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A Randomized Controlled Implementation Trial of a Multicomponent Integrated Care Program to Empower Mental Health Service Users and Their Relatives Throughout the Recovery Process

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Abstract

This study assessed the effectiveness of a psychosocial multicomponent program designed to empower individuals experiencing severe mental distress and their relatives throughout the recovery process. The program consisted of four consecutive interventions including orientation, psychoeducation, empowerment, and mutual-help. A randomized controlled implementation trial was conducted to investigate the program's impact on the recovery of individuals experiencing mental distress, as well as on the caregiving burden and perceived social support experienced by their relatives. Two hundred and twenty-two persons in recovery and one of their relatives from twelve different territories within Catalonia, Spain took part in the study. The intervention group exhibited higher recovery scores compared to the control group at six months, although this difference was not sustained at the twelve-month follow-up. No statistically significant differences were found for burden and social support scores between experimental groups. However, time effects were found for recovery and burden scores regardless of experimental group membership. Dose-effect analyses showed that participation was related to recovery and burden scores, with no time interactions observed. Upon examining the interaction with sociodemographic variables, we discovered statistically significant group-by-time interactions, suggesting a more positive progression of recovery scores when either the person in recovery was younger, their relative was female or lived outside of the Barcelona Metropolitan Area. These results allow us to conclude that the program has a positive effect on the recovery journey. However, the lack of effectiveness regarding burden and social support in relatives highlights the necessity of reconsidering implementation and evaluation strategies.

Public Policy Relevance Statement. Our study suggests that a multicomponent program, empowering mental health service users and their relatives shows promise for positive outcomes. However, evaluating this complex intervention with widespread implementation using an experimental design pose inherent challenges. Further investigation is needed to explore intervention effectiveness considering participant characteristics and contextual factors. Understanding these interactions can refine the program, ensuring positive outcomes.

Keywords: Community care; burden of care; integrated care; mental health; recovery; randomized controlled implementation trial; severe mental distress; social support.

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The trial was registered with the International Standard Randomized Controlled Trial Number (ISRCTN) registry, number 15181312 at <https://doi.org/10.1186/ISRCTN15181312>. Data have been anonymized and variables describing location are numerically coded, so identification of single individuals is not possible. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees.

The process of recovering from severe mental distress can have a significant impact on both affected individuals and their close social circle, as relatives often find themselves unexpectedly taking on the role of caregivers. It requires them to undergo a learning process to provide care and support for a person starting a complex recovery journey (Kuipers, 2010; Smith et al., 2014). The existing literature on unprepared care responsibilities for relatives suggests that such duties can have negative consequences for both the person in recovery and their family members. Relatives acting as informal caregivers may experience emotional distress, health issues, financial strain, and social isolation (Saunders, 2003). Consequently, insufficient support for caregivers can lead to burnout, thereby diminishing the quality of care provided and negatively impacting family functioning (Chang et al., 2016; Gérain & Zech, 2019; Singh & Ali, 2022). To tackle these challenges, psychoeducational programs involving relatives in the process of recovery have been developed. These programs provide a forum to learn about mental distress, treatment options, and how to communicate more effectively with the person in recovery. Evaluations of these programs have demonstrated that involving relatives in psychoeducational programs aimed at mental health service users' needs leads to reduced burden for the former and a reduced risk of relapse for the latter (Claxton et al., 2017). In addition, psychoeducational programs specifically tailored to the needs of relatives have been shown to be effective in enhancing their knowledge about mental health, appraisal about caregiving, perception of burden, and emotional support (Sin et al., 2017).

In addition to psychoeducational interventions primarily focused on providing information, alternative intervention frameworks focused on empowering individuals and their communities have been developed. In recent decades, models such as Trieste's (Bennett, 1985; Mezzina, 2014) and Recovery (Anthony, 1993) have had a significant impact, leading

to the implementation of innovative, transformative and evidence-based approaches such as co-designed service delivery (Martin et al., 2017), mutual-help groups (Pistrang et al., 2008) and peer support practices (Smit et al., 2022). Furthermore, international organizations are showing growing dedication to empowerment programs that incorporate co-produced training and awareness initiatives involving individuals in recovery, their relatives, and healthcare professionals (Arblaster et al., 2015; Steffen, 2011; World Health Organization Regional Office for Europe, 2010). All of these approaches have been developed with a strong commitment to enhancing respect for the rights and promoting social justice for individuals in the process of recovering from severe distress (Patel et al., 2018; World Health Organization, 2021).

Despite the evident innovative developments in mental health care systems, the programs are often limited in scope, and many service users and their relatives still feel disengaged from the recovery process (Newman et al., 2015). Acknowledging the persistent obstacles in achieving meaningful participation and inclusion of mental health service users and their relatives, efforts are underway in public health and service transformation initiatives that seek to ensure universal access to interventions that prioritize their empowerment. These interventions seek to go beyond symptom management and emphasize key dimensions such as participation, recovery, and full citizenship (Mezzina et al., 2006). The aim is to support individuals in their recovery journey and empower them to be active agents in their own care, while promoting social inclusion and reducing stigma associated with mental health diagnoses. By prioritizing these dimensions, mental health care systems can become more responsive to the needs of their communities and foster greater engagement and collaboration among service users, their families, and healthcare providers.

The present study

The current project, *Activa't per la Salut Mental* (Get Active for Mental Health in English; referred to as *Activa't* from now on), initiated in 2015 in Catalonia, aims to empower and improve the quality of life of individuals experiencing severe mental distress and their relatives throughout their recovery processes by providing specific interventions and transforming current services. To assess its potential inclusion in the public services portfolio, and expanding it across the entire territory, a collaborative implementation trial was commissioned by the Catalan Government and developed by multiple stakeholders, including organizations representing both relatives and service users. The program encompasses four consecutive interventions implemented over 12 to 18 months that are tailored to the specific needs of people in recovery and their relatives. These interventions include orientation, psychoeducation, empowerment, and mutual-help groups. The interventions were implemented across 12 territories with the collaboration of 11 mental health providers and 16 local associations of service users and their relatives. Hence, in order to assess the effectiveness of the *Activa't* program implementation, a randomized implementation controlled trial was conducted and overseen by an external agency (Moreno & Sanz, 2018; Sanz et al., 2018; Sanz & Segura, 2018). The trial results were expected to ascertain the effectiveness of the project and inform decisions on whether it should be scaled up and integrated into mental health services throughout the region.

