EFFECTIVENESS OF FORMAL FEEDBACK IN MENTAL HEALTH COMUNNITY IN SPAIN: A RANDOMIZED CLINICAL STUDY

EFECTIVIDAD DEL FEEDBACK FORMAL EN SALUD MENTAL COMUNITARIA EN ESPAÑA: UN ESTUDIO CLÍNICO ALEATORIZADO

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Abstract

The present research aims to evaluate the effectivity of the introduction of the formal feedback PCOMS instrument in psychotherapy in the Spanish national health system. To do this, it was a randomized controlled single blind clinical study in 4 mental health and primary care centers of the La Paz University Hospital, Spain. Patients assigned to the experimental group completed the measurements of the PCOMS instrument together with their therapist during each session, while patients assigned to the control group received treatment as usual. A total of 58 patients completed the study. The main variable was the therapeutic result, measured through the ORS scale. Secondary variables were symptomatology, through the GSI scale (SCL-90), satisfaction, through the CRES-4 scale, and dropouts. In the results, differences were found between the experimental and control groups in the therapeutic result. The number necessary to treat indicated that for every 7 patients treated in the experimental condition, deterioration or no change of 1 patient would be avoided. There were no differences in symptoms, satisfaction or premature abandonment. It is concluded that the PCOMS instrument can increase the effectivity of psychotherapy in mental health contexts of the Spanish national health system.

Keywords: *feedback, health, mental, Spain, study, randomized*

Resumen

El presente trabajo tiene por objetivo evaluar la efectividad de la introducción del instrumento de feedback formal PCOMS en psicoterapia en el sistema nacional de salud español. Para ello, se llevó a cabo un estudio clínico aleatorizado y controlado simple ciego en cuatro centros de salud mental y atención primaria del Hospital Universitario La Paz, España. Los pacientes asignados al grupo experimental completaron junto con su terapeuta las medidas del instrumento PCOMS durante cada sesión, mientras que los pacientes asignados al grupo control recibieron el tratamiento habitual. Un total de 58 pacientes completaron el estudio. La variable principal fue el resultado terapéutico, medida a través de la escala ORS. Las variables secundarias fueron la sintomatología, a través de la escala GSI (SCL-90), satisfacción, a través de la escala CRES-4, y abandono prematuro. En los resultados se encontraron diferencias entre el grupo experimental y control en el resultado terapéutico. El número necesario a tratar indicó que por cada siete pacientes tratados en la condición experimental se evitaría el empeoramiento o estancamiento de un paciente. No se obtuvieron diferencias en sintomatología, satisfacción o abandono prematuro. Se concluye que el instrumento PCOMS puede incrementar la efectividad de la psicoterapia en contextos de salud mental del sistema nacional de salud español.

Palabras clave: *feedback, salud, mental, España, estudio, aleatorizado*

Abstract

Objective: to evaluate the effectiveness of the introduction of the formal PCOMS feedback instrument in psychotherapy in the Spanish national health system.
Method: A single-blind, randomized, controlled clinical study was conducted in four mental health and primary care centers of Hospital Universitario La Paz, Spain. Patients assigned to the experimental group completed the PCOMS instrument measures together with their therapist during each session, while patients assigned to the control group received treatment as usual. A total of 58 patients completed the study. The main variable was the therapeutic outcome, measured through the ORS scale. The secondary variables were symptomatology, through the GSI scale (SCL-90), satisfaction, through the CRES-4 scale, and premature dropout. Result: differences were found between the experimental and control groups in the therapeutic outcome. The number needed to treat was: for every seven patients treated in the experimental condition, one patient would be prevented from worsening or no change. No differences were obtained in symptomatology, satisfaction or premature dropout.
Conclusions: the PCOMS instrument can increase the efficacy of psychotherapy in the Spanish national mental health system.

Keywords: *Feedback, Health, Mental, Spain, Study, Randomized*

Introduction

Despite the established efficacy of psychotherapy (Wampold & Imel, 2015), the rate of no improvement or worsening is between 20% and 50% (Lambert, 2013), and the dropout rate before completion of therapy by up to 25% (Swift and Greenberg, 2012). Furthermore, it seems that clinical experience is not enough to increase the effectiveness of therapists (Goldberg et al., 2016). Therapists tend to overestimate their own efficacy and the improvement of their patients (Walfish, McAlister, O'Donnell, & Lambert., 2012).

