CG) The mean age was 42,3 (±10), 39,2 (±10) in the CG. 39 (66%) users were affected by schizophrenia (20 of them in the CG), 15 (25%) by bipolar I disorder (6 of them in the CG), 5 (9%) by personality disorder (3 of them in the CG).

At the end of the study there were 48 patients. 27 (56%) were in the EG, 21 (44%) were in the CG. 33 (69%) were male (14 of them in the CG), 15 (31%) were female (7 of them in the CG). 43 (90%) patients were single (20 of them in the CG), 5 (10%) were engaged (1 int the CG); 43 (90%) were unemployed (20 in the CG), 5 (10%) were employed (1 of them in the CG). 33 (69%) users were affected by schizophrenia (16 of them in the CG), 12 (25%) by bipolar I disorder (4 of them in the CG), 3 (6%) by personality disorder, 1 of them in the CG).

The primary and secondary outcome of the sample and the statistical results

PSPS

In the EG the mean was 47.19 (sd: ±9.55) at t0, was 52.44 (sd: ±10.4) at t1; the difference pre-post was significant ($t=-23.7_{(26)}$ $p<0.001$). At t0 In the CG the mean was 49.05 (sd: ±8.07) at t0, 48.38 (sd: ±7.89) at t1; the difference pre-post was significant ($t=-3.4_{(20)}$ $p=0.001$). At t0 the difference between the groups was not significant ($t=0.020_{(46)}$ $p=0.98$), while at t1 it was significant ($t=2.02_{(46)}$, $p<0.05$).

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NEL

In the EG total score median was 147 (range 76-192) at t0, 165 (range 76-195) at t1; the difference pre-post was significant (Z=3.75, p<0.001). In the CG the median was 144 (range 111-174) at t0, 136 (range 111-170) at t1; the difference pre-post was not significant (Z=-1.25 p=0.209). At t0 the difference between the two groups was not significant (z=-0.790 p=0.429); at t1 the difference between the two groups was significant (z=-4.262 p<0.001).

STRESS scale

In the EG the total score median was 5 (range 0-15) at t0, 4 (range 1-13) at t1; the pre-post difference was significant (z=2.65, p=0.008). In the CG the median was 6 (range 1-13) at t0, 7 (range 3-27) at t1; the pre-post difference was not significant (z=0.836 p=0.403). At t0 the difference between the two groups was not significant (z=0.836 p=0.403); at t1 the difference between the two groups was significant (z=2,64 p=0.01).

BPRS

In the EG the total score median was 44 (range 29-81) at t0, 47 (range 29-68) at t1; the pre-post difference was significant (z=2.10 p<0.05). In the CG the median was 43 (range 28-71) at t0, 48 (range 28-71) at t1; the pre-post difference was not significant (z=1.90 p=0.057). At t0 and t1 the differences between the two groups were not significant, respectively with z=0.343 (p=0.731) at t0 and z=0.406 (p=0.685) at t1.

RBANS

In the EG the total score median was 74 (range 51-107) at t0, 82 (range 40-150) at t1; the pre-post difference was significant (z=2.73 p=0.01). In the CG the median was 69 (range 53-93) at t0, was 74 (range 40-120) at t1; the pre-post difference was not significant (z=2.25 p=0.24). At t0 and t1 the differences between the two groups were not significant, respectively with z=-.1.14 (p=0.25) at t0 and z=1.15 (p=0.248) at t1.

M-FPT, UDs

Both in the EG and in th CG the UDs score showed a median of 1 (range= 0-3) both at t0 and at t1; the pre-post difference was not significant (z=0.81; p=0.424; z= 0.82; p=0.414). At both t0 and t1 the differences between the two groups were not significant, respectively with z=-0.58 p=0.562 at t0 and z=0.166 p=0.868 at t1.

CSs

In the EG the CSs score showed a median of 2 (range = 0-4) both at t0 and at t1; the pre-post difference was not significant (z=0.853, p=0.39). In the CG the CSs score showed a median of 1 (range = 0-4) both at t0 and at t1; the pre-post difference was not significant (z=2.12 p=0.054). At both t0 and t1 the differences between the two groups were not significant, respectively with z=-1.31 (p=0.187) at t0 and z=1.01 (p=0.309) at t1.

ErrI

In the EG the ErrI score showed a median of 5.26 (range= 0-60) at t0, 3.00 (range= 0-13) at t1; the pre-post difference was significant (z=-3.329 p<0.001). In the CG the ErrI median was 2 (range: 0-25) at t0, 3 (range: 0-35) at t1; the pre-post difference was not significant (z=0.663 p=0.507). At t0 the difference between the two groups was significant (z=-1.963 p=0.050); at t1 the difference between the two groups was not significant (z=-0.107 p=0.915) (table 1).

