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Article

Interaction between participation and impact of a multicomponent empowerment-based psychosocial mental health intervention on service users and their relatives

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Abstract: Relatives play an important role in mental health service users' care. Interventions directed either at service users or their relatives may influence the other person as well. The project Activa't per la salut mental (Get active for mental health) consisted of a series of four interventions addressed at people diagnosed with mental disorders and their relatives to help them in their recovery process, increasing their agency and quality of life. The objective of the present study is to evaluate the interaction of the participation of service users on their relatives' outcomes and vice versa. The impact of the project was evaluated within an RCT. The treatment group had access to all the circuit interventions while the control group received treatment as usual and could only access one of the interventions. All participants were evaluated at baseline, six months, and twelve months after the end of the first intervention. Service users were evaluated with the Stages of recovery questionnaire, and relatives with the Family Burden Interview Schedule II and the Duke-UNC-11 questionnaires. The interaction between service users and their relatives was analysed by means of correlational analyses within the intervention group. Service users baseline characteristics influenced in the level of participation of relatives and vice versa. The results also indicated an interaction between service users' recovery score changes on the change of care burden of relatives. Service users' participation levels interacted with the decrease of relatives' burden. These results can be extremely helpful in fostering interactive benefits in future projects addressing the wellbeing of mental health service users and their relatives. Future studies could use specific designs to explore the directionality of the causality of these effects.

Keywords: community care; integrated care; mental health; service users and relatives' interventions; service users and relatives' interaction

1. Introduction

In the last decades there has been a shift towards community-focused systems of mental health care [1]. For instance, the Recovery movement, which started in the early nineties, has been highly influential in the recognition of the social dimensions of psychological distress and the and the redirection of interventions beyond targeting just symptomatology [2]. Recovery was defined as a personal, unique, and multidimensional process of changing one's attitudes, values, feelings, goals, abilities, and/or roles leading to living a satisfying and hopeful life, despite the potential limitations caused by disorders [3]. Interventions conceived within this movement are directed towards raising awareness among service users and their communities to become active agents of recovery.

However, this shift has occurred without ensuring that service users' relatives had the adequate structures and instruments to be able to be helpful in the recovery process, maintaining as well their own health and wellbeing [4,5]. If not properly addressed, the unexpected responsibility for the family can have deleterious consequences for both service users and their relatives [6,7]. Therefore, and within the progressive focus on community, it has become evident that service users in community settings as well as their relatives needed specific interventions [8]. It can also be hypothesized that if one of the members engaged in an intervention, the other member could benefit as well from their improvements.

The fact that targeting relatives can improve the progression of service users is a well-known phenomenon. Studies describing interventions directed to relatives measuring service users' outcomes show clear improvements [9]. Relatedly, there are some precedents of research on interventions designed to offer assistance to service users and their relatives as a unit [10]. However, most report data focus on just one of the parts [11].

To fill the gap in recovery care directed towards families with a member diagnosed with a mental disorder, an integrated multi-component intervention was designed by the Catalan Health Department together with federations of organisations managed by service users and their relatives. The intervention was aimed at helping in the recovery process, increasing the agency and quality of life of both service users with mental health disorders and their relatives. The project was named *Activa't* per la Salut Mental (Get Active for Mental Health in English; referred to as *Activa't* from now on). It consists of a succession of four packs of interventions targeted to mental health service users and their relatives.

The pilot implementation of this intervention was evaluated in terms of the effectiveness of the circuit on users and relatives independently. It became clear that the intervention is effective in reducing some aspects of carer's burden in relatives and in fostering recovery in service users, although long-term differences between a control and an intervention group did not show statistical significance [12]. However, the interaction between the two members of the family remains unexplored. Therefore, the present study aims at establishing the mutual interaction effects of the participation and outcomes of service users and their relatives benefiting from this multicomponent intervention.

2. Materials and Methods

2.1. Trial design

The present study is a correlational longitudinal study based on the data collected on the *Activa't* pilot implementation RCT. The random allocation of the pilot study was 111 family units to each the control group and the treatment group (total n=222). For the current analyses, we focused on participants that received the full *Activa't* intervention. The Clinical Research Ethics committees of all participating mental health centres approved the study. For more details, please consult the ISRCTN registry number 15181312[1].

2.2. Participants

Participants were recruited from 12 mental health centres from different municipalities in Catalonia. Participation was organized through family units. A family unit consisted of one mental health service user and a relative who was involved in his or her care. Mental health centres selected potential participants from their databases, following selection criteria. Potential participants were informed about the study either by phone, individually or through informative sessions organized by professionals from the project team together with mental health services.