In this context, instruments that monitor progress in psychotherapy have been introduced in recent years. One of these instruments is the Partners for Change Outcome Management System (PCOMS) (Duncan and Miller, 2008; Rodrigo-Holgado et al., 2018). A first meta-analysis evaluating the efficacy of PCOMS found a moderate effect size (g=.53) compared to treatment as usual (Lambert and Shimokawa 2011). A more recent meta-analysis of 18 studies and 2,910 patients has found a more modest effect size (g=.27), being less effective in psychiatric or hospital settings (g=.1) than in community settings (g=.45) (Østergård, Randa, and Hougaard, 2018).

There is evidence on the effectiveness of using of PCOMS in community settings in other countries and also in Spanish private settings. However, there are no published studies to this date focused on its effectiveness within the national health system (Gimeno-Peón, Barrio-Nespereira and Prado-Abril., 2018; Gimeno-Peón et al., 2019).

Method

Objectives: This study evaluates the effectiveness of PCOMS instrument in community mental health and primary care centers of the Spanish public health system. The main hypothesis is that the administration of the PCOMS will result in an improvement on the effectiveness of psychotherapy, measured through the therapeutic outcome, the decrease in symptomatology, the increase in satisfaction and the reduction in dropouts before the end of therapy.

Design

A single-blind, controlled, individual randomization clinical study carried out in three community mental health centers and one primary care center of the health area of La Paz University Hospital, in the Community of Madrid, Spain.

Participants

Patients who were referred by Primary Care Physicians or other professionals for various problems related to mental health were assigned to therapists during their rotation in mental health or primary care centers during the study period. The exclusion criteria were: 1) being under 18 years old; 2) being in psychotherapeutic treatment by more than one professional simultaneously.

The study was carried out between June 2017 and March 2019. Six psychotherapists participated, including five psychology and one psychiatry residents, assigned to La Paz University Hospital.

Intervention

Intervention group (PCOMS):
At the beginning of each session, the patient completed the Outcome Rating Scale (ORS), where they had to rate his current state in each of four 10-centimeter lines associated with four domains (individual, interpersonal, social and global), obtaining a total score of 40. Lower scores reflect a higher degree of severity, with the cut-off point for the clinical population being a global score of less than 25. According to the introduction protocol (Duncan et al. 2008), the therapist should explain that the ORS is a way to ensure that the opinión of the patient is central to the therapy, and is used to monitor the outcome of each session.

At the end of each session, the patient completed the Session Rating Scale (SRS), using a procedure similar to the previous one in the four domains (relationship with the therapist, goals or objectives, approach or tasks, and global). The cut-off point of this scale is 36, so that those patients who score below are at risk of deterioration of the working alliance. Whether the patient scores below or above the cut-off point, the therapist should acknowledge the feedback received and ask what could be done to improve in the next session. This way, the SRS scale provides a structure for talking about the alliance and possible problems that have arisen.

Control group:
Prior to the start of each session, the patient completed the ORS, on paper, in the waiting room, putting it in an envelope and sealing it. Upon entering the consultation, the patient handed the sealed envelope to the therapist, who incorporated it into their medical record. This way, the therapist did not access the score, nor was the SRS administered at the end of the session. There were no other differences between the intervention group and the control group.

Therapists were instructed in the administration of the two scales of the PCOMS protocol according to their authors' protocol and their doubts were resolved prior to the start of the recruitment phase (Duncan et al. 2008).

Outcome measures:

Main variable:
Therapeutic outcome: 1) The difference between the initial score of the first session and the score corresponding to the last session on the ORS scale was used.

Secondary variables:

Therapeutic outcome: 1) The results of the ORS scale were coded in a variable with 3 levels (worsening, no change, improvement) and the difference between the percentage of patients in both groups who experienced worsening (decrease of five or more points in the final ORS with respect to the initial score), no change (difference less than five points) or improvement (increase of five or more points) was used, according to the PCOMS interpretation protocol (Duncan et al., 2008).

Symptomatology: 1) The difference between the initial score and the score corresponding to the last session in the Global Severity Index (GSI) of the Spanish version of the Symptom Checklist 90-R scale (SCL, Derogatis & Savit, 1999; González-De-Ribera, De-La-Cuevas, Rodríguez-Abuín and Rodríguez-Pulido 2002) was used. It is a 90-item scale, applicable in community studies for the detection of general psychopathology and/or symptomatic changes induced by various treatments.

