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Evaluation of a psychoeducational intervention adapted from the Falloon model for first episode psychosis: a one-year follow-up real-world study

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Summary. Aim. To evaluate the effectiveness of the Falloon Psychoeducational Family Intervention (PFI), originally developed for the management of schizophrenia, afterwards adapted for early psychosis, in terms of adherence to the treatment, low relapse rate, improvement social functioning and stress management. **Methods.** This is a one-year, pragmatic, real-world observational study with subjects consecutively recruited at the Campobasso psychiatry ward (SPDC) or Mental Health Center (MHC) starting in November 2020 over an 18 month period. Patients recruited were asked for consent for family members' participation. The effectiveness of the intervention was evaluated in terms of treatment adherence, discontinuity, relapse rates, clinical symptoms assessed by BPRS and PANSS, improvement in social functioning and stress management. **Results.** 13 subjects were recruited; 10 males and 3 females, all singles, with a DUP inferior to one year. At the end of the intervention, significant improvements in treatment adherence, absence of drop-outs and relapses, statistically significant improvements in clinical symptoms, social functioning and stress management were found. **Discussion and conclusions.** The results clearly show that family psychoeducational intervention according to the adapted Falloon model, specifically focused on crisis and early stress management, is effective in improving treatment adherence, clinical outcome and social life of first-episode psychotic patients. The limit is the lack of a control and randomization

Key words. Early intervention, family psychoeducational intervention, first-episode psychosis, social functioning, stress management.

Valutazione di un intervento psicoeducativo adattato dal modello di Falloon per i primi episodi di psicosi: studio real-world di follow-up a un anno.

Riassunto. Scopo. Valutare l'efficacia dell'intervento psicoeducativo familiare di Falloon (PFI), originariamente sviluppato per la gestione della schizofrenia, successivamente adattato per le psicosi precoci, in termini di aderenza al trattamento, basso tasso di ricaduta, miglioramento del funzionamento sociale e gestione dello stress. **Metodi.** Si tratta di uno studio osservazionale pragmatico real-world della durata di un anno con soggetti reclutati consecutivamente presso il reparto psichiatrico di Campobasso (SPDC) o il Centro di Salute Mentale (CSM) a partire da novembre 2020 per un periodo di 18 mesi. Sono stati reclutati 13 soggetti; 10 maschi e 3 femmine, tutti single, con DUP inferiore a un anno. Ai pazienti reclutati è stato chiesto il consenso per la partecipazione dei familiari. L'efficacia dell'intervento è stata valutata in termini di aderenza al trattamento, discontinuità, tassi di recidiva, sintomi clinici valutati da BPRS e PANSS, miglioramento del funzionamento sociale e gestione dello stress. **Risultati.** Al termine dell'intervento sono stati riscontrati miglioramenti significativi nell'aderenza al trattamento, assenza di abbandoni e ricadute, miglioramenti statisticamente significativi nei sintomi clinici, nel funzionamento sociale e nella gestione dello stress. **Discussione e conclusioni.** I risultati mostrano chiaramente che l'intervento psicoeducativo familiare secondo il modello adattato di Falloon, specificamente focalizzato sulla gestione delle crisi e dello stress precoce, è efficace nel migliorare l'aderenza al trattamento, l'esito clinico e la vita sociale dei pazienti psicotici al primo episodio. Il limite del presente studio è la mancanza di un controllo e di una randomizzazione.

Parole chiave. Funzionamento sociale, intervento precoce, intervento psicoeducativo familiare, primo episodio di psicosi, stress management.

Introduction

As known, adherence to pharmacological treatment, to the treatment program, and the hospitalization rate in the FEP are aspects of fundamental importance, because they are closely linked one another. Relapses are obviously linked to adherence[1]. In a meta-analysis of 29 studies involving 3928 young patients with psychosis, nonadherence to antipsychotic medications resulted in a four-fold increase in the OR of relapse (OR 4.09, 95% CI 2.55, 6.56; p<0.01). An 18-month cohort study with 605 patients with early psychosis documented that 19% refused treatment with antipsychotic drugs[2]. In another retrospective cohort study on Early Psychosis, as many as 62% of patients discontinued treatment during the first year,