The purpose of this article is to present the results of the evaluation of the *Activa't* multi-component intervention's effectiveness in supporting the recovery process of mental health service users and enhancing their participating relatives' caregiving burden and social support. The study aimed to determine if the intervention had induced changes in the recovery stages of service users and the perceived social support and burden of their relatives.

Methods

Design

The study was designed as a randomized controlled implementation trial (Mixon et al., 2014; Wolfenden et al., 2021) that compared two groups of family units (see definition below). One group had access to all the Activa't interventions, while the other group only had access to orientation services (control). The trial was registered with the ISRCTN registry, number 15181312 (San Pío et al., 2017) and received ethical approval from the Sisters Hospitallers of the Sacred Heart of Jesus Clinical Research Ethics Committee (PR-2015-06). Outcomes were assessed for both groups after 6 and 12 months from the end of the first intervention received by the treatment group (psychoeducation).

Participants

Family units in this study were comprised of a mental health service user and one of their relatives. To be eligible for the study, neither the service user nor their relative should have received structured psychoeducation in the past 12 months. Both intervention and control groups of service users were receiving their usual treatment at community mental health centers. The eligible diagnoses for the study included Schizophrenia and other Psychotic Disorders (excluding substance-induced psychosis), Bipolar Disorder, and Major Depressive Disorder that had persisted for more than two years. Participants had to be between 18 and 63 years old, and have a moderate or severe level of disability, with a score lower than 60 on the Global Assessment of Functioning scale (Axis V of the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Text Revision; American Psychiatric Association, 2000). Participants were excluded from the study if they had been diagnosed with borderline personality disorder, had comorbid intellectual disability or severe somatic

pathologies, were legally incapacitated, had been placed under tutelage by a protection institution, or were residents of nursing homes, protected housing, or long stay units.

Relatives eligible for participation were required to be considered the primary caregiver for the person in recovery (although a minimum of contact with the person in recovery was not established) and have the practical availability to participate in all project activities. Those suffering from a psychiatric or severe non-compensated somatic disorder, including moderate and severe alcohol dependence requiring individual intervention, were excluded from the study.

All participants were required to give informed consent, agreement to participate in the study, and provide authorization for their personal data to be collected. Demographic information and baseline outcome measures were obtained from all participants prior to randomization. Outcome measures were collected again at six and twelve months after completing the psychoeducational activities. Upon completion of the assessments, family units in the control group were given the opportunity to participate in the full program, which is still ongoing.

Recruitment

To initiate the program's implementation, each of the 12 participating local mental health centers compiled a database of families that might be interested in taking part. Potential participants were chosen from these databases, adhering to the selection criteria mentioned above. They were then informed about the intervention via phone calls and through informational sessions held in conjunction with mental health providers. Families who expressed an interest in participating were then requested to provide informed consent and answer baseline questionnaires.

Interventions

The program consisted of four components. The first was the *Espai Situa't* (position yourself space) service, which offers orientation to the population in participating towns, including families in the control group. Its aim is to connect people with available services and help them navigate the system. Twelve *Situa't* services were established in civic centers across Catalonia, facilitating their interaction with the health and social support systems. The second component involved two psychoeducational programs specifically tailored for individuals in recovery and their relatives respectively. These programs could be considered the initial evaluated intervention as they were exclusively attended by the intervention group until the completion of the evaluation. The two psychoeducational programs, namely *Klave de Re* (“D-clef”; Ugas, 2017; Ugas & Ribas, 2006) composed of 22 weekly sessions addressed at service users, and “Training and educational program for families and caregivers of people with serious mental disorders” (Programa de Entrenamiento y Capacitación para Familiares y Cuidadores de Personas con Trastorno Mental, *PROENFA* by its acronym in Spanish; Rojo, 2016), composed of 14 weekly sessions, were provided by local mental health providers. These programs aim to equip individuals in recovery and their relatives with skills and knowledge to manage severe mental distress, including information on pharmacological and psychotherapeutic treatments, prevention skills, and strategies to handle complex situations. The third component was the PROSPECT empowerment training program (San Pío, 2007; Steffen, 2011), elaborated by The European Federation of Associations of Families of People with Mental Illness. The intervention’s objective is to foster empowerment among both relatives and service users, while also facilitating the development of empowerment-promoting skills among professionals. This is achieved through structured sessions delivered by trained service users, relatives or mental health professionals. This peer

delivered intervention comprises four modules: a 12-hour (3 sessions) module for service users, a 16-hour (4 sessions) module for family members, an 8-hour (2 sessions) module for professionals, and a 4-hour common module in which all participants collaborate to address communication obstacles and identify potential solutions. Finally, the fourth component consisted of mutual-help groups hosted by mental health advocacy organizations. The groups, tailored for individuals in recovery or their relatives, were facilitated by individuals who had themselves experienced recovery or were relatives who had undergone training as group facilitators within the program. The complete description as well as the manuals of the four interventions can be found on the project website¹.

Given the highly structured nature of the psychoeducation and empowerment interventions, as well as the participatory nature of mutual-help, a fidelity assessment of the session content for each intervention was not conducted. The former interventions followed a structured approach with predefined thematic sessions, while the latter was self-managed by each group, adhering to the principles of mutual-help philosophy. However, as commented above, all persons involved in the implementation of the PROSPECT and mutual-help groups interventions as facilitators went through a specific training process. Additionally, a supervision team oversaw that the implementation of the interventions was done in accordance with the ethical and methodological principles of the project.

Outcomes

The evaluation of recovery among participant service users was conducted using the Spanish version of the Stages of Recovery Instrument (STORI; Andresen et al., 2006). The STORI has 50 items and allows for the quantification of five consecutive stages of recovery. The stages are defined as moratorium (stage of personal withdrawal characterized by a

¹ <http://activatperlasalutmental.org>

feeling of profound loss and absence of hope), awareness (incipient personal consciousness about how not everything is lost and perception of potential improvement), preparation (stage in which the person is conscious about the advantages and drawbacks of recovery and starts to think, in a practical level, in how to recover), rebuilding (stage in which the person works actively in their recovery, stating attainable objectives and regaining control over their own life) and growth (stage in which one lives a fruitful life, characterized by the personal regulation of the disorder, resilience and positive feelings about oneself). The items are quantified using a 6-point (0-5) Likert scale. We averaged the items of each stage to establish a score range of 0-5. A high score on the items of a particular stage means that the person shows traits of that stage. Therefore, it can be inferred that high scores in the initial stages of the recovery process, particularly in the moratorium stage, indicate that the individual is in the early stages of recovery. On the other hand, high scores in later stages such as rebuilding or growth, suggest that the individual is in an advanced stage of recovery. Reliabilities in our study ranged $\alpha = .746$ to $.893$ at baseline, $\alpha = .693$ to $.900$ at 6 months, and $\alpha = .717$ to $.924$ at 12 months.