Satisfaction: 1) The Spanish adaptation of the Consumer Reports Effectiveness Scale (CRES-4, 1995; Feixas et al., 2012) was used. This scale has four items and was created to assess the patient's degree of satisfaction with the treatment, the degree to which they consider that their problem have been resolved, and the change in their emotional state.

Process

Patients selection was carried out according to the aforementioned criteria as they were referred to each therapist. After an initial interview, each patient was given informed consent, a questionnaire about her demographic characteristics, the ORS scale, and the SCL questionnaire. The randomization of patients to each group was carried out by the therapist of each patient, through a web program to generate two random numbers (https://www.augeweb.com/azar/) once the consent was signed. Number one is indicated for inclusion in the PCOMS condition, and number two is indicated for inclusion in the control condition. Each therapist carried out the intervention in both conditions. At the end of treatment, each patient was asked to complete the ORS scale and the SCL scale again, in addition to the CRES-4 satisfaction questionnaire.

The initial protocol of the study was approved by the Ethics Committee for research with clinical trials of La Paz University Hospital on July 28, 2017 and code 4897, and was in accordance with the principles of the Declaration of Helsinki (Mazzanti, 2011).

Statistical analysis:

Sample size calculation:

There are no previous studies where the effectiveness of this feedback intervention has been estimated in a clinical context comparable to our research. To calculate the sample size, and given the heterogeneity of effect sizes in different

previous studies (Østergård et al., 2018), we took the widely cited study by Whipple (2003) as a reference for the expected effect size. In this study, which included nearly 1,000 patients seen in ordinary clinical practice by therapists of different orientations, the difference in effect between patients of therapists who received a feedback intervention, compared with those who did not, was estimated to be 0.70 (a mean effect according to the Lipsey 1990 criteria). Assuming a similar effect size, a statistical power = 0.80 and an alpha error probability = 0.05, 34 participants per study arm would be necessary for a total sample size of 68. The final sample size was 58 patients, mainly due to a lower number of patients recruited than estimated.

Baseline characteristics of participants included in the intervention and control groups were compared using Pearson's Chi-square test and Student's t-test for independent samples for categorical and continuous variables, respectively.

Subsequently, outcomes on the post-intervention ORS and SCL scales were compared in both groups using Student's t-test; and Fisher's exact test to analyze the difference between the proportion of patients who experienced worsening, no change, or improvement in each intervention.

Finally, the difference between groups, in terms of post-intervention ORS and SCL scales, was modeled using multilevel analysis and general estimating equations (GEE). Both models were built using the measure of post-intervention scales as an outcome variable, and the intervention group as a predictor variable. Both models were adjusted for the baseline measure of each scale (pre-intervention ORS for the post-intervention ORS model and pre-intervention SCL for the post-intervention SCL model). GEE models are suitable for this study since they allow longitudinal observations to be considered nested in the same individual, controlling for differences between study groups by intra-individual variation.

The multivariate models additionally included a second level to adjust the estimators according to the therapist who performed the intervention, to control for differences between therapists, similarly to previous studies (Janse et al., 2016; Van Oenen et al., 2016). Both approximations were performed to obtain doubly robust effect estimators, by way of sensitivity analysis.

The results of the multilevel and GEE models are expressed as beta: variation, between control group and PCOMS, of the mean scores of (i) baseline ORS and SCL, and (ii) post-study ORS and SCL adjusted for ORS and GSI baseline, respectively; and include the 95% confidence interval and a p-value measure.

Statistical analysis were performed with the Stata 15 statistical package for PC (StataCorp, College Station, TX).