Service users' inclusion criteria were: a) being diagnosed with one of the following mental disorders: schizophrenia, schizotypal, schizoaffective, delusional, bipolar or recurrent depressive; b) having had symptomatology for at least two years (without this implying necessarily the existence of a diagnosis or a treatment during the whole two years); c) being between 18 and 63 years old; and d) having a moderate or severe disability degree

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lower than 60 according to Global Assessment of Functioning (GAF), the Axis V of the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Text Revision criteria [13]. Exclusion criteria for service users were: a) diagnosis of a borderline personality disorder; b) comorbidity with mental retardation; c) presence of severe associated somatic pathology; d) being incapacitated and having tutelage by a protection institution, or being resident of nursing homes, protected housing, or long stay units, e) having received structured psychoeducation or having participated in mutual support groups in the last 12 months. Relatives had to fulfil the following inclusion criteria: a) being the main carer of a person with the mental disorder diagnoses specified above, and b) having the practical availability to participate in all the *Activa't* activities. The exclusion criteria for relatives were: a) suffering from a psychiatric or severe somatic non-compensated disorder (including moderate and severe alcoholic dependency requiring intervention), and b) having received structured psychoeducation in the last 12 months.

All participants (service users and relatives separately) had to accept informed consent and participation compromise and accept personal data treatment. They filled demographic questionnaires and baseline outcome questionnaires prior to randomization. All participants filled outcome psychometric questionnaires again at six and twelve months after the treatment group completed the first block of interventions.

2.3. Sample size

The sample size calculation was performed before the start of the recruitment phase and it considered the maximum number of relatives that the mental health centres could treat (both intervention treatment and treatment as usual). The power size calculation indicated that 240 family units would allow for the detection of a Minimum Detectable Effect (MDE) of 0.36. The final sample size was of 222 family units, which was considered sufficient to detect the mentioned effects. As commented above, just the intervention group is used for the current study.

2.4. Interventions

The Activa't programme is composed by four components, each of them lead by a different stakeholder. The first one was called Espai Situa't (locate yourself space), a non-therapeutic counselling service provided by Salut Mental Catalunya (the Catalan federation of relatives and mental health service users). It also offers response to any information demand about mental health that people may have, and about the services available at each geographic area. The service is accessible to the public in general and could be used (or not) at any time of the trial by both the control and intervention groups. Twelve Espais Situa't were created in community centres at all 12 municipalities involved. The second component, which could be considered the first active intervention of the circuit, was a psychoeducation programme validated specifically for service users (Klau de Re) or relatives (PROENFA) which were carried out in mental health centres by their clinical staff. The third component, was an empowerment training programme called PROSPECT [14] provided also by Salut Mental Catalunya. The training aims at enhancing empowerment amongst relatives and users, and at developing empowerment-promoting skills among professionals. Finally, the fourth component consists of self- managed peer support groups linked to advocacy groups. Peer-support groups were led by service users or by relatives (specific for each group) who had previously received specific training as group facilitators within the programme.

2.3. Outcomes

2.3.1. Recovery perceived by mental health service users

The Spanish version of the Stages of Recovery (STORI; [15]) questionnaire was used to evaluate recovery among service users. STORI has 50 items and allows for the quantification of five consecutive stages of recovery. The stages are moratorium (stage of personal abandonment characterised by a feeling of profound loss and absence of hope), consciousness (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), reconstruction (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, characterised by the personal regulation of the disorder, resilience and a positive feelings about oneself). The items are quantified using a 6-point (0-5) Likert scale. We averaged the items of each stage so scores range 0-5. A high score on the items of a particular stage means that the person shows traits of that stage. From this follows that high scores on initial stages of the process, especially in moratorium, imply that the person is in an incipient moment of their recovery process, while high scores in later stages, such as rebuilding or growth, imply that the person is in an advanced stage of their recovery. Reliabilities in our study ranged α = .734 to .897 at baseline, α = .693 to .900 at 6 months, and α = .717 to .924 at 12 months and were considered adequate.