The Spanish version (Vilaplana et al., 2007) of the second version of the Family Burden Interview Schedule (FBIS-II) questionnaire (Tessler & Gamache, 1996) was used to assess the burden of care among participating relatives. The instrument assesses different dimensions of the burden of care: A) service user's routine, B) service user's disrupted behaviors, C) financial burden, D) disruption of caregiver's routine, E) concern, F) available help, G) repercussions on health, and H) assessment of general burden. This information is assessed measuring presence of each burden element (yes/no), and just if the burden element is present, frequency (0-4), level of concern (0-3, just for items from modules A and B) and time (1-7, just for items from module A and an overall in module B). Additionally, module

C measures financial burden in euros. For each module in which it was applicable, the total presence of different types of burden, the average scores of the frequency of burden, the average scores of the concern experienced by the relative, the sum of time, and a total sum of the money invested in the service user were calculated. Therefore, we created five frequency scores (help in daily-life activities, disruptive behaviors, change in relative's routine, concern, and global burden), one cost score (economic burden), and two concern scores (concern about help in daily-life activities and concern about disruptive behaviors). To facilitate understanding, total scores were created summing or averaging items across modules: a score with the total count of presence (yes/no) items that add burden to the relative across all modules (total presence of burden), scores of the average frequency of burden, scores of the average concern experienced by the relative and a sum of the time invested in the care of the service user. Additionally, using the latter, a total score was created multiplying the presence of burden by the averages of the frequency and concern and by the total time. High scores in all these indicators represent high burden levels. Reliabilities could only be calculated for scores that were replied by all participants using the same scale, i.e., the presence (yes/no) items ($\alpha = .659$ at baseline, $\alpha = .633$ at 6 months, and $\alpha = .630$ at 12 months).

Social support was measured using the Spanish caregiver version (Cuéllar-Flores & Dresch, 2012) of the Duke-UNC-11 (Broadhead et al., 1988). The instrument evaluates social support in three ways: confidential support, i.e., the degree to which the person has close people to communicate with, affective support, i.e., the intensity with which the person receives demonstrations of love, affect, and empathy, and global support, a composite score of the above. The questionnaire is composed by 11 items, with scores ranging from 1 to 5 in a Likert scale. We calculated the average score for each dimension by averaging the scores

of its individual items, resulting in a score range of 1-5. High scores on the Duke-UNC-11 questionnaire represent a high perception of social support. Reliabilities in our study were $\alpha = .852, .718, \text{ and } .873$ at baseline, $\alpha = .871, .796, \text{ and } .904$ at 6 months, and $\alpha = .879, .828, \text{ and } .915$ at 12 months.

Sample size

Before the recruitment phase began, a sample size calculation was conducted to determine the number of family units required to achieve sufficient statistical power for comparing the control and intervention groups. The sample size calculation also considered that a maximum of 25 family units could be attended at each territorial site. The result of the calculation indicated that 240 family units would allow for the detection of a Standardized Minimum Detectable Effect of 0.36.

Randomization

The process of random assignment to either treatment or control group was performed independently by an external agency (Sanz, 2015) using a pairwise randomization system for each mental health center. This form of randomization ensured an equivalent distribution of the conditions between the treatment and control groups within each study site.

Blinding

Blinding was only possible in the analysis phase, since both the participants and the professionals developing the intervention were aware of the group in which each family unit was located.

Statistical analyses

Baseline data from persons in recovery and relatives were analyzed comparing the treatment to the control group using chi-squared or Student's t-tests depending on whether variables were categorical or quantitative. We also performed comparisons on demographic

data to determine if there were differences between those who completed the study and those who did not. Additionally, per protocol, outcome measures were compared at baseline, 6-, and 12-months using t-tests.

To perform intention-to-treat longitudinal analyses, as all STORI and Duke scores were normally distributed, linear mixed fixed effects models were performed for each of the outcomes. However, due to the nature of the FBIS-II scores, which encompass both counts and durations and exhibited non-normal distributions in certain cases, we employed generalized linear mixed gamma fixed effects models for their analysis. The within-group component was time (baseline, 6, and 12 months), while the between-groups component was being in the control or in the intervention group. We subsequently incorporated the sociodemographic variables used to characterize the sample independently for both service users and their relatives into the models, to assess if they interacted simultaneously with the differential evolution of outcome scores and experimental group membership.

A subsequent dose-effect analysis was performed also through generalized linear mixed analyses. For these analyses, we replaced the experimental group dichotomous variable with a quantitative covariable that counted the number of sessions attended. This variable was always zero for the control group and had a range of 0-44 for people in recovery and 0-36 for their relatives in the intervention group.

A database and Statistical Package for the Social Sciences (SPSS) syntax are available as supplemental material at <https://doi.org/10.1037/ort0000704.supp>.

Results

Participant flow

The participant flow is depicted in figure 1. As it can be seen, two of the families randomized to the control group requested to participate in the interventions. They were

allowed even though their baseline scores were excluded from the evaluation process. The final sample comprised 111 family units in the intervention group and an equivalent number of 111 families in the control group. Relatives included in the study were primarily parents (62%) and partners or spouses (23%), followed by siblings (10%), children (3%), other relatives (2%), and friends (0.5%).

Figure 1. Participant flow.