Discussion

To our knowledge, the evaluation of the effectiveness of RGs for patients with SMI to improve empowerment by the involvement of significant others is rare. This multicenter randomized clinical trial is one of the first following that of Tjaden et al.[7]. Also, in our study the results seem quite promising showing that empowerment improved significantly when RGs were integrated into an effective approach elaborated to improve the functioning like the FM&R[20]. In fact, the difference between the groups that received FM&R-RG and the control group was statistically significant (p<0.001). In addition, the importance of the involvement of significant others is also demonstrated by the number of drop-outs very high in the CG; 8 patients abandoned the day-care center and refused to go on with the approach and also with the research. It is important to keep in mind that the CG received a similar approach but less structured and without the involvement of the significant others. The FM&R approach, particularly oriented to facilitate the involvement of significant others by the creation of an RG, led to findings consistent with the previous studies on the RG method[7], even if some were uncontrolled[31-33]. These results confirm that involving relatives, caregivers, friendly people living in the same community of patients is very important to improve functioning and facilitate the recovery for people with SMI.

According to the previous results of Tjaden et al.[7] «the strongest effects of the RGs were observed for empowerment, as we expected». Our explanation is similar to that given by this Author: by means of prompting patients to think and discuss about important aspects of their care, functioning and recovery goals, we obtain that «their ownership concerning

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Table 1. Primary and secondary outcome.

Variable	Experimental Group T0	Experimental Group T1	Experimental Group T0 vs T1 (a)	Control Group T0	Control Group T1	Control Group T0 vs T1 (a)	Experimental vs control T0 (b)	Experimental vs control T1 (b)
PSPS	$\bar{x}$ = 47.19 s.d. = 9.55	$\bar{x}$ = 52.44 s.d. = 10.48	t=-23.7(26)*** Cohen'd = 0.52	$\bar{x}$ = 49.05 s.d. = 8.07	$\bar{x}$ = 48.38 s.d = 7.89	t=-3.4 (20) *** Cohen'd = 0.08	t=0.020(46) ns Cohen'd = 0.21	t=2.02 (46) * Cohen'd = 0.43
NEL Scale	md = 147 (range76-192)	md = 165 (range 76-195)	z =3.75*** r = 0.72	md = 144 (range 111-174)	md = 136 (range 111-170)	z = -1.25 ns r = 0.27	z = -0.790 ns r = 0.11	z = -4,262 *** r = 0.62
STRESS Scale	md = 5 (range 0-15)	md = 4 (range 1-13)	z = 2.65** r = 0.51	md = 6 (range 1-13)	md = 7 (range 3-27)	z = 0.836 ns 3 = 0.18	z=0.836 ns r = 0.12	z = 2,64 ** r = 0.38
BPRS Total score	md = 44 (range 29-81)	md = 47 (range 29-68)	z = 2.10* r = 0.40	md = 43 (range 28-71)	md = 48 (range 28-71)	z =1.90 ns r = 0.41	z = 0.343 ns r = 0.05	z = 0.406 ns r = 0.0685
RBANS Total score	md = 74 (range 51-107)	md = 82 (range 40-150)	z = 2.25 ns r = 0.43	md 69 (range 53-93)	md 74 (range 40-120)	z = 2.73 ** r = 0.59	z = -1.14 ns r = 0.16	z = 1.15 ns r = 0.17
M-FPT UDs	md = 1 (range 0-3)	md = 1 (range 0-3)	z = 0.81 ns r = 0.16	md = 1 (range 0-3)	md = 1 (range 0-3)	z = 0.82 ns r = 0.18	z = 0.58 ns r = 0.08	z = 0.166 ns r = 0.02
M-FPT CSs	md = 2 (range 0-4)	md = 2 (range 0-4)	z = 0.853 ns r = 0.16	md = 1 (range 0-4)	md = 1 (range 0-4)	z = 2.12 ns r = 0.46	z = -1.31. ns r = 0.19	z = 1.01 ns r = 0.15
M-FPT ErrI	md = 5.26 (range 0-60)	md = 3 (range 0-13)	z = 3.329*** r = 0.64	md = 2 (range 0-25)	md 3 (range 0-35)	z = 0.663 ns r = 0.14	z = -1.963 ns r = 0.28	z = 0.107 r = 0.02

(a) Paired Samples t Test was used for the PSPS variable; Wilcoxon signed-rank test for paired samples was used for the other variables.
(b) Student's t-test was used for the PSPS variable; Mann-Whitney U-Test was used for the other variables. The effect size is written below the t (as Cohen's d) and z (as r)
*** p<0.001; ** p<0.01; * p<0.5; ns = not significant.
Legend: $\bar{x}$ = average; s.d.= standard deviation; md= median; PSPS= Personal and Social Performance Scale; NEL= Netherland Empowerment Scale; BPRS= Brief Psychiatric Rating Scale; RBANS= Repeatable Battery for the Assessment of Neuropsychological Status; M-FPT= Modified Five-Point Test; UDs= Unique Drawings; CSs= Cumulative Strategies; ErrI= Error Index.