2.3.2. Perception of social support perceived by relatives

Social support was measured using the Spanish carer version [16] of the Duke-UNC-11 [17]. The instrument evaluates social support in three ways: confidential support, i.e., the degree to which the carer has close people to communicate with, and affective support, i.e., the intensity with which the carer receives demonstrations of love, affect, and empathy, and global support, a composite score of the above. High scores of the Duke questionnaire represent a high perception of social support. The questionnaire is composed by 11 items, with scores ranging from 1 to 5 in a Likert scale. We averaged the items of each dimension so scores range 1-5. Reliabilities in our study ranged α = .718 to .873 at baseline, α = .796 to .904 at 6 months, and α = .828 to .915 at 12 months and were considered adequate.

2.3.3. Care burden perceived by relatives

The Spanish version [18] of the second version of the Family Burden Interview Schedule (FBIS-II) questionnaire [19] 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 behaviours, C) financial burden, D) caregiver's routine, E) concern, F) available help, G) repercussions on health, and H) assessment of general burden. This information is assessed measuring absolute occurrence (yes/no), and, just if the burden element is present, frequency (0-4), level of concern (0-3, except for the concern module) and time when applicable (1-7). Additionally, module C measures financial burden in euros. Different indicators were created for analysis: average scores of the frequency of burden for each module (if applicable), average scores of the concern experienced by the carer for each module (if applicable) and a total sum of the money invested in the service user. This use of the questionnaire led to the creation of five frequency scores (help in daily-life activities, disruptive behaviours, change in carer'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 behaviours). Total scores were also created (summing or averaging items across modules): a score with the count of "yes or no" items that add burden to the relative across all modules (total presence of burden), a score of the average frequency of burden, a score of the average concern experienced by the carer 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 elements by the averages of the frequency and concern and by the total time. High scores in all these indicators represent high burden of the carer. Reliabilities could only be calculated for scores that were replied by all participants using the same scale.

2.4. Analyses

We used participation data measured as total sessions attended to determine effects of higher or lower participation. To facilitate the analysis, we considered that participation could be divided into low participation (subjects below median participation score) and high participation (subjects above median participation score). The data from service users and relatives were analysed as a unit and the low participation groups data were compared to the high participation groups data. Subsequently, we carried out correlational and a regression analyses. Firstly, participation scores were correlated with all psychometric scores. Secondly, the differential outcome variables of the questionnaires from baseline to both follow-up points (i.e. t0 – t6 and t0 – t12) were correlated. Henceforth, all outcome variables were analysed using general linear models with participation of the other member of the family unit as covariate.

All analyses were performed with IBM SPSS 23.0. Significance was set at p<.05.

3. Results

3.1. Interaction of levels of participation with characteristics and outcomes

The participation of service users was 19±11.54 sessions while their relatives' was 15±10.18 (r = .356, p<.0001). To show a clearer picture, tables 1 and 2 show baseline characteristics of service users and relatives based on the dichotomised version of their total participation at the end of the programme's pilot implementation. As it can be seen, in the case of service users, educational level was the only predictor of participation. However, in the case of relatives, confident social support and financial burden would be the parameters that could predict the level of participation, although these effects would disappear if Bonferroni corrections were applied.

We then compared service users' baseline parameters by relatives' levels of participation and vice versa. Statistically significant results for relatives' participation included service users' relationship status, educational level, employment, and age.

Relatives' educational level and perceived frequency of disruptive behaviours had a statistically significant influence on service users' participation.

Table 1. Sociodemographic characteristics and baseline scores of service users recruited into the study by level of participation of both groups.

	Service users' participation							**Relatives' participation**						
	High (58)		**Low (53)**		**Statistical significance**			**High (58)**		**Low (53)**		**Statistical significance**		
	N	%	N	%	OR. 95% CI	p		N	%	N	%	OR. 95% CI	p	
Gender (% females)	22	37.9	22	41.5	0.86. .40-1.84	.700		21	37.5	23	41.8	0.84. .39-1.79	.642	
Couple (% in a relationship)	14	27.5	17	38.6	0.60. .25-1.43	.246		**10**	**20**	**21**	**46.7**	**.29. .12-.71**	**.006**	
Cohabitation (% autonomous)	15	32.6	18	38.3	1.28. .55-3.01	.566		17	34	16	37.2	1.15. .49-2.7	.747	
Education (% at least secondary)	**37**	**63.8**	**21**	**39.6**	**2.69. 1.25-5.79**	**.011**		**36**	**64.3**	**22**	**40**	**2.7. 1.25-5.8**	**.010**	
Employment situation (% em-	3	5.2	1	1.9	2.84. .29-28.14	.354		**4**	**7.1**	**0**	**0**	**1.08. 1-1.16**	**.044**	
	M	**SD**	**M**	**SD**	**t**	**p**	**d**	**M**	**SD**	**M**	**SD**	**t**	**p**	**d**
Age (M±SD)	39.38	10.10	42.02	10.85	-1.328	.187	-0,25	**36.77**	**10.44**	**44.58**	**9.07**	**-4.208**	**<.0001**	**-0,80**
STORI at baseline														
Moratorium	2.30	1.06	2.45	1.12	-0.701	.485	-0,13	2.19	1.05	2.56	1.11	-1.827	.070	-0,79
Awareness	3.19	0.78	3.21	0.83	-0.095	.925	-0,02	3.28	0.78	3.12	0.82	1.045	.298	-0,86
Preparation	2.98	1.04	3.14	1.11	-0.795	.429	-0,15	3.20	1.01	2.92	1.12	1.371	.173	-0,35
Rebuilding	3.09	0.95	3.28	1.14	-0.955	.342	-0,18	3.24	1.01	3.13	1.09	0.525	.601	-0,35
Growth	2.85	1.11	3.07	1.27	-0.955	.342	-0,18	3.17	1.05	2.74	1.30	1.924	.057	-0,34