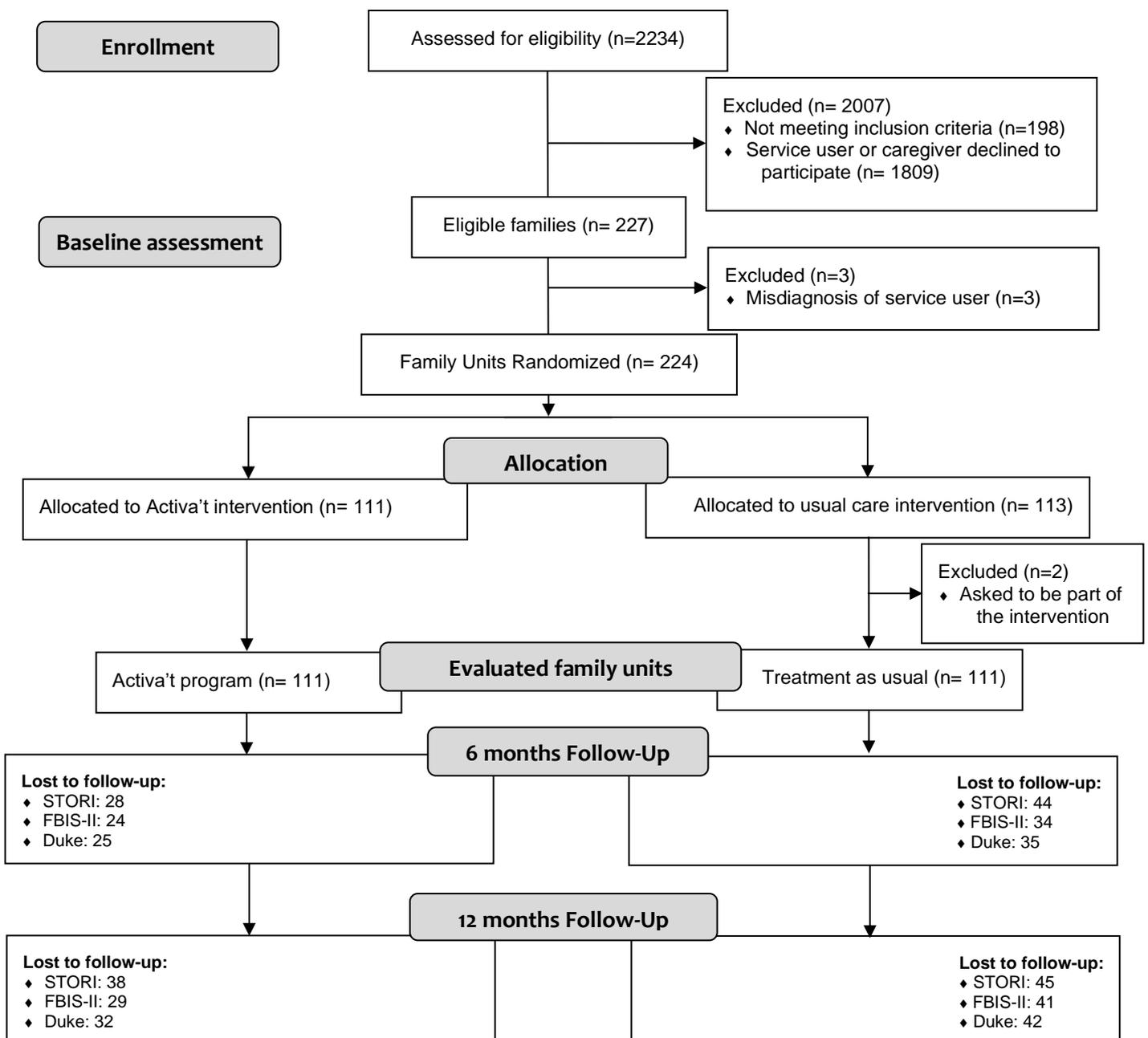


Table 1. Sociodemographic characteristics and baseline scores of persons in recovery recruited into the study.

	All (N=222)		Intervention (N=111)		Control (N=111)		Statistical significance	
	N	%	N	%	N	%	<i>O.R., 95% CI</i>	<i>p</i>
Gender (% female)	84	37.8	44	39.5	40	36.0	1.17, 0.68-2.01	.580
Partner or spouse (% married or in a relationship)	56	30.6	31	32.6	25	28.4	1.22, 0.65-2.30	.536
Cohabitation (% independent)	52	30.8	33	35.5	19	25	0.61, 0.31-1.19	.142
Education (% at least secondary)	119	53.6	58	52.3	61	55	0.90, 0.53-1.52	.686
Employment situation (% employed)	15	6.8	4	3.6	11	9.9	0.34, 0.11-1.10	.061
	M	SD	M	SD	M	SD	<i>t</i>	<i>p</i>
Age (M±SD)	40.99	10.03	40.46	10.50	41.33	9.57	-0.514	.607
STORI								
Moratorium	2.43	1.09	2.37	1.09	2.49	1.09	0.796	.427
Awareness	3.20	0.80	3.20	0.80	3.21	0.80	0.076	.940
Preparation	3.03	1.03	3.06	1.07	3.00	0.99	0.414	.679
Rebuilding	3.14	1.05	3.19	1.05	3.09	1.05	0.698	.486
Growth	2.90	1.17	2.96	1.19	2.83	1.15	0.765	.445

Note. STORI: STages Of Recovery Instrument

Table 2. Sociodemographic characteristics and baseline scores of relatives recruited into the study.

	All (N=222)		Intervention (N=111)		Control (N=111)		Statistical significance	
	N	%	N	%	N	%	<i>O.R., 95% CI</i>	<i>p</i>
Gender (% female)	158	71.2	80	72.1	78	70.3	1.09, 0.61-1.95	.767
Partner or spouse (% married or in a relationship)	125	72.3	64	72.7	61	71.8	1.05, 0.54-2.04	.888
Cohabitation (% independent)	76	49.4	39	47.6	37	51.4	1.17, .62-2.20	.635
Education (% at least secondary)	107	48.2	61	55.0	46	41.4	1.72, 1.01-2.93	.044
Employment situation (% employed)	81	36.5	46	41.4	35	31.5	1.54, 0.89-2.66	.125
	M	SD	M	SD	M	SD	<i>t</i>	<i>p</i>
Age (M±SD)	57.80	12.27	56.68	12.73	58.93	11.74	1.370	.172
FBIS-II								
Frequency of help in daily-life activities	2.26	0.89	2.33	.89	2.19	.89	1.123	.263
Frequency of disruptive behaviors	1.09	0.99	1.08	1.01	1.07	.99	0.052	.959
Frequency of change in caregiver's routine	0.66	0.79	.71	.79	.62	.79	0.872	.384
Frequency of worry	2.40	0.89	2.41	.90	2.40	.90	0.118	.906
Frequency of global burden	1.72	1.24	1.77	1.27	1.67	1.20	0.546	.586
Financial burden	614,55	865.46	606,98	725,60	624,31	1026,73	0.1	.920
Worry about help in daily-life activities	1.45	0.82	1.46	.84	1.44	.79	0.113	.911
Worry about disruptive behaviors	2.07	0.81	2.04	.82	2.11	.81	0.630	.529
Totals								
Duke-UNC-11								
Affective Social Support	16.80	4.33	16.83	4.25	16.75	4.44	0.027	.899
Confident Social Support	20.81	5.89	20.63	5.72	20.98	6.08	0.443	.659
Global Social Support	37.60	9.35	37.46	8.99	37.74	9.75	0.220	.826

Note. FBIS-II: Family Burden Interview Schedule, Duke-UNC-11: Duke-University of North Carolina Functional Social Support Questionnaire

Table 3. Descriptive statistics of outcome scores, statistical significance, and effect sizes of the difference between groups at 6 and 12 months.