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illness and recovery was vitalized»[7]. The importance of relatives and social network to the process of empowerment in facilitating self-esteem and self-efficacy has been well known for years[20]. At the same time also the implementation of problem-solving strategies within psychoeducational interventions has an «impact on clinical and functional outcomes, by providing patients with long-lasting resources to manage daily life more effectively»; that means, in other words, empowerment[34]. FM&R dedicate many training sessions to the problem-solving. However, from the archaic work of Falloon et al.[31] up to the recent one of Lee et al.[3], empowerment should not be considered only as an outcome but also as a mediator factor for Functioning. This is very important for us, because in our salutogenic perspective, as discussed in previous papers[13,20], the emphasis is on the Functioning. Work is then more focalized on comprehension, significance and meaningfulness of adverse events and stressful conditions, as well as on the capability to use personal and environmental resources. At the same time, pragmatic work by means of the Behavioural Changement Shedule (BCS) illustrated in detail in our paper by Veltro et al.[20] plays a fundamental role. In fact, patients are invited in the group to formulate goals of behavioral changement for each dimension of the Functioning, as for instance self-care, sleeping, activities, hobbies, mastery and so on, as suggested by the dimensions of International Classification of Functioning[34]. Functioning score is improved by 5 points in the EG, while in the CG the score decreases by about 1 point. However, the amelioration of functioning is consistent with the results obtained in the previous studies using the FM&R[20] and InteGRO[13]. A similar impact was found on the Stress level between the two groups ($p<0.01$). The link between stress management and Problem-Solving Training has been known since 1990[35] and well investigated also in Real World[36,37].

A general overview about the positive results of outcomes, that means Functioning, Empowerment and stress, deserves a consideration about the contents of the approach. In fact, we would like to underline that many training sessions included in the FM&R-RG regard emotional literacy and recognition of emotions on others' faces; the importance of emotional processing for social functioning in people with psychotic disorders has been well known for years[38]. In Galderisi et al.[39] emerged that the connection between emotion recognition and functional capacity highlights the role of social and emotional processing in general psychosocial functioning. For Thaler et al.[38], a patient capable to comprehend social and emotional stimuli acquires better interpersonal skills needed for some functional capacity tasks. We also believe, on the basis of our long experience with this kind of approach, that the salutogenic approach and the use of positive psychology play an important role. In fact, prompting high levels of positivity, which means to see life and experiences in a positive light as well as to consider adverse events as challenges, is associated to better functioning[40,41]. According to Martinelli et al.[41], people with a diagnosis of schizophrenia and higher positivity levels showed improved interaction skills, work abilities, and engagement in pleasant activities. In addition, working in groups creates supportive pair-to-pair interactions and encourages to set realistic and pleasant goals for personal and interpersonal changes and to improve the capacity to evaluate progress[42].

For what concerns the secondary outcomes, no differences between groups were found in psychopathology. We hypothesize this may be due, at least in part, to the fact that total scores of BPRS were not high. Moreover, this could also be due to high levels of drug adherence in both the EG and CG; indeed, we observed both a psychopathology improvement in the EG and a trend toward improvement in CG. Adherence was assured by the attendance of patients to the day-care centers, a basic condition to participate in the activities of the facilities. Similar results were found about cognitive functioning; no differences between groups were found; in the EG we observed a statistically significant pre-post improvement, ($p<0.01$) but not in the CG. Probably the more structured problem-solving sessions which took place in the EG could explain this improvement, while in CG the free discussion sessions may have been useful but less effective and thus did not lead to statistical significance. However, this is a clinical observation because unfortunately the lack of significance between groups does not strongly support this consideration. No differences were found between the two groups at the end of the study about cognitive flexibility, an ability of mind common in psychopathology[43] and one of the most important to promote psychological wellbeing[44], which may be nevertheless very difficult to improve in SMI because of altered whole-brain functional connectivity[45].

Conclusions

To our knowledge, this is the first randomized controlled multicenter study testing the effectiveness of a psychoeducational recovery-oriented intervention with a RG, based on a salutogenic approach, with the explicit goal to improve empowerment of people with SMI living in the community. There are other studies with RG, the most recent with a randomized controlled study design but it is not entirely psychoeducational and it is not based on the salutogenic approach[7]. However, the version of FM&R with the RG has been elaborated thanks to the experience and the work of the team of Malm et al.[32,33] and of Thiaden et al.[7].