Table 2. Sociodemographic characteristics and baseline scores of relatives recruited into the study by level of participation of both groups.

	Relatives' participation							**Service users' participation**						
	High (58)		**Low (53)**		**Significance**			**High (58)**		**Low (53)**		**Significance**		
	N	%	N	%	OR. 95% CI	p		N	%	N	%	OR. 95% CI	p	
Gender (% females)	43	76.8	37	67.3	1.61, .70-3.72	.264		39	73.6	41	70.7	0.87, .0.38-1.99	.734	
Couple (% in a relationship)	31	68.9	33	76.7	.67, .26-1.73	.408		28	70	36	75	1.29, 0.50-3.29	.600	
Cohabitation (% autonomous)	25	53.2	14	40.0	.59, .24-1.42	.237		15	39.5	24	54.5	0.54, 0.23-1.31	.173	
Education (% at least secondary)	33	58.9	28	50.9	1.38, .65-2.93	.396		**23**	**43.4**	**38**	**65.5**	**2.48, 1.15-5.34**	**.019**	
Employment situation (% em-	23	41.1	23	41.8	.97, .46-2.06	.936		18	34	28	48.3	1.82, 0.84-3.91	.126	
	M	**SD**	**M**	**SD**	**t**	**p**	**d**	**M**	**SD**	**M**	**SD**	**t**	**p**	**d**
Age (M±SD)	57.96	9.91	55.36	15.06	1.077	.284	0.20	56.71	11.30	56.64	14.2	0.027	.979	0.01
Duke Social Support Index at baseline														
Global Social Support	35.86	9.15	39.09	8.59	-1.918	.058	-0.36	3.34	0.77	3.47	0.87	-0.816	.416	-0.16
Affective Social Support	16.57	3.99	17.09	4.51	-.643	.522	-0.12	3.36	0.78	3.37	0.93	-0.092	.927	-0.02
Confident Social Support	**19.29**	**5.93**	**22.00**	**5.19**	**-2.564**	**.012**	**-0.49**	3.33	0.89	3.55	1.02	-1.219	.226	-0.23
FBIS-II at baseline														
Frequency of help in daily-life activ-	2.39	0.77	2.27	1.01	.671	.504	0.13	2.21	0.93	2.45	0.84	-1.34	.183	-0.27
Frequency of disruptive behaviours	1.01	0.98	1.16	1.03	-.718	.475	-0.15	**0.86**	**0.96**	**1.34**	**1.01**	**-2.386**	**.019**	**-0.49**
Frequency of change in carer's rou-	0.83	0.82	0.59	0.74	1.644	.103	0.31	0.68	0.73	0.74	0.85	-0.356	.722	-0.07
Frequency of concern	2.51	0.89	2.31	0.90	1.170	.244	0.22	2.34	0.93	2.49	0.86	-0.883	.379	-0.17
Frequency of global burden	1.96	1.33	1.56	1.18	1.663	.099	0.32	1.68	1.30	1.86	1.25	-0.746	.457	-0.14
Financial burden	**759.1**	**827.7**	**294.63**	**260.17**	**2.380**	**.021**	**0.67**	700.0	785.2	500.1	648.	1.047	.3	0.28
Concern about help in daily-life ac-	**1.64**	**0.79**	**1.27**	**0.87**	**2.267**	**.026**	**0.45**	1.56	0.83	1.36	0.86	1.234	.22	0.25
Concern about disruptive behav-	2.01	0.86	2.07	0.78	-.364	.717	-0.08	**1.88**	**0.89**	**2.23**	**0.69**	**-2.104**	**.038**	**-0.44**
FBIS-II totals														