	T6							T12						
	Intervention		Control		Statistical significance		Effect size	Intervention		Control		Statistical significance		Effect size
	M	SD	M	SD	<i>t</i>	<i>p</i>	<i>d</i>	M	SD	M	SD	<i>t</i>	<i>p</i>	<i>d</i>
STORI														
Moratorium	1.86	1.13	2.18	1.14	1.742	.084	0.283	1.92	1.01	2.16	1.15	1.329	.186	0.225
Awareness	3.34	0.66	3.04	0.80	2.574	.011	0.418	3.40	0.72	3.15	0.77	1.926	.056	0.326
Preparation	3.43	0.91	3.10	0.94	2.202	.029	0.358	3.38	0.97	3.11	0.96	1.619	.108	0.274
Rebuilding	3.62	0.84	3.11	1.07	3.256	.001	0.529	3.51	0.96	3.19	1.07	1.867	.064	0.316
Growth	3.38	1.09	2.99	1.26	2.06	.041	0.335	3.24	1.23	3.13	1.24	0.554	.581	0.094
FBIS-II														
Frequency of help in	1.96	.91	1.82	.89	0.865	.388	0.145	1.76	.79	1.77	.96	0.067	.947	0.012
Frequency of disruptive	1.18	1.00	1.38	1.14	0.919	.36	0.180	1.17	1.06	1.10	.99	0.316	.753	0.067
Frequency of change in	.39	.65	.48	.69	0.776	.439	0.121	.38	.66	.36	.47	0.299	.765	0.049
Frequency of worry	2.21	.89	2.15	.88	0.431	.667	0.067	2.06	.89	2.08	.90	0.133	.895	0.021
Frequency of global	1.34	1.06	1.43	1.14	0.547	.585	0.086	1.49	1.18	1.17	1.12	1.644	.102	0.274
Financial burden	480.38	565.41	414.45	415.47	0.530	.598	0.130	325.85	743.99	399.72	991.81	0.701	.486	0.196
Concern about help in	1.44	.85	1.27	.82	1.206	.23	0.203	1.29	.81	1.17	.78	0.777	.439	0.142
Concern about disruptive	1.61	.94	1.75	.86	0.78	.437	0.153	1.72	.97	1.80	.85	0.409	.683	0.086
Totals														
Total presence of burden	9.77	4.29	9.74	4.47	0.039	.969	0.006	9.09	4.69	8.90	4.63	0.243	.808	0.039
Average frequency of	1.27	0.64	9.77	4.29	0.148	.969	0.023	1.16	0.60	1.13	0.57	0.35	.727	0.057
Average concern about	1.49	0.82	1.25	0.65	0.677	.883	0.109	1.31	0.85	1.36	0.79	0.352	.726	0.060
Total time	8.79	7.43	1.27	0.64	0.067	.883	0.011	8.03	7.20	6.79	5.46	1.138	.257	0.191
TOTAL FBIS-II	3.26	7.44	1.40	0.79	0.522	.500	0.085	2.98	5.51	1.82	2.92	1.531	.129	0.254
Duke-UNC-11														
Affective Social Support	17.84	4.74	16.86	4.80	1.31	.192	0.206	17.15	4.92	17.14	5.49	0.011	.992	0.002
Confident Social Support	21.64	6.09	21.29	6.18	0.368	.714	0.058	20.89	6.38	21.63	6.66	0.641	.523	0.105
Global Social Support	39.48	10.12	38.14	10.30	0.833	.406	0.131	38.04	10.61	38.77	11.47	0.379	.705	0.062

Note. STORI: STages Of Recovery Instrument, FBIS-II: Family Burden Interview Schedule, Duke-UNC-11: Duke-University of North Carolina Functional Social Support Questionnaire

Table 4. Fixed effects of time, experimental group, and their interaction on outcomes.

	Time		Group		Interaction	
	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>
STORI						
Moratorium	12.642	<.001	1.270	.261	0.364	.547
Awareness	0.622	.431	0.180	.672	2.672	.103
Preparation	4.515	.034	0.746	.389	1.076	.300
Rebuilding	4.388	.037	1.955	.163	1.389	.239
Growth	5.908	.016	1.632	.202	0.027	.868
FBIS-II						
Frequency of help in daily-life activities	14.766	<.001	0.093	.761	1.336	.264
Frequency of disruptive behaviors	1.412	.246	0.545	.461	0.941	.391
Frequency of change in caregiver's routine	2.661	.072	1.329	.250	0.145	.865
Frequency of worry	6.699	<.001	0.014	.907	0.248	.781
Frequency of global burden	3.873	.022	0.158	.691	1.757	.174
Financial burden	1.735	.179	0.015	.903	0.374	.689
Concern about help in daily-life activities	0.756	.470	1.498	.222	0.115	.892
Concern about disruptive behaviors	4.691	.010	0.001	.974	0.32	.726
Totals						
Total presence of burden	12.092	<.001	0.145	.704	0.031	.969
Average frequency of burden	43.931	<.001	0.458	.499	0.061	.940
Average concern about burden	4.273	.014	0.202	.653	0.319	.727
Total time	14.186	<.001	1.037	.309	0.339	.713
TOTAL FBIS-II	16.765	<.001	0.302	.583	1.844	.159
Duke-UNC-11						
Affective Social Support	0.747	.388	0.249	.618	0.020	.888
Confident Social Support	0.703	.402	0.036	.850	0.019	.889
Global Social Support	0.847	.358	0.010	.919	0.0001	.990

Note. STORI: STages Of Recovery Instrument, FBIS-II: Family Burden Interview Schedule, Duke-UNC-11: Duke-University of North Carolina Functional Social Support Questionnaire

Table 5. Fixed effects of time, degree of participation, and their interaction with outcomes.