Results

A total of 69 patients signed the informed consent and were included in the study. Baseline and end of treatment data on the primary measure were obtained from 58 patients (PCOMS condition, n=29, 68% female, mean=36.9 years; control condition, n=29, 72% female, mean=44.1 years).
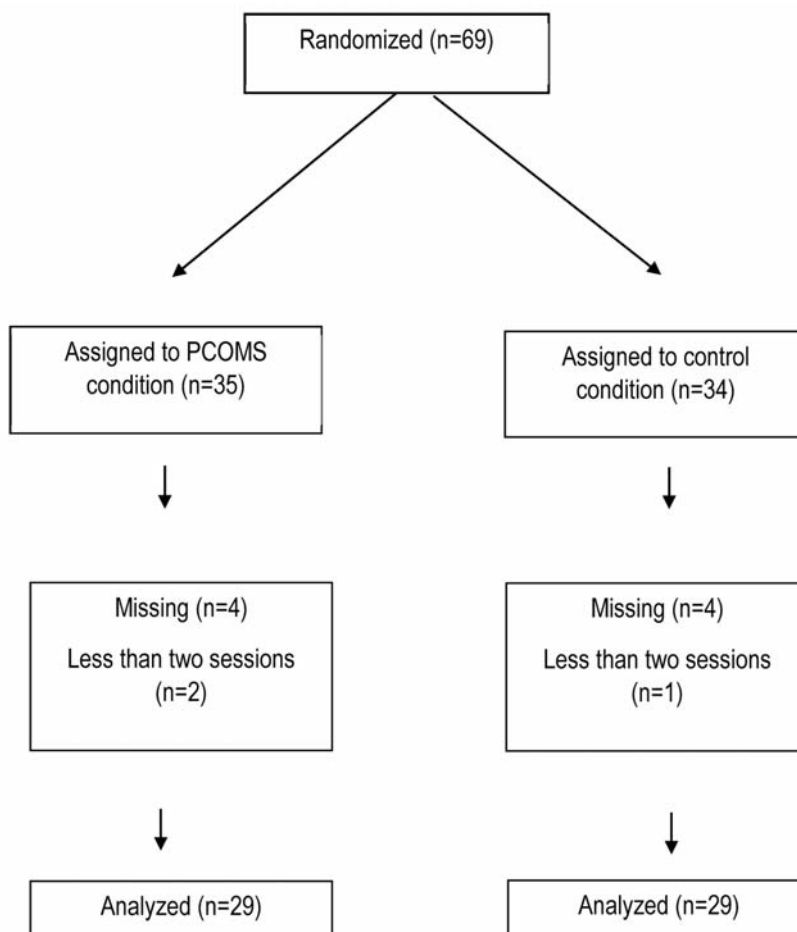
Figure 1. *Participants*

Data on the number of patients assigned, lost, incomplete and analyzed in both treatment conditions.

Recruitment of patients was carried out individually by each therapist during their rotation period in the corresponding mental health or primary care center, throughout the development period of the study.

The most common diagnostic category was adjustment disorder (N=23, 39%), followed by anxiety disorder (N=14, 24%). Each therapist treated an average of nine patients (9.6, range 5 to 15). Eleven patients were treated in a primary care center, while the remaining 47 (80%) were treated in the three mental health centers in the area. The family and social support perceived by the patient through the clinical interview was mostly concentrated in the low-medium range. A total of 26 patients (44%) completed university studies, and a total of 25 lived with their partner and/or children. The predominant marital status was single (N=24, 40%)

and in a relationship or married (N=24), and 22 patients were actively working at the time of the study, while 13 were unemployed.

The pre-treatment median was 18 for the ORS scale (17 for the PCOMS group and 18 for the control group), and 1.5 for the GSI scale (1.4 for the PCOMS group and 1.6 for the control group). No differences were observed in demographic variables and baseline scores between the control group and the PCOMS group. The mean number of sessions was 4.98 (three sessions mode), once a week or two weeks, and no differences were found between both conditions.

Table 1
Demographic characteristics. N (%)

Variable	PCOMS group	Control group	Missing
Years, mean (Standard deviation)	36.9 (2.3)	44.1 (3.1)	
Gender			
Men	9 (31)	9 (31)	
Diagnosis			1 (3)
Adjustment disorder	10 (34)	13 (45)	
Anxiety disorder	8 (28)	6 (21)	
Depressive disorder	4 (14)	5 (17)	
Anxiety-depressive disorder	2 (7)	2 (7)	
Psychotic disorder	0 (0)	1 (3)	
Personality disorder	4 (14)	2 (7)	
Bipolar disorder	1 (3)	0 (0)	
Therapist			
1	3 (10)	3 (10)	
2	2 (7)	3 (10)	
3	5 (17)	7 (24)	
4	8 (28)	7 (24)	
5	6 (21)	5 (17)	
6	5 (17)	4 (14)	
Center			
Mental health center 1	5 (17)	6 (21)	
Mental health center 2	5 (17)	8 (28)	
Mental health center 3	13 (45)	10 (34)	
Primary care center	6 (21)	5 (17)	
Family support			
Low	13 (45)	8 (28)	
Medium	9 (31)	12 (41)	
High	7 (24)	9 (31)	
Social support			
Low	9 (31)	8 (28)	