16% at month 1 and 34% at month 3. While treatment discontinuation was predictive of involuntary hospitalization (HR: 7.14 p=0.015 95% CI=[1.48 -34.52]) at the first month and of the total number of hospitalizations (HR:6.86 p<0.0001 95% CI=[2.47-19.05]), the predictive factor of good adherence was the higher number of outpatient visits (HR: 0.85 p<0.0001 95% CI=[0.0-0.9]). Initial management of the care also appeared to play an important role[3]. Studies have recently turned towards Long-Acting Injection (LAI) drugs since in some meta-analyses they have shown to be superior to oral treatment in terms of adherence and reduced discontinuity of treatment[4], to be effective and safe even for the first episodes of psychosis[5-7]. With LAIs, benefits are observed when professionals are able to provide person-centered care and when the options among the various LAIs are extensively discussed with the patient[8]. In one of the most recent meta-analyses, the authors conclude that educating patients and family members about the benefits of LAIs can help choose the best treatment options to achieve optimal clinical outcomes[9]. Therefore, even if LAIs can be considered the best drug treatment option, it is necessary to integrate them with psychoeducational interventions and the involvement of family members. Indeed, for this reason family psychoeducational interventions are recommended by most guidelines also for the early psychosis[10]. As known, they are considered not only effective, but necessary and a priority for severe psychiatric disorders as shown by several, regularly updated meta-analyses[11]. Among these interventions, the interventions developed by Falloon deserve a particular mention for the consolidated experience enduring over 20 years[12], for their use among the optimal evidence-based treatment strategies[13], for being considered of fundamental importance at onset[14]. These interventions have also proved effective in Italy in reducing relapses and re-hospitalizations through an increase in the adherence to pharmacological therapy even at 11 year-follow-up[15], in improving clinical symptoms, social functioning and in decreasing family burden[15,16]. In our country there have been various adaptations for Bipolar Disorder[17] with efficacy results at 5 years[18] and for multifamily intervention[19] also with the subsequent elaboration of an ad hoc structured manual[20]. No specific adaptations of Falloon's intervention for FEP are known. Indeed, the author himself, in one of his last contributions[21] declared that an optimal treatment for the first cases of schizophrenia has not yet been well defined and that further research is required. He hypothesized that probably even the simplest educational programs would be sufficient for some first episodes, while for others more articulated and complete therapeutic programs to achieve and sustain a satisfactory recovery would be necessary. We agree with Falloon that all evidence-based interventions are far from perfect and therefore continuous readjustment is necessary[21]. This is what has been done in the last 20 years by the team of the Community Mental Health Center of Campobasso (CMHC) who, with consolidated experience, have adapted these interventions in different contexts[22] and to different purposes[23]. The team also routinely applied Falloon's approach in the CMHC, unlike what happens in Italy where there has been historical resistance in the application of psychoeducational interventions[24]. Therefore, the adaptation, as considered by Falloon himself, also responds to the limits of an approach generally proposed with a psycho-didactic modality focused on information as critically highlighted by some authors[25]. The contents of the information component reworked by the CMHC team concern: a) the experience of the crisis, i.e. what happens in terms of experience and perception of change; b) explanation of symptoms according to stress and bio-psycho-social vulnerability; c) the meaning of the crisis also as a function of understanding what happened before; d) knowing how to accept the crisis as a basis for changing lifestyles and behaviors. These changes are substantial because the psychotic onset has a significant impact on the life of the person and the family. Nevertheless, in most cases, with the exception of the few services activated ad hoc, FEP is approached by doctors merely from a professional point of view as an acute event of a long-term disorder. Conversely, more and more attention must be paid, as already considered in guidelines[26], to the fact that onset is a process that evolves in different phases and must be approached phase by phase, also in order to instill a sense of hope[27]. The awareness of the importance of DUP in prognostic terms has led to the creation of specific services for early interventions; anyway, these services, we underline, are few and much attention is given to reduce stigma and symptoms, to provide a strong taking charge with psychosocial support to the person and his family. However, even in these services, attention is less focused on what young people with an onset find most pressing in a phase of "challenges" and calls of daily life[28]. An *ad hoc* study on this issue has revealed that young people with FEP experience considerable challenges in their social life before and after DUP[29]. An interesting contribution has recently been published for a qualitative investigation of how young people experience and understand the process of developing a FEP[25]. Our re-elaboration of the intervention carried out in 2020 on the first component (Definition of Goals) and above all on the second one (Informative) of the Falloon intervention[30] agrees with what was claimed by Hansen et al.[25]. Attention was therefore focused on issues relating to:

a) "stressful life situations" which refers to the period prior to the psychotic experience;

b) "personal description and definition of the emotional, behavioral and cognitive problems of the psychotic experience", specifying that these problems actually concern both the psychopathological aspects of psychosis and the symptoms of stress-related discomfort associated with emotional experiences;
c) "redefining the meaning of psychosis in terms of acceptance of a new phase of one's existence", characterized by a new life path also centered on the awareness that stress is an integral part of the presence of "everyday challenges". Therefore, a salutogenic intervention addressed to the necessary changes for the future and not a medicalizing approach based on clinical remission to restorate abilities at prior level.