Total presence of burden	12.30	4.94	10.96	4.69	1.466	.145	0.28	11.09	4.49	12.25	5.17	-1.264	.209	-0.24
Average frequency of burden	1.64	.76	1.46	.69	1.356	.178	0.26	1.45	0.72	1.66	0.73	-1.506	.135	-0.29
Average concern about burden	1.81	0.74	1.64	0.71	1.242	.217	0.24	1.75	0.77	1.70	0.69	0.387	.7	0.07
Total time	12.85	9.26	11.31	9.19	.854	.395	0.17	11.17	8.29	13.00	10.0	-1.024	.308	-0.20
TOTAL FBIS-II	10.28	19.61	5.21	8.87	1.703	.093	0.34	6,55	10,85	8,89	18,8	-0.789	.432	-0.15

Table 3. Pearson correlations between service users' and relatives' participation and scores at all time points.

	Service users' participation			**Relatives' participation**		
	t0	*t6*	*t12*	*t0*	*t6*	*t12*
STORI						
Moratorium	-0.128	-.283**	-.234*	-0.153	0.008	-0.136
Awareness	0.124	.217*	0.159	0.129	0.136	0.085
Preparation	0.114	.246*	.296*	0.146	0.189	0.213
Rebuilding	0.082	0.027	0.167	0.131	0.071	0.173
Growth	0.047	0.146	.241*	.200*	0.076	.230*
Duke						
Global Social Support	-0.056	-0.064	-0.172	-0.13	0.055	-0.011
Affective Social Support	0.000	-0.006	-0.083	-0.043	0.084	0.039
Confident Social Support	-0.089	-0.101	-.225*	-0.173	0.025	-0.047
FBIS-II						
Total presence of burden	-0.183	-0.13	-0.033	0.031	0.087	0.21

Average frequency of burden	0.065	-.237*	-0.068	0.119	-0.013	-0.069
Average concern about burden	-.228*	-.254*	-0.089	0.035	0.057	0.135
Total time	-0.174	-.244*	-0.074	0.035	-0.083	0.037
TOTAL FBIS-II	-0.126	-.279*	-0.069	0.079	0.008	0.095

*p<.05, ** p<.01, *** p<.001

Table 4. Pearson correlations between service users' and relatives' differential scores.

		Service user's outcomes (STORI subscales)									
		Moratorium		Awareness		Preparation		Rebuilding		Growth	
Relatives' outcomes		t0-t6	t0-t12	t0-t6	t0-t12	t0-t6	t0-t12	t0-t6	t0-t12	t0-t6	t0-t12
Duke Social Support Index											
Global Social Support	t0-t6	.029	.217	.039	-.030	-.027	-.166	-.077	-.126	-.060	-.148
	t0-t12	.124	**.290***	-.077	-.053	-.101	-.120	-.184	-.103	-.205	-.131
Affective Social Support	t0-t6	.010	.132	.125	.073	.012	-.051	.030	.008	.053	-.001
	t0-t12	.063	.245	-.023	-.025	-.101	-.067	-.135	-.055	-.081	-.092
Confident Social Support	t0-t6	.038	**.254***	-.026	-.098	-.051	-.229	-.140	-.207	-.130	-.236
	t0-t12	.152	**.291***	-.105	-.066	-.091	-.142	-.194	-.124	**-.261***	-.143
FBIS-II											
Frequency of help in daily-life activities	t0-t6	.016	.147	-.033	.003	-.060	-.097	.057	.012	.024	.085
	t0-t12	-.108	.119	-.061	-.065	-.086	-.250	-.037	-.123	.021	-.105
Frequency of disruptive behaviours	t0-t6	-.003	.020	-.056	-.129	-.101	-.285	-.152	-.220	-.122	-.219
	t0-t12	-.147	-.020	-.254	-.224	-.285	-.259	-.317	-.177	-.247	**-.380***
Frequency of change in carer's routine	t0-t6	.149	.153	-.145	-.212	-.149	-.167	**-.244***	-.226	-.168	-.157