Variable	PCOMS group	Control group	Missing
Medium	14 (48)	13 (45)	
High	6 (21)	8 (28)	
Education level			1 (3)
Primary studies	3 (10)	9 (31)	
Secondary studies	4 (14)	4 (14)	
Bachelor studies	6 (21)	5 (17)	
University studies	16 (55)	10 (34)	
Coexistence			1 (3)
Alone	5 (17)	3 (10)	
With friends	2 (7)	5 (17)	
Partner and/or children	11 (38)	14 (48)	
Father and/or siblings	9 (31)	5 (17)	
Others	2 (7)	1 (3)	
Civil status			1 (3)
Single	14 (48)	10 (34)	
In a couple or married	14 (48)	10 (34)	
Divorced	1 (3)	7 (24)	
Widower	0 (0)	1 (3)	
Employment situation			3 (10)
Student	5 (17)	4 (14)	
Active	13 (45)	9 (31)	
Sick Leave	2 (7)	3 (10)	
Unemployed	8 (28)	5 (17)	
Retired	1 (3)	5 (17)	

Post-intervention ORS measurements in the intervention and control groups were 27.1 and 22.72, respectively ($p=.02$) and post-intervention SCL measurements were 1.11 and 1.27, respectively ($p=0.76$).

Therapeutic outcome: both the General Estimating Equations model ($\beta=.16$; 95% Confidence Interval = .05, .26) and the Multilevel model ($\beta=.14$; 95% Confidence Interval = .04, .25) found differences between the PCOMS condition and the control condition in the mean post-intervention ORS score, adjusted for the pre-intervention ORS score.

Of the 58 patients who completed the study, a total of 30 experienced improvement during the intervention, 17 in the PCOMS condition and 13 in the control condition. A total of 20 patients, 8 in the PCOMS condition and 12 in the control condition, experienced no change. Finally, a total of 8 patients worsened, four in the PCOMS condition and four in the control condition. The differences between both conditions were not statistically significant ($p= .55$). The calculation of the

number needed to treat (NNT=7.14) indicated that for every seven patients treated in the PCOMS intervention, one patient would be prevented from worsening or not changing.

Symptomatology: No differences were obtained between the mean of the GSI scale of the post-intervention SCL questionnaire of the PCOMS and the control condition, both in the General Estimation Equations model (β= -.02; Confidence Interval at 95% = -.67, .62.) and in the Multilevel model (β= -.02; Confidence interval at 95% = -.67, .62.).

Satisfaction: A total of 39 patients completed the CRES-4 satisfaction survey, 20 of them assigned to the PCOMS condition and 19 assigned to the control condition. The mean satisfaction with the treatment on the scale from 0 to 10 was 8.64, 8.8 for the PCOMS condition and 8.58 for the control condition, with no statistically significant differences between the two groups.

Dropouts: a total of seven patients dropped out of the intervention prematurely and without the consent of their therapist, three of them assigned to the PCOMS condition and four to the control condition.

Table 2
Distribution of patients who experienced worsening, no change or improvement

	Worsening	No change	Improvement	P-value [1]
Total N(%)	8 (13.8)	20 (34.5)	30 (51.7)	0.55
PCOMS group N(%)	4 (13.8)	8 (27.6)	17 (58.6)	
Control group N(%)	4 (13.8)	12 (41.4)	13 (44.8)	

Note 1. Fisher exact test.

Table 3
Comparison of results between patients receiving the PCOMS intervention versus patients receiving the control intervention

	Unadjusted differences		General Estimating Equations Model1			Multilevel Model2		
	Mean difference	P-value	Beta estimation	Confidence interval at 95%	P-value	Beta estimation	Confidence interval at 95%	P-value
ORS Post-Intervention	4.4	.06	.16	.05, .26	.003	.14	.04, .25	.007
SCL Post-Intervention	-.1	.59	-.02	-.67, .62	.95	-.02	-.67, .62	0.95

Note 1. The General Estimating Equations models are adjusted by the baseline measures of the outcome scales (pre-intervention ORS and SCL, respectively).
Note 2. Multilevel models are adjusted by the baseline measures of the outcome scales (pre-intervention ORS and SCL, respectively) and include a second level by the therapist.

Discussion

This study is the first to evaluate the effectiveness of formal feedback in psychotherapy, through the PCOMS instrument, in community mental health settings of the Spanish national health system.