This approach has not been entirely manualized yet. The Psychiatric Rehabilitation Technician (TeRP) who delivered the intervention is an expert and a trainer in psychoeducation as well as in the art of Socratic dialogue or questioning, co-author of various manuals in this sector[20,23]; TeRP used for this approach written procedures with various examples of dialogue. It is a psychoeducational approach anyway, but specifically adapted from the Falloon model for First Episode Psychosis (FEP).

In this paper we show the results of a real-world study carried out on a consecutive sample of previously untreated young adults at onset, candidates for early intervention, admitted for the first time to the SPDC or who went to the CMHC for psychiatric emergencies. Our hypotheses were that the psychoeducational intervention, as specifically adapted for FEP, would be well accepted by patients and family members, with an estimated dropout rate of less than 5%, good adherence to the course of care, to drugs and to psychosocial intervention, with discontinuity of less than 10%, relapses less than 10%, and an improvement in social functioning and optimal stress management.

Methods

This is a one-year observational naturalistic study carried out in the real world between 2020 and 2023 on young adults with FEP consecutively enrolled in the Psychiatry ward (SPDC) and the Center for Mental Health (CMHC) of Campobasso. The primary outcomes are: a) Drop outs <5%; b) discontinuity of treatment and/or non-adherence to drugs and treatment program <10%; c) relapses <10%; d) improvement on the FPS scale greater than 10 points from the baseline level. The secondary outcomes were significant improvement in stress management and significant decrease in symptoms.

Recruitment

Starting from November 2020, in each of the two health centers, patients with FEP were consecutively invited to participate if they met the following inclusion criteria: a) age between 18 and 30; b) absence of previous treatments; c) cohabiting with at least one relative, aged between 18 and 70, not affected by any disabling physical or mental disorder; d) informed consent to participate in the study and to involve key relatives. Patients were excluded if they: a) had previously received a psychiatric diagnosis and/or been treated for a psychiatric disorder; b) were suffering from a severe physical illness requiring intensive medical care; c) lived with a family member suffering from a serious physical illness requiring intensive medical care; d) suffered from alcohol or substance addiction; e) showed antisocial traits that prevented negotiating treatment.

All patients who agreed to participate were asked for permission to contact and involve their family members. Key family members were defined as those who spent the greatest number of hours in contact with the patient in the last year.

The intervention was designed to be suspended if the patients or family members could not participate in more than 4 psychoeducational sessions or if they withheld their consent. The patients included in the study received the routine treatment that is provided at the CMHC of Campobasso which includes, on the basis of the personalized therapeutic program, pharmacological treatment based on the NICE guidelines, psychotherapy and/or individual psychological support and individual rehabilitation project where necessary, based on the evaluation of the dedicated team. Systemic or strategic-relational family therapy was excluded.

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. All patients and relatives received detailed study information and provided written informed consent before inclusion in the study.

Description of the intervention

The experimental treatment is based on the psychoeducational family intervention developed by Falloon[30] for patients affected by schizophrenia and their families, adapted by our research group to be used in the introductory part in a new way with the original one. The substantial changes, as briefly described in the introduction, concern both the first (Definition of Goals) and the second (Informative) component of the Falloon intervention. As far as the first component, a family session explicitly dedicated to the definition of pleasant goals is scheduled. In this session, the definition of the stress-vulnerability-

coping model is first introduced to the patient and the family members; secondly, the definition of pleasant goals and the importance of developing pleasant goals are described; thirdly, every single patient is required to identify and choose at least one pleasant goal according to the SMART methodology (i.e. specific, but also challenging according to the authors; measurable; achievable but also self-esteem related according to the authors; relevant; time-based).

Furthermore, our changes mainly focused on the second part of the intervention, i.e. the informative one. As briefly described in the introduction, we chose to focus especially on three issues: a) "stressful life situations"; b) "personal description and definition of the emotional, behavioral and cognitive problems of the psychotic experience"; c) "redefining the meaning of psychosis in terms of acceptance of a new phase of one's existence".