	Service users' participation						Relatives' participation					
	Time		Participation		Interaction		Time		Participation		Interaction	
	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>
STORI												
Moratorium	4.794	.029	4.480	.035	0.390	.533	7.113	.008	3.262	.072	0.030	.863
Awareness	0.094	.759	1.876	.172	1.537	.216	0.0001	.993	1.817	.179	0.884	.348
Preparation	0.500	.480	2.929	.088	1.477	.225	1.158	.283	3.491	.063	0.777	.379
Rebuilding	0.756	.385	2.605	.108	0.962	.327	1.153	.284	3.735	.054	0.747	.388
Growth	1.695	.194	2.042	.154	0.498	.481	3.269	.071	5.296	.022	0.004	.950
FBIS-II												
Frequency of help in daily-life activities	10.741	<.001	0.313	.576	0.295	.745	7.621	<.001	0.003	.954	1.379	.253
Frequency of disruptive behaviors	0.947	.389	4.138	.043	0.054	.947	1.754	.175	2.917	.089	0.493	.611
Frequency of change in caregiver's routine	1.840	.161	0.070	.791	0.303	.739	3.374	.036	3.563	.060	0.574	.564
Frequency of worry	4.069	.018	1.877	.171	0.126	.882	4.348	.013	0.429	.513	0.018	.982
Frequency of global burden	1.718	.181	0.413	.521	1.315	.270	1.403	.247	1.503	.221	1.774	.171
Financial burden	1.524	.220	0.444	.506	0.535	.586	0.556	.574	0.948	.331	0.153	.858
Concern about help in daily-life activities	0.239	.787	0.017	.897	0.15	.860	0.506	.603	1.81	.179	0.198	.820
Concern about disruptive behaviors	3.11	.046	1.293	.256	0.756	.470	3.078	.047	0.07	.791	0.048	.953
Totals												
Total presence of burden	8.321	<.001	0.656	.418	0.175	.839	9.288	<.001	1.91	.168	0.256	.774
Average frequency of burden	26.036	<.001	1.960	.162	0.307	.736	28.541	<.001	1.855	.174	0.091	.913
Average concern about burden	1.958	.142	0.126	.723	0.309	.734	2.144	.118	0.136	.712	0.103	.902
Total time	9.698	<.001	0.588	.444	0.763	.467	9.512	<.001	0.625	.429	0.652	.521
TOTAL FBIS-II	11.79	<.001	1.576	.210	2.446	.088	13.874	<.001	0.909	.341	1.372	.255
Duke-UNC-11												
Affective Social Support	0.677	.411	0.246	.620	0.061	.805	0.132	.716	0.069	.794	0.216	.643

Confident Social Support	1.294	.256	0.384	.536	0.445	.505	0.165	.685	1.279	.259	0.254	.615
Global Social Support	1.145	.285	0.030	.862	0.254	.614	0.172	.678	0.366	.545	0.289	.591

Note. STORI: STages Of Recovery Instrument, FBIS-II: Family Burden Interview Schedule, Duke-UNC-11: Duke-University of North Carolina Functional Social Support Questionnaire

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Baseline data

Baseline data by experimental group can be found in tables 1 and 2. Statistical comparisons revealed no statistically significant differences between participants randomized to intervention and control groups except for relative's education level.

Attrition and participation

Out of the 222 family units participating in the study, 118 (53.2%) persons in recovery and 138 (62.2%) relatives completed all questionnaires in all time points. Persons who completed the program and those who did not complete it did not differ in any sociodemographic characteristic or baseline outcome scores. However, when performing crossed comparisons (characteristics of people in recovery by relatives' attrition and vice versa) we found that relatives were more likely to respond when persons in recovery had at least secondary education ($OR = 1.860$, $95\% CI = 1.075 - 3.220$) and were younger ($t(220) = 2.573$, $p = .011$, $d = .356$). Persons in recovery were more likely to respond when relatives had lower burden scores on help in daily-life activities ($t(220) = 2.588$, $p = .010$, $d = .367$) and disruptive behaviors ($t(220) = 2.654$, $p = .009$, $d = .389$).

Regarding participation within participants randomized to the intervention group, the mean number of sessions attended was 19.15 ± 11.6 (*Situa't* 1.1 ± 0.3 , *Klave de Re* 13.4 ± 7.39 , *PROSPECT* 2.8 ± 1.6 , mutual-help groups moderator training 3.8 ± 3.5 , mutual-help groups 5.7 ± 4.5) for service users and 15 ± 10.18 (*Situa't* 1.5 ± 0.9 , *PROENFA* 9.2 ± 5 , *PROSPECT* 3 ± 1.7 , mutual-help groups moderator training 5.7 ± 2.3 , mutual-help groups 5.3 ± 4.5) for relatives randomized to the intervention group. Persons in recovery participated more if they had at least secondary education [$t(109) = 3.080$, $p = .003$, $d = .585$] and if their relatives had at least secondary education [$t(109) = 2.291$, $p = .024$, $d = .437$], lower

perception of disruptive behaviors ($r = -.256, p = .013$) and lower average frequency burden scores ($r = -.223, p = .018$). Relatives had higher participation rates when they lived outside of the Barcelona Metropolitan Area [$t(109) = -2.132, p = .018, d = -.405$], they had spent more money in their relative during the last month ($r = .313, p = .017$), and when the person in recovery whom they were accompanying was younger ($r = -.367, p = <.001$), was married or in a relationship [$t(93) = 2.708, p = .008, d = .593$], at least secondary education [$t(109) = 2.512, p = .013, d = .477$] and higher growth scores at baseline ($r = -.200, p = .036$).

Effectiveness of the intervention

Outcome descriptive statistics, statistical significance, and effect sizes of the difference between the scores reported by participants randomized to both experimental groups at six and twelve months can be seen in table 3. The results of the t-tests indicated statistically significant differences in all STORI scores, except for Moratorium at six months. However, none of the statistically significant differences persisted at the twelve-month follow-up. No differences were observed for burden or social support reported by participants at either six or twelve months.

Lineal mixed model analyses using the STORI, FBIS-II and Duke-UNC-11 scores reported by participants as dependent variables can be seen in table 4. These analyses yielded time effects for several STORI and FBIS-II subscales, but no statistically significant group effects or time x group interactions. Statistically significant interaction effects with time and group were observed for participants' age and relatives' gender across all STORI subscales, except for the levels of Awareness experienced by people in recovery, in both cases (all $p < .05$). Additionally, type of territory influenced the evolution of the STORI Awareness subscale scores reported by persons in recovery [$F(329.842) = 4.057, p = .045$]. The observed interactions indicated that increased variations were observed when either service users were

younger, participated alongside a female caregiver or lived outside of the Barcelona Metropolitan Area. It should be noted that the first two variables exhibited a noteworthy relationship, as service users who participated with a female relative were, on average, five years younger than those who participated with a male relative [$t(220) = 2.912, p = .004, d = .432$].