Taken as a whole, the patients in our sample obtained an improvement in the psychotherapeutic intervention, as well as a decrease in their symptoms, high satisfaction with the treatment and a reduced percentage of premature dropouts compared to other contexts (Swift et al., 2012). The percentage of patients who experienced improvement is similar to that found in community settings in other countries, with patients with diagnoses and severity similar to the patients in our sample (Janse et al., 2016; Van Oenen et al., 2016).

The results suggest an increase in the effectiveness of the psychotherapeutic intervention, measured through the ORS scale, in the condition treated using the PCOMS instrument compared to the control intervention. The calculation of the number needed to treat indicated that for every seven patients treated in the PCOMS intervention, one patient would be prevented from worsening or not changing.

No differences were found between the experimental and control groups in the decrease in symptoms, measured through the GSI scale of the SCL questionnaire. No differences were found either in the level of patient satisfaction with the treatment, measured through the CRES-4 questionnaire, or in the number of premature dropouts in both conditions.

The results coincide with what was found in some studies that include other measures to evaluate the effectiveness of the intervention together with the ORS of the PCOMS protocol (Janse et al., 2016; Van Oenen et al., 2016), but not in others (Brattland et al., 2018; Davidsen et al., 2017). As argued in Van Oenen (2016), a better score on the ORS scale may be due in part to the expectation of improvement on the part of the therapist administering the scale during the session, so that the patient responds to those expectations more or less implicitly. Thus, patients in the PCOMS condition would obtain a better score on the ORS compared to the control condition, which may not reflect a real improvement. For this reason, the present study has followed the recommendation to introduce other measures. Since the differences have only been found on the ORS scale, we cannot rule out this hypothesis.

Another explanation is that formal feedback, through the PCOMS instrument, is effective for variables related to therapeutic progress, as is the case with the ORS scale, but not for other dependent variables. A recent meta-analysis (Pejtersen, Viinholt, & Hansen, 2020) found that the effect size of the PCOMS intervention was not significant in variables related to psychological well-being included in six studies, similar to the satisfaction scale in our study. In addition, as indicated in Janse (2016), the correlation between symptom scales such as the SCL-90 and the ORS is moderate, and it is possible that they measure different concepts.

A first limitation of the present study is that only a total of 32 patients com-

pleted the GSI scale (SCL-90) before and after treatment. This is in part because, due to the characteristics of the context, a large number of patients did not come to submit the GSI scale post-treatment once it had finished. The missing data of the GSI scale and the CRES-4 satisfaction survey limit the validity of the results in these variables. This did not occur in the main variable (ORS) because the last ORS measurement was taken as reference, which coincided in all cases with the last session. Another limitation is the difference between duration and intensity of treatment for each patient and that the coexistence of psychopharmacological treatment was not controlled. These limitations are related to the characteristics of the naturalistic context in which the study took place. However, no differences were found between the two conditions in the diagnosis, number of sessions or early dropouts, variables that may be related to the duration and intensity of the intervention and the probability of receiving psychopharmacological treatment. On the other hand, therapists' fidelity to the PCOMS protocol was not systematically measured, however, peer and interview supervision was performed, similar to other studies (Van Oenen, 2016). Lastly, the small sample size limits the statistical power of the study, since the final sample was 58 patients when its calculation according to the design characteristics was for 68 patients.

A strength of the present study is that it was carried out in the context of the Spanish national public health system, in line with the demand for integration between research and clinical practice in psychotherapy in our environment in recent years (Fernández-Álvarez et al., 2020). In addition, the importance of including other dependent variables indicated in reviews and meta-analyses on the effectiveness of formal feedback through the PCOMS instrument was addressed (Østergård et al., 2018; Pejtersen et al., 2020). Finally, its design had the objective of reducing the variability attributable to the difference between therapists and their allegiance to feedback in psychotherapy (Wampold, Baldwin, Holtforth, & Imel, 2017). This was achieved by assigning therapists to both conditions, together with the inclusion of the therapist factor in the multilevel statistical analysis.

In conclusion, this is the first study to evaluate that formal feedback in psychotherapy, through the PCOMS instrument, could increase the effectiveness of the intervention in community mental health settings of the Spanish national health system. Future studies with a larger sample size could be useful to verify the effectiveness in other variables such as symptom reduction, satisfaction with treatment or reduction in the number of premature dropouts, variables between which no differences were found in this study.

Notes

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