As far as stressful situations, our work tries to lead patients to identify anomalous experiences and delusional beliefs in the first place. Second, patients are asked to clarify antecedents of onset using the stress/vulnerability model and to identify stressful events that preceded onset. Thirdly, a normalizing interpretation of psychotic symptoms and the identification of dysfunctional ways of thinking are facilitated. Fourth, a generalization is fostered to consider positive symptoms as an attempt to explain emotional distress and unusual perceptual experiences. Finally, factors facilitating relapse and its prevention are analysed. All these activities are crucial to reconstruct the prodromal symptoms and their meaning together with the patient and the family.

After prodromal symptoms, psychotic experiences are addressed. The TeRP helps the patient achieve a personal description and definition of the emotional, behavioral and cognitive problems concerning the psychotic experience. In this phase work is focused on different issues at the same time, seeking to address psychotic symptoms, secondary emotional experiences, and stress-related discomfort.

The third phase aims at redefining the meaning of psychosis in terms of acceptance of a new phase of one's existence. A new vision is fostered, inviting the patient and family members to consider the FEP as an experience, a challenge to which a meaning can be attributed. All these processes take place outside of a medicalizing context and within a salutogenic context of approval and support.

The overall structure of the intervention consists of the following traditional sessions: a) individual and family evaluation; b) definition of goals; c) exchange of information on the basis of the Socratic dialogue, about the three themes of the informative component previously illustrated; d) personalized information on treatment and early signs of relapses; e) communication skills; f) problem solving skills; g) specific strategies to deal with a personal problem, isolation and organization of daily life; h) booster sessions. Sessions take place every week for three months, every fortnight for the next three months, then every thirty days for the next 6 with supervision sessions every three months. Each session lasts approximately 90 min. The location, outpatient and/or home, is adapted to the needs of families and the tasks and workloads of mental health professionals. All outpatient meetings take place at the CMHC by the expert Terp. There are written handouts for encounters b) and f), while for the other encounters reference is made to the Falloon manual[30].

Assessment tools

For the improvement of the patients' social functioning, the Italian version (FPS) of the PSPS scale was used[31] as in CMHC professionals' routine. The FPS was completed by the patient's referral personnel designated at community team meetings. Likewise the other tools, the FPS evaluates the personal and social functioning of the person with a semi-structured interview and the information available from acquaintances and from the operators themselves. There are 4 main areas: 1) socially useful activities (including work and study); 2) personal and social relationships; 3) care of appearance and hygiene; 4) disturbing and aggressive behaviors. The overall score ranges from 0 (worst possible performance) to 100 (excellent performance).

The referring physician assessed the clinical status of the patients by the Brief Psychiatric Rating Scale (BPRS) and by the PANSS; the level of Stress also was rated bimonthly.

The BPRS is a semi-structured interview on psychopathological status, comprising 24 items, grouped into four subscales: positive symptoms, negative symptoms, depressive-anxious symptoms and manic-hostile symptoms. Each item is rated on a seven-level scale, ranging from 1 (no symptoms) to 7 (very severe symptoms)[32].

The PANSS (Positive And Negative Syndrome Scale) integrates 18 items of the BPRS with 12 of the Psychopathology Rating Scale - PRS[33] and divides the 30 new items into three distinct clusters, one for positive symptoms (7 items), one for negative (7 items) and one for general psychopathological symptoms (16 items). The handbook accompanying the scale provides a detailed explanation of the individual items and symptom quantification criteria (which are rated on a 7-point scale).

Stress was assessed using the Stress Scale[34] made up of 9 items taken from the well-known and widespread Goldberg tool for investigations in routine conditions with a no-yes dichotomous answer, which evaluates the presence of stress if the score is greater than 10.

The clinical and sociodemographic characteristics of the patients, as well as the sociodemographic characteristics of the relatives at baseline were recorded by an ad hoc questionnaire. Information included DUP measured in days, age, gender, schooling, other psychosocial treatments received during the intervention. Complete adherence to drug treatment was mandatory at the start of the study.

Statistical analysis

Sociodemographic and clinical differences in the patients at baseline and end of intervention were tested using paired-samples t-tests for parametric variables. Non-parametric tests, such as the Wilcoxon test, were used for variables with a non-normal distribution. SPSS 21.0 software (SPSS Inc., Chicago, IL, USA) for macOS was used for analyses.