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The results of this study showed a positive impact of the intervention on the primary outcome measures, above all Functioning, Empowerment and Distress. Regarding the secondary outcome measures, the impact has been not so good as we expected and less relevant than what we observed with similar approaches previously. We are referring especially to the cognitive functions. However, should these data be confirmed, this intervention could be integrated with dedicated approaches, cognitive remediation programs for instance.

The strengths of this intervention are that it is structured, manualized, and based on a psychoeducational and salutogenic approach, and it includes a Resource Group. On the basis of the results observed, it may also be considered efficient because of the limited number of sessions and the improvement consolidating over time. The limit could concern the organizational problem about the involvement of relatives or significant others to create a RG.

The strength of the study is the large number of variables explored, the methodology and that it is a randomized controlled multicenter study in different geographic contexts. At the same time due to the type of a study, which is multicenter, the patients evaluated at the end of study were only 48 out of the 60 who started the study and this represent a limit even if the results can be indicative and encouraging.

The limit of the study can be the drop-out rate for the intervention as well as for the assessment at the end of study that affected above all the CG, which could have influenced the statistical comparison between the two groups.

We have then to consider conducting future studies with a more targeted choice of secondary outcome variables; the replication of the results is also recommended.

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Availability of data and materials: the datasets generated and/or analyzed during the current study are not publicly available because individuals with mental disorders did not provide consent for their data to be shared with third parties. However, data may be available from the corresponding author upon reasonable request and with added patient consent for such data to be shared.

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Consort 2010 Guidelines: we followed the Consort 2010 guidelines.

Informed consent for participation: prior to their participation in the study, all individuals were fully informed about the study scope, objectives, methodology, and components, and they provided written informed consent. They were also informed that their participation was voluntary and they could withdraw from the study at any time. All participants provided written informed consent to participate in the study.

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Contributions: FV conceived the study and wrote the first draft, GL performed statistical and co-wrote the first draft, CP contributed to the statistical analyses and co-wrote the first draft, MA and FC conceived the study and provided feed-back, MB conceived the study and provided feed-back, LS and GC were in charge of data collection and provided feed-back, IN and IP co-write the first draft, DM and SI provided feedback and participated for finalizing the manuscript, FM&R-RG Working group provided feedback.

Ethics declarations: ethical approval of the experimental protocols. The study was conducted according to the Declaration of Helsinki. The protocol was submitted to and approved by the relevant ethical and review boards Comitato Etico Interaziendale AO Santa Croce e Carle di Cuneo AASSLL Cuneo 1, Cuneo 2, Asti, Via Monte Zovetto, 18 – 12100 CUNEO, reference "ASL CN1/PSICH. 4" (Report 75/22 of 27/04/2022; prot. n. of General Management Resolution Measure 01121153 of 09/09/2022). Prior to their participation in the study, all individuals were fully informed about the study scope, objectives, methodology, and components, and they provided written informed consent. They were also informed that their participation was voluntary and they could withdraw from the study at any time. The informed consent of the participants was obtained before the study.

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Appendix: the units of the manual that are equivalent to the meetings with patients

Meeting Numbers	Topics covered
1	First meeting to illustrate the presentation to each other and the work to be done
2	Stress-Vulnerability model
3	To identify personal stressful events
4	To define social network and identify 2-3 key-people for each participant to contact for the next joint meeting
5	Meeting users (Us) and Key-People (RG) to explain what we do, the goal and the role of RG
6-7	Definition of 2 Pleasant Goals for each patient
8-9	Problem Solving Training
10	Meeting Us+RG to explain what we did, the defined goals of Us and what we will do
11	Better understanding of the fear and its purpose
12	Better understanding of the sadness and its purpose
13	Better understanding of the shame and its purpose
14-15	Definition of Life Goals: starting to work with the Behavioral Changement Schedule (BCS)
16	Meeting Us+RG to explain what we did, the defined goals of Us and what we will do
17	Better understanding of the joy and its purpose
18	Better understanding of the anger and its purpose
19-20-21	The ABC Restructuring Thinking Model
22	Meeting Us+RG to explain what we did, the defined goals of Us and what we will do
23	Jumping to conclusions: introduction and exercises
24-25	How to recognize the emotion on the other face: the use of a double blackboard
26	To modify Life-Style: Planning the Behaviour change using the BCS
27	Calm your mind through the conscious breathing
28	Meeting Us+RG to explain what we did, the defined goals of Us and what we will do
29-32	Booster Sessions

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