

Counseling in Primary Care Improves Depression and Quality of Life

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Summary: *Introduction:* To measure the effectiveness on Quality of Life of adjunctive cognitive behavioral counseling in the setting of General Practitioners (GPs) along with the treatment as usual (TAU;) for the treatment of depression.

Methods: Six month-controlled trial of patients who were referred to randomly assigned GPs (four for experimental group of patients and ten for the control) was done. Experimental sample had 34 patients with DSM-IV diagnosis of Depression (Depressed Episode, Dysthymia, or Adjustment Disorder with Depressed Mood) receiving the TAU supplemented with counseling. Control group had 30 patients with diagnosis of Depression receiving only the TAU.

Results: The Beck Depression Inventory (BDI) score improved in both groups. Patients in the experimental group showed greater improvement compared to the control group at T2. The World Health Organization Quality Of Life Questionnaire (WHOQOL) score also improved in the experimental group but not in the control group. The improvement in the experimental group was statistically significant in terms of both BDI and WHOQOL scores.

Conclusions: Adding counseling to TAU in general medical practice settings is more effective in controlling the symptoms of depression and improving the quality of life as measured over a period of six months, than TAU alone. These results while encouraging, also calls for a larger study involving a larger sample size and a longer period of time.

Keywords: Counseling, Primary Care, Depression, Quality of Life, Cognitive Behavior Therapy.

INTRODUCTION

Depressive disorders are considered a serious public health problem, causing high levels of disability, impairment in quality of life, and decreased life expectancy [1]. Moreover, depression is associated with enhanced healthcare visits, work absenteeism, decreased performances at work with elevated direct and indirect health costs [2, 3]. Epidemiological studies indicate that Depressive Disorders have a high prevalence in primary care, ranging from 2.6% to as high as 29.5% [4-6]. Therefore, the role of general practice is central to organizing care and research for mood disorders. In recent decades, a system of co-operation between general practice and secondary medical services has been established [7-10].

This study was carried out in Sardinia (Italy). Fifty percent of the Sardinian population live in communities with less than 5,000 residents, often isolated without access to the secondary care services and include higher proportions of adolescents and elderly due to migration of adult people to urban areas [11]. Such a condition is common in many European countries, particularly in the southern and the east

ern parts [12]. According to the literature, adolescents and the elderly, the age groups most at risk for suicide, are also the ages who are most unwilling to seek help from public mental health service facilities [13], but they are more likely to visit primary care providers. Thus improving care provided by GPs by adding a psychosocial component may offer significant benefits. This can be particularly significant in view of lack of specialized services such as psychiatric consultations in such of area.

This Research aims to evaluate the effectiveness of an integrated intervention option (cognitive behavioral counseling + TAU) on depressive patients administered by GPs in primary care setting. Current literature unequivocally supports the claim that cognitive behavioral psychotherapy simultaneously given with pharmacological treatment, is most effective over a long period of time, and helps prevent relapse [14], diminishes residual symptomatology and reduces the risk of chronicity [15].

The aim of this study is to evaluate the efficacy and feasibility of an adjunctive counseling approach in Primary Care setting for patients who have no ready access to secondary care or specialized psychotherapy.

The subjective perception of quality of life is a construct that is very relevant to measures of outcomes in chronic dis-

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ease [16-18], particularly in patients with diseases that impact heavily the daily life of the affected patients and their families such as depressive disorders [19].

Thus, objective of this study was to evaluate the impairment on quality of life of an adjunctive counseling approach in Primary Care setting for patients who have no ready access to secondary care or specialized psychotherapy.

METHODS

Catchment Area

The catchment area has a total population of 20,000 residents, living in six villages (from 1,000 to 6,000 residents). The territory is located in the south west part of Sardinia, with an average distance of 25 Km of mountain roads from the closest hospital and urban center.

Study Design

The study is a controlled trial with patients attending to GPs. Fourteen GPs were recruited from the catchment area on the basis of their willingness to participate in the study. The assignment was randomized with four GPs for recruiting the experimental sample, ten for recruiting the control group. The four GPs of the experimental group were working in two villages with 1500 and 3500 residents, respectively. The other ten GPs were in the villages of the same area. The 14 participating GPs were given preliminary training in Psychiatric Diagnosis of 10-hours by the PS at the beginning of the trial. The GPs were not reimbursed for their participation.