Results

Sample

The sample consisted of 13 patients, 10 males and 3 females, singles, with an average age of 25.77 (±5.3), an average schooling of 14.15 (±3.1) and with an average DUP of 154.23 (±96.01). Pharmacological treatment was shared between the patient and the referring psychiatrist. Psychological support was offered for three patients and was accepted.

No drop-outs were observed both in patients and in family members.

Sociodemographic characteristics of the relatives included: a total of 30 subjects, average age 48 (±8.2), 44% male/56% female, 33,3% mothers/33,3% fathers /3.3%partner/30%siblings.

During the intervention, patients did not experience relapses, hospitalizations, and clinical worsenings requiring a significant change in the drug treatment. No discontinuity of drug therapy was observed. Adherence to the treatment plan and to psychological support was 100%. The adherence to the psychoeducational intervention by patients and family members was 100%.

In the analyses (table 1) an improvement in the BPRS total score was found with a difference of -32.54 between the initial score (88.46±13.22) and T1 score (55.92±11.09; p<0.001). An analogous improvement concerned the PANSS total score with a difference of -69 between the initial score (141.46±19.46) and T1 score (72.46±15.64; p<0.001). The same results were obtained for the subscales of positive and negative symptoms and general psychopathology (table 1). Stress level decreased from 14.4 (±2.6) to 11.69 (±2.25) with a difference of -2.71 (p=0.35). FPS improved by 14.69 points (p<0.001) from baseline mean value of 43.46 (±6.79) to final mean value of 58.15 (±9.00).

Discussion

To our knowledge, this is the first study testing the effectiveness of a modified version of Falloon's early psychoeducation method. This study has a strengths, i.e. it is a real-world study recruiting patients in a context of a health care service with the adoption of broad inclusion criteria for patients and family members. Our study hypotheses were all confirmed. Firstly, the adherence of the intervention by the entire family nucleus showed no drop-outs. The patients correctly took therapy as discussed and agreed with the referring psychiatrist, a rare event since non-adherence is reported as widely present and a predictor of relapses in these subjects[1-9,35,36]. Adherence cannot be explained even by the chosen drug types and pharmacological efficacy, since discontinuity and consequent relapses are also present with the use of LAI[3,4,9]. The use of LAI itself may not guarantee adherence, but it should be underlined that this formulation is perceived coercive by many patients, and also in this case psychoeducational strategies are needed to strengthen this type of treatment[37]. It has been shown that also first-episode patients like to re-

Table 1. Clinical and Social improvement at 1 year follow-up±.

	T0 (m ± ds)	T1 (m,ds)	Delta	t	IC 95%	p
FPS	43,46 ± 6.79	58.15 ± 9.00	14.69	6.6	9.84 19.54	0.000
BPRS*	88.46 ± 13.22	55.92 ± 11.09	- 32.54			0.001
PANSP	32.77 ± 1.40	14.31 ± 2.98	- 18.46	14.5	15.69 21.22	0.000
PANSN	33.23 ± 5.67	19.38 ± 5.00	- 13.88	12.83	11.49 16.19	0.000
PANSGN*	75.46 ± 6.79	39.15 ± 8.96	-36.31			0.001
PANST	141.46 ± 19.46	72.46 ± 15.64	- 69	15.56	59.01 78.21	0.000
STRESS	14.4 ± 2.6	11.69 ± 2.25	- 2.71	2.39	.26 5.43	0.34

* Wilcoxon Test.