	t0-t12	.051	.060	-.169	-.253*	-.126	-.119	**-.317****	**-.289***	-.178	-.212
Frequency of concern	t0-t6	.099	-.109	-.005	.093	-.050	.122	-.063	.054	-.077	.073
	t0-t12	.078	-.049	-.032	.143	-.003	.101	-.008	.118	-.026	.168
Frequency of global burden	t0-t6	.122	.074	-.056	-.010	-.129	.026	-.098	-.047	-.116	.024
	t0-t12	.103	.059	-.144	-.093	-.085	-.086	-.101	-.097	-.124	-.083
Financial burden	t0-t6	-.217	.069	.042	-.180	.112	-.168	-.001	-.204	.090	-.184
	t0-t12	-.066	-.232	-.082	-.050	-.099	-.176	-.132	-.119	.001	-.040
Concern about help in daily-life activities	t0-t6	.171	.116	-.013	-.080	-.058	-.204	.015	-.013	-.073	-.052
	t0-t12	.104	-.119	-.106	-.027	-.090	-.121	-.099	.002	-.128	.017
Concern about disruptive behaviours	t0-t6	-.130	-.105	.044	-.107	-.045	-.131	-.005	-.119	-.034	-.098
	t0-t12	.024	.100	.241	.070	.195	.001	-.008	-.148	.054	-.170
FBIS-II totals											
Total presence of burden	t0-t6	.095	.126	-.057	-.203	-.163	-.164	**-.286***	**-.293***	**-.254***	**-.251***
	t0-t12	.000	.011	-.023	-.134	-.025	-.077	-.167	-.197	-.112	-.185
Average frequency of burden	t0-t6	.141	.095	-.174	-.137	-.207	-.138	-.169	-.161	-.179	-.069
	t0-t12	.104	.110	-.212	-.183	-.159	-.184	-.207	-.199	-.158	-.170
Average concern about burden	t0-t6	-.004	.015	.001	-.101	.009	-.170	.091	-.049	.036	-.033
	t0-t12	.028	-.226	.058	.134	.087	.079	.038	.146	.041	.157
Total time	t0-t6	.033	.221	-.193	-.241	**-.337****	**-.348****	**-.369****	**-.273***	**-.264***	-.178
	t0-t12	.115	.251	-.190	-.224	**-.283***	**-.300***	**-.352****	**-.269***	-.183	-.174
TOTAL FBIS-II	t0-t6	.030	**.393****	-.128	**-.382****	-.192	**-.375****	**-.343****	**-.470*****	**-.258***	**-.447*****
	t0-t12	.097	.224	-.066	-.244	-.050	-.171	**-.287***	**-.368****	-.167	**-.370****

*p<.05, ** p<.01, *** p<.001

3.2. Correlational analyses

Pearson correlations between service users' and relatives' participation and scores at all time points can be seen in table 3. Participation of service users had a statistically significant correlation with various STORI scores at *t6* and *t12*, one Duke score at *t12* and various FBIS-II scores at *t0* and, especially, *t6*. Participation of relatives correlated just with STORI's *Growth* at *t0* and *t12.* Correlations of participation by differential scores showed statistical signification just for FBIS-II *Average concern about burden t0 – t6* (r = .228, p<.005) in the case of service users and STORI's *Moratorium t0 – t6* (r = .233, p<.005) in the case of relatives.

Results of the correlational analyses carried out with differential scores for relatives' by service users' outcomes can be seen in table 4. Statistical significant results can be seen for DUKE's *Global* and *Confident* social support scores with STORI's *Moratorium* and *Growth.* FBIS-II's *Frequency of disruptive behaviours, Frequency of change in carer's routine,* and *Total presence of burden* correlated with STORI's *Rebuilding* and *Growth*. FBIS-II's *Total time* correlated with *Preparation*, *Rebuilding*, and *Growth*. The FBIS-II total score correlated with all STORI subscales, with the peculiarity that *t0 – t6* differentials of the former correlated with *t0 – t12* differentials of the latter in all cases, while FBIS *t0 – t12* correlated with STORI *t0 – t12* only in the case of *Rebuilding*, and *Growth*.

3.3. General lineal models

We used general linear models to include the three time points of outcome variables as a single dependent variable and to include level of participation as a factor. Statistical significant interactions were only found for the total FBIS-II with the total participation of service users (F = 3.151, p <.05, η_p^2 = 0.050).