Table 5 presents the dose-effect analyses, indicating that the degree of participation influenced specific outcomes of individuals in recovery (STORI Moratorium and FBIS-II Frequency of disruptive behaviors) as well as of their relatives (STORI Growth). Despite these observations, no statistically significant interaction between participation and time was found for any of the scores reported. As a result, we could not definitively determine the impact of individuals in recovery and their relatives' participation on the evolution of their outcomes.

Discussion

The aim of this study was to assess the effectiveness of a multi-component integrated care program, specifically designed to empower individuals who have undergone severe mental distress and their relatives throughout the recovery process. Within a randomized controlled implementation trial, we examined changes in the recovery stages of individuals using mental health services and the caregiving burden and perceived social support scores of their relatives.

The effects of allocation to the intervention group on service users' recovery were noticeable at six-months but not at twelve months. Additionally, belonging to either the intervention or control group did not yield any statistically significant effects in terms of reducing burden or enhancing the perception of social support. The evolution of recovery scores showed an interaction with caregiver gender, suggesting that the program had an

impact in the case of female caregivers but not male caregivers. Furthermore, younger participants were more likely to complete the assessment and have their relatives actively involved. The association between these two variables was remarkably strong, posing challenges in differentiating their individual predictive values. In addition, we observed a positive impact on the participation of relatives and the evolution of the consciousness of individuals in recovery when the intervention was implemented in territories beyond the Barcelona Metropolitan Area. Moreover, it is worth noting that the degree of participation was influenced by other factors, including the educational levels of individuals in recovery and their relatives. Finally, in line with previous studies (Eiroa-Orosa et al., 2022) associations were found between participation rates and specific outcome variables for individuals in recovery (STORI Moratorium and FBIS-II Frequency of disruptive behaviors) and their relatives (STORI Growth). However, these relationships did not exhibit any time-related patterns, indicating that the degree of participation cannot be considered a reliable predictor of the evolution of outcomes in the current study.

While the existing literature has explored gender differences in burden (Treichel et al., 2020), quality of life, and mental health (Sharma et al., 2016) among caregivers of individuals with mental health diagnoses, the reciprocal impact on the recovery journey of service users remains largely unexplored. In our study, given that the activities were predominantly customized for each specific group (people in recovery or relatives), it is reasonable to hypothesize that the nature of interaction dynamics between female relatives and individuals in recovery inside as well as outside the program varied qualitatively when compared to their male counterparts.

Additionally, qualitative differences have been reported in the process of recovery of older people. Daley et al. (2013) discovered that older individuals display a lesser inclination

to embrace and adapt to a new and revised sense of identity, and they are less inclined to seek peer support from individuals with lived experience of severe mental distress. The program's interventions were based precisely on these elements, which seem to be better received by younger people. It is plausible that the older adults in our study held different values and recovery goals compared to the younger adults, which might have contributed to their lower interest in what was being offered by the program. In future recovery-oriented initiatives involving diverse age groups, it could be valuable to incorporate a values clarification assessment and provide orientation to help individuals identify their personal values in terms of selection of interventions or recovery goals.

The educational level of people in recovery and their relatives influenced participation. When considering persons in recovery, the completion of secondary education might be associated with the age of symptom onset. The later the onset of symptoms, the lesser their impact on critical developmental windows, as well as cognitive and psychosocial aspects (Sheffield et al., 2018). The amount and complexity of written materials involved in the psychoeducation and empowerment interventions should probably be reconsidered to engage people with shorter educational backgrounds.

The differential impact on recovery and variations in participation rates between the Barcelona Metropolitan Area and areas outside of it may be attributed to territorial differences, including the availability of services and innovative resources. Within the Metropolitan Area, there is a broader range of mental health services, easily accessible via public transport. However, outside of this area, lower population density and a more rural lifestyle often result in fewer health services, weaker transportation systems, and, in some instances, limited exposure to cutting-edge initiatives. In our study, the intervention involved 12 distinct mental healthcare community centers, operated by 11 different health providers,

across 13 different towns or cities in Catalonia. This diverse implementation, in collaboration with 16 local advocacy associations, and with unique professional coordinators for each territory, introduced specific contextual variations that were partially documented but not fully considered in the current effectiveness evaluation. Numerous aspects may have influenced the intervention's impact, such as the willingness of professionals to be involved, the timing of psychoeducation sessions (morning or afternoon), the physical locations where sessions were held, the expertise of the facilitators (both professionals and volunteers), the pre-existing service offerings, the attitudes of local leaders, and the prevailing culture in each geographical area. While some measures were in place to ensure adherence to core criteria, the project was designed with the flexibility to adapt to local realities, as is recommended for evaluating complex interventions.

Regarding burden, our analyses did not reveal any statistically significant differences in the evolution of relatives who were randomized to either the intervention or control groups. Nevertheless, regardless of whether individuals in recovery or their relatives participated in the interventions, there was a noticeable decrease in burden over time. This phenomenon is widely reported in the literature under the name of naturalistic change or spontaneous improvement (Krogsbøll et al., 2009; Rutherford et al., 2012). However, the phenomenon observed in our study is particularly noteworthy as its underlying rationale is not readily apparent. It has been reported that some symptoms of mental distress tend to improve with time, but the same response for caregiver burden was not expected. Some explanations might include inherent bias related to the participation in intervention studies. People who chose to participate are usually more likely to be experiencing more burden or difficulties than usual. As severe mental health conditions are often episodic in nature, challenging situations may naturally improve over time, regardless of the level of support received. Also, there were

chances of cross contamination. On the one hand, relatives in the control group also have access to interventions outside the program under scrutiny. On the other hand, the implementation of the program was also accompanied by training for professionals (PROSPECT), which could influence both groups. To address these possible confounding factors in future evaluations, a possible approach is to employ clustered designs. While these designs have their own limitations (Donner & Klar, 2004), they allow for the assessment of differences between territories where a program has been implemented and those where it has not yet been implemented. By employing such designs, researchers can gain insights into the impact of program implementation across different sites, helping to enhance the validity of the evaluation.