ceive information about pharmacological treatment, and that adherence can be explained by information given about the drugs taken[35]. In our study there were no relapses, recurrences or hospitalizations during one year. This is a very important finding, because in other studies of first episodes the relapse rate is estimated to be up to 37.7%[36]. No significant changes in therapy and/or drug dosage were observed during the course of the study, since the careful assessment of the early signs of crises and the strategies adopted by the patient and his family were timely and effective in avoiding a psychopathological exacerbation. This is also explicitly proven by the lack of access to the Emergency Department or by the request for emergency interventions at the CMHC. However, it should be noted that among the FEP there were no subjects suffering from addiction as well as subjects using amphetamine-like substances (which represent a predictive factor of relapses) because they did not match the inclusion criteria[1]. Social functioning improved substantially (table 1). Historically, in early studies, relapse rates and clinical remission are often used as a clinical outcome, even with psychoeducational intervention conducted with the single family or with the multifamily[38]. Recently, however, social functioning[39] and lifestyle changes[40] have been the most frequently considered outcomes. We also used the social functioning outcome which is more difficult to achieve as an objective outcome over a year, but certainly harmonizes with the type of intervention. In fact, in our approach patients are invited to establish small pleasant goals at the beginning of the intervention and more structured personal goals (i.e. studying, working, improving social network) after the first three months of the intervention. We explain the improvement not only as a consequence of the clinical improvement fully ascertained with two different assessment tools, but above all as a result of problem-solving training and as a result of the participation of family members as protagonists. In this intervention, the relative becomes a helper, i.e. an informal lay-worker integrating the service team in a support network in order to facilitate patients achieving personal goals. Thanks to the intervention, family members are put in a position to better understand the nature of the disorder, the role of stress, the relevance of stressful situations already present before onset. The improvement in professional help provided by family members confirms their need to receive information and support from mental health professionals and to have a key-role in the care of their loved ones[17]. The large number of patients and relatives who participated in all the intervention sessions may indicate that this approach, focused on stress and on giving meaning to the crisis as an opportunity for growth and change, manages to involve them deeply. The same happens with severe mental disorders with a long history of illness[15,17], but in our study we observed more promising results. In fact, we have to consider the marked improvement in functioning and the absence of hospitalizations and relapses which represent an extraordinary result. Finally, it should be noted how important the involvement of families is; indeed, in southern European countries families have proved to be very cooperative and supportive when a member suffers from very serious health problems[41-43]. We were not able to detect statistical differences between patients recruited in the ward and patients recruited in the mental health center, as only one person was recruited in the ward during the study. As regards our clinical observations, in this latter case we noted a greater emotional involvement by the family members, which resulted in a more engaged commitment in understanding the events that led to hospitalization and a closer support to their relative during the intervention. In our opinion, this is especially important, as relatives and caregivers play a crucial role in service engagement, which in turn is related to DUP reduction and functioning outcomes[44,45].

Conclusions

This real-world study has several limitations. Most importantly, this is an uncontrolled randomized clinical trial. Furthermore, due to a very low sample size (13 recruited patients consisting, among other things, mainly of males), the possibility to generalize the results is severely limited and future studies with larger samples should be planned. The gender prevalence probably was affected by the exclusion criteria that influenced girls to a greater degree, and by a known lower accessibility to services for psychotic disorders for the female gender in the Molise region.

This is a pragmatic study carried out in the “real world” at a SPDC and a CMHC dedicated to routine care with evidence-based interventions that may have had a “cointervention” and “confounding” effect. However, it is noteworthy that all the patients and all their families adhered to the treatment, differently from most other studies using similar types of approach; indeed this kind of interventions, even if well conducted and effective in improving adherence, tend to record some lack of consent at the start of treatment and a small percentage of dropouts during treatment[18]. These outcomes counterbalance the limitations relating to the study design, since we are faced with a result in which the absolute best possible benefit was observed: absence of drop-outs, absence of discontinuity, absolute adherence to drug treatment and proposed intervention, absence of relapses. These findings are associated with marked improvement in personal and social functioning that improved the FPS scale performance by one level.

Some might argue that the stress level, albeit significantly improved, remained high. This fact is to be considered positively, as all the users kept active. As a consequence they had to face the daily challenges represented by studies, social relationships, the commitment to achieve pleasant goals and goals related to life changes, as expected in Falloon's psychoeducational interventions. On the basis of the many improvements observed, the authors set themselves four objectives. Firstly, to manualize the intervention. Secondly, to propose to the patients and family members of this study participation in multifamily care based on problem-solving[20]. Thirdly, to carry out monitoring during the next year, totalling two years. Fourthly, to carry out a multicenter study, in which larger samples are needed, using a randomized controlled trial design.

Declarations:
- All methods were carried out in accordance with relevant guidelines and regulations.
- *Consent for publication*: all authors gave their consent for publication.
- *Availability of data and materials*: the datasets generated and/or analysed during the current study are not publicly available because data are currently under analysis for further pubblication but are available from the corresponding author on reasonable request.
- *Competing interests*: there are not competing interests.
- *Fundings*: no fundings were requested for the study.
- *Authors' contributions*: F.V., G.L., I.P. wrote the manuscript; G.L., C.P., F.V. made data analysis and statistics; I.N. and L.Z. prepared the figure and references and contributed to discussion and conclusions. All authors reviewed the manuscripts.

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