4. Discussion

This study aimed at determining whether the participation of service users and relatives in the *Activa't* programme had an interaction on each other's outcomes evolution and if that evolution correlated with each other. We found that the level of participation of both service users and relatives correlated with baseline characteristics and scores, as well as scores during the trial. Furthermore, differential scores of both groups correlated. Especially the higher stages of recovery negatively with the total load level. Finally, the evolution of the total FBIS-II scores was found to interact with service users' participation levels.

Before entering into details on these results, it is important to mention that the correlation between users' participation and relatives' participation was significant. This positive correlation implies that the more one of the members of the family unit participated, the more the other member participated as well. This implies that there is a group of participating family units that were especially involved in the intervention.

We know that the intervention is effective in improving recovery in users and reducing some aspects of burden in relatives, and that this is linked to the level of participation in the case of relatives [20]. Thus, knowing that the participation of one of the members of the unit fosters the participation of the other and their journey into recovery, the *Activa't* components can be understood as key resources for recovery. It would be interesting to explore how this co-evolution occurs with a more specific design with the intention of increasing both the participation and the impact obtained by service users and their relatives in the future.

Although different cross-influences can be seen, it seems that the participation of service users had a greater impact on the outcomes of their relatives, than vice versa. Although carried out with a very different philosophy and focus on other outcomes, these results seem to contradict reviews on the use of psychoeducation where the effects were clearer on service users' clinical status and disability than the burden of their relatives [21,22]. This apparent contradiction probably responds to the different nature of the intervention evaluated in the present study, made up of more components than the purely psychoeducational ones. Furthermore, we cannot forget that the results of this study are focused more on the interaction of participation and impact than on efficacy understood as a comparison with a control group, the results of which can be found in other publications [12,20].

In terms of generalizability, the intervention is directed towards all the population who suffers or has relatives who suffer from a severe mental disorder. In this sense, it is a broad population, for which the trial has the potential for a great generalizability. It is important, however, to determine more precisely if the population that finally enrolled in the study and fulfilled all the evaluation time points is representative of the general population that may need access to this intervention. The strict criteria for enrolment may have had a dissuasive effect for some individuals. However, the recruitment process included different municipalities, from rather rural and urban areas, and the project was offered massively to most of the patients of the centres that fulfilled criteria.

The present study has, of course, some limitations. The main one is that, although the original study was a randomised controlled trial, this was a correlational study carried with the active group of the latter. Furthermore, by working with participation data, we could be over representing the trends of the groups of participants whose participation was more intense.

5. Conclusions

This study gave insight into how an intervention for mental health service users can contribute to reducing the relatives' burden and how an intervention for relatives of the users can contribute to foster users' recovery. The optimization of this type of intervention can improve the prospects of thousands of people who face severe mental illness.