Sample

The Inclusion criteria were: Aged 16 years or over; Depressed (Depressed Episode, Adjustment Disorder with depressed Mood, Dysthymic Disorder according DSM-IV TR) by a score of ≥ 14 on Beck depression inventory. The Exclusion criteria were: Severe Depressive symptomatology such as with severe suicidal intent, psychotic symptoms, previously recorded severe manic episodes and need for psychiatric care, restricted mobility and organic brain syndromes.

The experimental group included 42 patients, 28 females and 14 males aged between 16 and 68 years, with a DSM-IV diagnosis of depression (Depressed Episode, Dysthymia, or Adjustment Disorder with Depressed Mood), referred to the counselors by the four GPs over a period of six months.

The control group included patients selected by the other group of ten GP's during the same time period. Controls were matched for severity of depression, measured by total BDI score (score ± 4); age (± 3 years) and sex. For the control group, from among the 69 patients referred to by the GPs, 42 were selected for their match with the experimental group of patients.

Participation in the study was voluntary and written informed consent was obtained from each of the patients. Patients were also informed that they could withdraw their consent to participate at any time, with no negative consequences on their future medical treatment. Patients who wished to withdraw from the study received TAU. Eligible patients were given the explanation of the study procedures

and were asked to sign an informed consent. The study protocol was approved by the Ethics Committee of the Università Europea del Mediterraneo.

Intervention

The control group received treatment as usual (TAU) provided by GPs, while the experimental group received TAU by GPs plus cognitive behavior counseling. The counseling was carried out for a period of six months by two trained psychologists in individual sessions once in every two weeks in primary care setting. The training of psychologists consists of a five-days course conducted using case vignettes.

In this study, we used the counseling method described in the manual "Depression: What is it and how to surpass it" [20]. This manual was based on the treatment program developed at the Clinical Research Unit for Anxiety and Depression in Sydney, Australia. [21], focusing on patients who suffer from depression. Because, this manual is written in a simple and clear manner, with specialized terms described in common language to the extent possible. The intervention strategy was based on "active listening and show of empathy towards the patient". This approach is guided by the idea that patients, because of their mental status, are unable to fully recognize their own abilities, and when enlightened, will overcome this mental status. The counselor's job is essentially to facilitate and support the patient during the process, while stimulating the patient to actively participate in the therapy [20]. The manual teaches how to recognize "dysfunctional" thoughts and mistakes in reasoning that are often the basis for depression. It aims to help people to be more balanced and to maintain or regain social relations and proposes a self-help tool for those who suffer from only marginal mental disturbance. In short, a cognitive-behavioral self-healing process is stimulated, an approach characterized by active listening and sympathy typical of traditional counseling, facilitated by a specific manual.

Finally, monthly discussions were conducted between each counselor, the GP and the Psychiatrist (PS) during the course of the study.

Assessment

The psychiatric diagnoses were given according to DSM-IV-TR (APA 2000) [22] by the PS with an external supervision who had not interviewed the patient. In the experimental group, the decision of whether or not a patient receives counseling treatment was made by the GPs on the basis of their diagnosis and the inclusion criteria.

The evaluation during the trial was carried out in blind (experimental versus control) by four psychologists and two psychiatry residents,

The evaluation criteria used were the Beck Depression Inventory (BDI) [23], the Quality of the Life Questionnaire of the World Health Organization (WHOQOL-Bref) [24,25] and the Clinical Global Impression (CGI, [26]). The evaluations were conducted at the start of the trial, after three months and at the end of the trial (6 months). The dosage of daily antidepressants administered from the beginning to the end of the trial were quantified by defining the minimum daily dose indicated for depression for each antidepressant