Several explanations can justify the lack of effectiveness of the intervention in reducing the burden of caregivers in this study. One plausible explanation could be attributed to the relatively low participation of people randomized to the intervention group, where, on average, participants engaged in less than half of the planned program sessions. Another cause could be the complexity of the family burden phenomenon. Many different variables, such as their coping skills, the clinical conditions of persons in recovery they care for, stigma, and social resources influence the family burden (Pai & Kapur, 1981; Schene et al., 1994). Another plausible explanation is that complex variables of this nature might necessitate a higher intensity or longer duration of intervention to produce significant changes. Lastly, it is worth noting that the assessment instrument used in our study may not be the most optimal choice for psychometric research. As a semi-structured interview, it encompasses a broad spectrum of burden aspects that caregivers may experience, which can persist or increase even if the individuals in recovery make progress on their journey. The assessment interview might influence the subjective perception of burden in both study groups, considering that

the interviews were conducted by social care professionals who also served as the professional referents of the *Situa*'t orientation services, coordinating the intervention at the local level in each territory. Furthermore, during the participation in the intervention, relatives may encounter new situations, potentially leading to the emergence of new concerns.

Regarding social support, our analysis found no statistically significant differences between the experimental groups in any of the follow-up assessments or in the longitudinal analyses. In this case, there was no effect of time either, which indicates that social support did not change throughout the study for the whole sample. Moreover, the dose-effect analysis did not reveal any differences between groups either in this case. When interpreting these findings, it is crucial to note that mutual-help groups were anticipated to have higher impact on improving social support. However, evaluating their specific impact within the context of the overall trial might be obscured. Due to attrition and the order in which interventions were implemented, certain participants did not have the opportunity to attend mutual-help groups. Additionally, among those who did attend, not all were able to participate in a sufficient number of sessions. Moreover, it is plausible that the selected instrument for measurement may lack sensitivity to detect subtle changes that can arise within this particular context. Consequently, it is crucial that future iterations of the program ensure that the evaluation of social support incorporates measures that account for participants' level of engagement in mutual aid group activities.

Regarding participation rates, the intervention group exhibited relatively low averages compared to what was expected. Additionally, there were variations in participation within family units. The qualitative project report (Moreno & Sanz, 2018) shed light on various weaknesses of the project that served as deterrents to attendance. Notably,

participants expressed concerns about the program's duration and rigid participation criteria, which included a specific order of interventions. Therefore, following the conclusion of the evaluation phase, valuable insights were gained, prompting beneficial refinements. The order of interventions was made more flexible, enhancing the program's adaptability to individual needs. Moreover, adjustments were made to the length and frequency of sessions to improve engagement. Furthermore, in recognition of diverse family dynamics, the requirement for simultaneous participation of two family members was removed, making the program more accessible and inclusive. In addition, in an effort to establish a standardized criterion, participation in the present study was measured solely by the number of sessions attended. However, this approach assumed an equal impact for any session across all interventions included in *Activa't*. It is essential to acknowledge that sessions varied in terms of duration, frequency, objectives, and dynamics, ranging from introductory and theoretical to practical elements. Consequently, these sessions cannot be considered inherently equivalent in their impact. The task of defining suitable implementation indicators, such as dose-effect analysis, in multi-component complex interventions presents an ongoing and challenging area of interest (Skivington et al., 2021).

The present study has, of course, some limitations. The primary limitations stem from the temporal alignment between the program implementation and its evaluation conducted using an experimental design. Consequently, it becomes unfeasible to distinguish whether the effectiveness being measured pertains to the implementation itself or the specific interventions employed. Another possible problem are the measurement tools, as has already been commented regarding the FBIS-II and Duke-UNC-11 instruments. In relation to the contested notion of Recovery, during the implementation of this project, it was necessary to engage in negotiations with various sectors that held differing levels of knowledge and

understanding of the concept. These sectors varied in their recognition of Recovery values as catalysts for system transformation. In this context, the utilization of the STORI scale offered the advantage of assessing five interrelated yet independent constructs, capable of capturing a certain advancement in individuals' perception of their ability to initiate or progress on the path of self-determination. While we acknowledge that the scale is not flawless, and that a singular instrument may not be able to capture the construct accurately or comprehensively, we contend that a viable option was selected given the significant demand from funders and external evaluators. Furthermore, in addition to the inherent limitations of conducting experimentation with social interventions, which present challenges in measuring and controlling all potential confounding variables, this project was implemented within the context of broader enhancements in the Catalan mental health system. This factor has the potential to blur the distinctions between the experimental groups, making it more challenging to detect changes that can be attributed to participation. Furthermore, the relatively small number of participants, considering the open recruitment strategy, raises the possibility of a significant self-selection bias. Additionally, although for a few subjects, the number of participants expected in the sample calculation was not reached. Finally, due to the nature of the interventions, no fidelity assessments were carried out. When contemplating the cumulative impact of all these study limitations, it becomes necessary to acknowledge the possibility that a comprehensive evaluation of the effectiveness of the interventions under scrutiny might not have been achieved.

Conclusions

Our strong belief in the potential inclusion of the *Activa't* program in the public services portfolio drove us to choose the most rigorous assessment design, a randomized controlled trial, despite the inherent challenges of applying this method to widespread

multicomponent programs. By reporting on the complexities involved in the implementation and evaluation processes, we aim to provide valuable insights for implementation science. Our study offers a meaningful contribution by shedding light on the use of randomized controlled trials in multi-component interventions aimed at scaling up. Through our findings, we seek to encourage the development of recommendations that can guide future efforts in implementing and evaluating similar interventions on a larger scale.

The program demonstrated promising effects on the recovery of service users at six months. However, no statistically significant effects were observed for reported recovery stages at twelve months, nor for the care burden and social support perceived by relatives when comparing scores from the participants randomized to control and intervention groups at either of the two follow-up points. Notably, the program displayed a positive impact on the recovery journey of service users among younger participants, when accompanied by a female relative, or in cases where they reside outside the Barcelona Metropolitan Area. The remarkable reduction in burden scores observed in participants from both experimental groups raises the possibility of self-selection bias, sample cross-contamination or other unexpected effects, which should be carefully considered in future evaluations of burden reduction programs employing clustered designs. Regarding social support, we did not observe any statistically significant differences between the relatives who were randomized to the control group and those in the intervention group. Future research is needed to determine whether active participation in a sufficient number of mutual-help group sessions results in an increase in the perception of social support.

Drawing from the experience gained through the implementation and evaluation of the *Activa't* program, we can confidently assert that it holds promise for being scaled up. Nonetheless, certain adjustments would be essential to foster increased participation among

both individuals in recovery and their relatives. Special attention should be focused on participants with lower educational levels, individuals residing in metropolitan areas, older age groups, and male caregivers. To reinforce knowledge on the program's effectiveness and impact on outcomes, further research is warranted. This would involve revising outcomes and measurement tools to measure the effectiveness of specific interventions, and to evaluate the influence of the adjustments made after its first implementation. By carefully examining these factors, we can enhance the program's effectiveness when implemented on a larger scale.

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