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References

1. World Health Organization *Comprehensive Mental Health Action Plan 2013–2020*; Department of Mental Health and Substance Abuse: Geneva, Switzerland, 2013;
2. Davidson, L. The Recovery Movement: Implications for Mental Health Care and Enabling People to Participate Fully in Life. *Health Aff.* **2016**, *35*, 1091–1097, doi:10.1377/hlthaff.2016.0153.
3. Anthony, W.A. Recovery from Mental Illness: The Guiding Vision of the Mental Health Service System in the 1990s. *Psychosoc. Rehabil. J.* **1993**, *16*, 11–23, doi:10.1037/h0095655.
4. Nordby, K.; Kjønsberg, K.; Hummelvoll, J.K. Relatives of Persons with Recently Discovered Serious Mental Illness: In Need of Support to Become Resource Persons in Treatment and Recovery. *J. Psychiatr. Ment. Health Nurs.* **2010**, *17*, 304–311, doi:10.1111/j.1365-2850.2009.01531.x.
5. Waller, S.; Reupert, A.; Ward, B.; McCormick, F.; Kidd, S. Family-Focused Recovery: Perspectives from Individuals with a Mental Illness. *Int. J. Ment. Health Nurs.* **2019**, *28*, 247–255, doi:10.1111/inm.12528.
6. Saunders, J.C. Families Living with Severe Mental Illness. *Issues Ment.* **2003**, *24*, 175–198, doi:10.1080/01612840390160711.
7. Shah, A.J.; Wadoo, O.; Latoo, J. Psychological Distress in Carers of People with Mental Disorders. *Br. J. Med. Pract.* **2010**, *3*, a327.
8. Kuipers, E. Time for a Separate Psychosis Caregiver Service? *J. Ment. Heal.* **2010**, *19*, 401–404, doi:10.3109/09638237.2010.510155.
9. Claxton, M.; Onwumere, J.; Fornells-Ambrojo, M. Do Family Interventions Improve Outcomes in Early Psychosis? A Systematic Review and Meta-Analysis. *Front. Psychol.* **2017**, *8*, doi:10.3389/fpsyg.2017.00371.
10. Norton, M.J.; Cuskelly, K. Family Recovery Interventions with Families of Mental Health Service Users: A Systematic Review of the Literature. *Int. J. Environ. Res. Public Health* **2021**, *18*, doi:10.3390/ijerph18157858.
11. Lobban, F.; Postlethwaite, A.; Glentworth, D.; Pinfold, V.; Wainwright, L.; Dunn, G.; Clancy, A.; Haddock, G. A Systematic Review of Randomised Controlled Trials of Interventions Reporting Outcomes for Relatives of People with Psychosis. *Clin. Psychol. Rev.* **2013**, *33*, 372–382, doi:10.1016/j.cpr.2012.12.004.
12. Rojo Rodés, E.; San Pío Tendero, M.J.; Eiroa Orosa, F.; Marcet, G. Get Active for Mental Health: A Project Evaluated for Active Involvement of Families and Users. *Int. J. Integr. Care* **2019**, *19*, 419, doi:10.5334/ijic.s3419.
13. American Psychiatric Association *Diagnostic and Statistical Manual of Mental Disorders, Text Revision (DSM-IV-TR)*; American Psychiatric Association, Ed.; Fourth Edi.; Washington, DC, USA, 2000;
14. Steffen, S. European Federation of Associations of Families of People with Mental Illness Initiatives on Person-Centred Care. *J. Eval. Clin. Pract.* **2011**, *17*, 344–346, doi:10.1111/j.1365-2753.2010.01579.x.
15. Andresen, R.; Caputi, P.; Oades, L. Stages of Recovery Instrument: Development of a Measure of Recovery from Serious Mental Illness. *Aust. N. Z. J. Psychiatry* **2006**, *40*, 972–980, doi:10.1111/j.1440-1614.2006.01921.x.
16. Cuéllar-Flores, I.; Dresch, V. Validación Del Cuestionario de Apoyo Social Funcional Duke-UNK-11 En Personas Cuidadoras. *Rev. Iberoam. Diagnostico y Eval. Psicol.* **2012**, *2*, 89–101.
17. Koenig, H.G.; Westlund, R.E.; George, L.K.; Hughes, D.C.; Blazer, D.G.; Hybels, C. Abbreviating the Duke Social Support Index for Use in Chronically Ill Elderly Individuals. *Psychosomatics* **1993**, *34*, 61–69, doi:10.1016/S0033-3182(93)71928-3.
18. Vilaplana, M.; Ochoa, S.; Martinez, A.; Villalta, V.; Martinez-Leal, R.; Puigdollers, E.; Salvador, L.; Martorell, A.; Muñoz, P.E.; Haro, J.M.; et al. Validation in Spanish Population of the Family Objective and Subjective Burden Interview (ECFOS-II) for Relatives of Patients with Schizophrenia. *Actas Esp. Psiquiatr.* **2007**, *35*, 372–381.
19. Tessler, R.; Gamache, G. The Family Burden Interview Schedule – Short Form (FBIS/SF). In *Outcome assessment in clinical practice*; Sederer, L., Dickey, B., Eds.; Williams & Williams: Baltimore, MD, US, 1996; pp. 110–118.
20. San Pío, M.J.; Sibuet, I.; Marcet, G.; Rojo, E.; Eiroa-Orosa, F.J. A Randomized Controlled Trial on the Effectiveness of a Multi-

doi:10.20944/preprints202209.0213.v1

Component Integrated Care Intervention on the Care Burden and Social Support of Relatives of People Diagnosed with Mental Disorders. *Am. J. Orthopsychiatry*.

21. Magliano, L.; Fiorillo, A. Psychoeducational Family Interventions for Schizophrenia in the Last Decade: From Explanatory to Pragmatic Trials. *Epidemiol. Psichiatr. Soc.* **2007**, *16*, 22–34, doi:10.1017/s1121189x00004589.
22. Sin, J.; Gillard, S.; Spain, D.; Cornelius, V.; Chen, T.; Henderson, C. Effectiveness of Psychoeducational Interventions for Family Carers of People with Psychosis: A Systematic Review and Meta-Analysis. *Clin. Psychol. Rev.* **2017**, *56*, 13–24, doi:10.1016/j.cpr.2017.05.002.