Table 1. Sample Analysis of Patients Completing the Trial

	Experimental Cases N=34	Controls N=30	Differences by Groups
Females	22 (64.7%)	20 (66.6%)	X ² =0.1, P=0.925 1DF
Age	42.2±19.1	42.8±18.5	F=0.1, P=0.922, DF 1, 62.63
Antidepressants at the start	22 (64.7%)	23 (76.7%)	X ² =0.1, P=0.921 1DF
Antidepressants at the end	10 (29.4%)	16 (53.5%)	X ² =2.8, P=0.091 1DF
Depressive Episode MDD	4 (11.8%)	2 (6.7%)	X ² =0.1, P=0.788 1DF
Depressive Episode BP	3 (8.8%)	2 (6.7%)	X ² =0.1, P=0.884 1DF
Adjustment Disorder with Depressed Mood	20 (58.8%)	16 (53.3%)	X ² =0.1, P=0.937 1DF
Dysthymia	7 (20.6%)	10 (33.3%)	X ² =2.0, P=0.155 1DF

drug as *one unit*, and totaling the units for each patient. For example: Fluoxetine 20 mg = 1; Clomipramine 75 mg = 1; Mirtazapine 30 mg = 1. Thus, 10 mg of Fluoxetine (= 0.5) plus 60 mg of Mirtazapine (= 2) made a total of 2.5.

Statistical Analysis

The analysis of the data was carried out with the help of the statistical open source software R (Project for statistical Computing [http://www.r-project.org/]). Test χ^2 was used for the comparison of data on a nominal scale. Analysis of Variance (ANOVA) was used for the comparison of data on a numerical scale. Multivariate Analysis of Variance (MANOVA) was used for the comparison of data on a numerical scale, evaluating the effect of the counseling within and between the groups over time.

RESULTS

Characteristics of the Groups at the Beginning of the Trial (T0)

In the experimental group, five patients (11.9%) were suffering from a Major Depressive Episode with likelihood of Major Depression; four patients (9.5%) from a Major Depressive Episode with likelihood of Bipolar Disorder (I, II or NOS); 25 (59.5%) patients from an Adjustment Disorder with Depressed Mood; and eight (19.0%) patients from Dysthymia.

The main concomitant diagnoses were: Personality Disorder of Cluster B: six cases (14.3%); Panic Disorder: four cases (9.5%); Social Phobia: three cases (7.1%); General Anxiety Disorder: five cases (11.9%); Obsessive Compulsive Disorder: one case (2.4%); Bulimia: four cases (9.5%); Eating Disorder NOS: three cases (7.1%); Substances Abuse or Dependence: five cases (11.9%). Of the 42 control patients, 28 (66.7%) were females and 14 (33.3%) were males.

The diagnoses in the control group were Major Depressed Episodes that would likely lead to Major Depression: three cases (7.1%); Major Depressed Episodes that would likely lead to Bipolar Disorder (I, II or NOS): three cases (7.1%); Adaptation Disorder with depressed mood, 21 cases (50%); Dysthymia: 15 cases (35.7%).

The main concomitant diagnoses were: Personality Disorder Cluster B: four cases (9.5%); Panic Disorder: five cases (11.9%); Social Phobia: two cases (7.1%); General Anxiety Disorder: four cases (9.5%); Obsessive Compulsive

Disorder: two cases (4.8%); Bulimia: two cases (4.8%); Eating Disorder NOS: two cases (4.8%); Substance Abuse or Dependence: four cases (9.5%).

Perhaps we should tabulate these above information

Characteristics of Sample Completing the Trial

The characteristics of the sample completing the trial are shown in Table 1. Of the 42 patients in the experimental group, 34 concluded the trial. Of the eight who missed the follow-up (19.0%), four gave no reason (9.5%), three indicated to the GP that they had problems of "understanding" or "communication" with the counselor (7.1%). One subject was unable to continue the therapy due to work-related reason (2.4%).

Of the 42 patients in the control group, 12 patients (26.7%) did not attend the scheduled evaluation visit

There was no significant difference in follow-up absenteeism between the experimental group and the control group ($\chi^2=1.23$, 1DF, P=0.27).

The final evaluations were carried out for 34 cases in the experimental group and 30 cases in control group.

Depressive Symptoms, General Clinical Condition and Quality of the Life

Table 2 shows scores for BDI (depressive symptoms), CGI (general clinical condition) and WHQOL-BREF (quality of the life) of patients in the experimental and control groups at the 3 assessment points. In addition, the results of comparisons between experimental and control group at T0, T1 and T2 as well as comparisons within each group across the three assessment points are also shown.

As shown, BDI had improved in the both groups at T1, and the improvement was even greater at T2. However, at T2 there was a significant difference between the two groups, with a lower score in the experimental group. Moreover, while the global clinical judgment (CGI) had not improved in the control group, it did so in the experimental group at T2 compared to T1. At T2, the CGI scores were lower in the experimental group than in the control group. Finally, the Quality of the life (WHQOL-BREF) had also improved in the experimental group compared to the control group from T0 to T2. These results indicate a positive effect of the counseling on patient recovery that can be recorded within 3 months of starting the treatment regimen.

Table 2. Multivariate Analysis of Variance (MANOVA) of the Performance of the Cases and Control Groups

Evaluation	t0	t1	t2		
BDI Experimental Cases*	18.7+/-9.1	10.6+/-5.2	6.3+/-4.7	F interaction 3.019 DF: 2, 226	p-value 0.0497699
BDI Controls**	17.1+/-6.4	12.3+/-8.2	10.2+/-8.3	F groups 1.962 DF: 1, 226	p-value 0.1626876
				F time 35.559 DF: 2, 226	p-value 0.0000000
CGI Experimental Cases	3.3+/-0.9	3.0+/-1.1	2.7+/-0.8	F interaction 1.864 DF: 2, 246	p-value 0.1571592
CGI Controls	3.2+/-0.7	3.1+/-0.8	3.1+/-0.7	F groups 1.570 DF: 1, 246	p-value 0.2113954
				F time 3.631 DF: 2, 246	p-value 0.02792359
WHQOL Cases	68.5+/-14.4	62.7+/-10.8	58.6 +/-12.3	F interaction 3.001 DF: 2, 246	p-value 0.04495382
WHQOL Controls	64.3+/-11.3	63+/-12.3	62.8+/-9.8	F groups 0.004 DF: 1, 246	p-value 0.946898
				F time 4.911 DF: 2, 246	p-value 0.0081015

*Cases N = 34, **Controls N = 30

To statistically confirm the difference between the experimental and control groups, we used Multivariate Analysis of Variance (MANOVA) and evaluated the effect of the counseling within and between the groups over time. The results of this analysis are shown in Table 2. As shown, a significant difference between time and treatments was found in terms of BDI and WHQOL but not for CGI.

Use of Antidepressant Drugs

Out of 42 patients in the experimental group, 28 used antidepressants (15 SSRI, 10 SNRI, 3 other) at the onset of the trial, with an average dosage of 1.2 ± 0.3 . Of these, 8 used antidepressants at sub-threshold dosages and 6 used more than one antidepressant. 14 patients also took benzodiazepine and 4 patients took benzodiazepine alone. Among those who completed the study (34), 10 used antidepressants, of which 5 were under-dosed. Of the 42 controls, 34 used antidepressants (18 SSRI, 8 SNRI, 8 others) upon entering the trial, with an average dosage of 1.1 ± 0.4 . Of these, 8 used antidepressants at sub-threshold dosages and 10 used more than one antidepressant. 10 also took benzodiazepine and 6 were prescribed benzodiazepine alone. The difference in the proportion of people taking antidepressants at the end of the trial is not statistically significant between experimental and control groups ($\chi^2=2.8$, 1 DF, $P=0.91$).

DISCUSSION

The literature reviewed shows consistent evidence that counseling improves quality of life in cancer and other chronic diseases [27, 28]. This is the first study producing evidence that counseling as adjunctive treatment improves Quality of Life in patients attending primary care for depression.

Despite an expansion of GP based counseling at primary care settings, there is limited evidence for the effectiveness of this approach [29-32]. In a retrospective analysis of an earlier study [29] non-directive counseling was found to be more effective in the subgroup of patients who scored above

a threshold of 14 on BDI. Then a large controlled trial of Ward and Coll. [33] confirmed that patients who scored ≥ 14 on BDI recovered more quickly if followed with counseling for 4 months rather than under the care of general practitioner. But, after 12 months of follow-up, the patients in all study groups (2 of psychotherapies, one of usual GP care) had improved to the same extent. The lack of a significant difference between the treatment groups appears to have resulted from an improvement of patients in the GP care group from t4-month to 12-month follow-ups [33].

Our study shows that counseling, in addition to TAU in a primary care setting is more effective in reducing symptoms of depression after six months of treatment than TAU alone. Moreover, the added counseling regimen produced significant improvements in the quality of life measured by WHOQOL-BREF. In fact the continued difference in the depressive symptoms, between experimental group and control group, for a much longer duration compared to the one observed by Ward and Coll [33] is likely due to the fact that the counseling was administered for a much longer time (six month) in our study.

A recent trial in India found that a collaborative care intervention led by trained lay counselor can improve recovery from Common Mental Disorders among patients compared to the patients who received the usual primary care without any additional intervention [34]. In this study the "collaborative stepped-care intervention" offered case management and psychosocial interventions, provided by a trained lay health counselor, supplemented by antidepressant drugs by the primary care physician and supervision by a mental health specialist [34].

However, in this above trial as was in our present study, the target of the counseling treatment was not a particular diagnosis (as for example "Major Depressive Disorder") but a broad range of disorders [Common Mental Disorders in Patel and Coll [34] and "Depression" including a broad range of mental disorders in our current study].

One of the determinants of the efficacy of the counseling in these studies may be related with the use of the treatment, according to its use in the real practice, against a large even sub-threshold spectrum of affective diseases than to use counseling for single targeted diagnosis as in clinical randomized trial (RCT).

Another issue common to the Indian trial and our present study is that the assignment of patients between experimental treatments versus controls will be the case in a rigid like RCT method (e.g., "pharmacotherapy with counseling" or "counseling alone"). The assignment was done in a flexible manner (as one would find in a real primary care setting) allowing the GP to decide which patient should take antidepressants, which patient should be treated with counseling, etc.

The fact that counseling may be useful in a non-restricted target of patients is of particular utility in primary care settings. In such settings, the clinical finding of a GP is often a diagnosis of "depression", but it may be one of the signs of an evolving psychopathology, even though often this may not be obvious [35]. Patients who have functional somatic symptoms [36], such as anxiety, personality disorder, eating and substance abuse disorders associate themselves with depressed episodes, however, it is difficult to establish which occurred first, and therefore the connection between depression and these mental disorders [37]. For these reasons, it may be difficult to adopt the RCT model in a primary care, General Practice setting and more flexible models such as those adopted in our study as well as in the Indian study [34], may be better suited and complementary to the RCT.

According to a recent study, patient preference and expectation about treatment options appears to play a role in the outcome of the treatment regimen in primary care settings [38]. A better outcome was observed with in patients who preferred say psychotherapies and were given psychotherapies as opposed to those who were given psychotherapies even though patients did not show preference to such a treatment. Similar results were also observed with drugs as well. Thus, it is important to consider this as a significant factor in a clinical trial involving psychological treatment for depression. The treatment choice of the GP depending up on the preference of the patient is possible in a flexible model such as the strategy used in our study. This model takes into consideration patient-doctor relationship as opposed to the more structured RCT, which does not consider patient choice.

A large amount of studies show that antidepressants are an effective treatment for depression in general practice [39, 40]. Antidepressant drugs present a "wide spectrum", that are able to improve a majority of anxiety symptoms [40]. Nevertheless, given the symptomatic complexity involved in cases of substance dependences, bipolar disorders or personality disorders, a counseling intervention used in a flexible manner clearly represents a better option than drugs alone. This approach also offers a low cost supplementary tool. Moreover antidepressants must be used with caution in specific certain types of patients such as in adolescents and those with bipolar disorder [41].

The proposed model (with counseling carried out in the general practice or primary care clinics) has obvious differences with other models proposed, particularly with the "Bo-

logna Project" [7]. In Bologna model, psychiatric interventions integrating general medicine creates a specialized service outside the general medicine setting. The GP, in this case favors consultancy beyond his own practice. In our opinion, the Bologna model would be difficult to apply in isolated rural areas such as those represented in this study, where the GP clinic remain central to the treatment and the GP is a facilitator for counseling [42, 43].

To be sure, our study has limitations. For instance, only the GP were randomized and the patients were not. Furthermore, the sample size was small and the control group was not subject to any placebo effect of the counseling, making it difficult to measure, if any, of the improvement is due to some non-specific therapeutic effect. Perhaps our flexible model should be evaluated in a larger sample size along with complementary more focused RCT.

CONCLUSION

While this small-scale study needs to be replicated on a larger scale, the model presented appears to offer enhanced benefits of counseling intervention and particularly useful in isolated areas.

CONFLICT OF INTEREST

The authors confirm that this article content has no conflicts of interest.

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