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Behavioral Activation Intervention Delivered by a Community Physician to Treat Depressed Female Patients Resident at King Faisal National Guard Residential City in Jeddah, from 18 Years Old and More, Randomized Control Trial, 2017

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Abstract

Background: Depression becomes one of the commonest mental illness that needs early screening and intervention. Behavioral activation is one of the treatment modalities that can be conducted by trained health care professional. The patient learned how to cope with depression using the behavioral activation technique and that can lead to prevent future relapse.

Aim: To apply behavioral activation intervention in the primary health care centers and to be delivered by trained nurses.

Objectives: This Randomize Controlled Trial (RCT) conducted to study the effectiveness of behavioral activation intervention among depressed patients.

Methodology: Depressed patients were recruited through a community screening using the Beck Depression Inventory II (BDI-II) questionnaire, 16 participants volunteered and randomize for the RCT stage in a ratio of intervention to control (1:1). Post intervention assessment conducted by (BDI-II). Behavioral activation working sheets used during the intervention.

Result: The behavioral activation is effective and simple intervention with significant P value among the interventional group (P=0.017).

Conclusion: The behavioral activation intervention is effective to manage the depression among the study population. A nationwide survey to accurately determine the cost-effectiveness of behavioral activation program to reduce the burden on health care system is required.

Keywords: Depression; Behavioral activation; Community medicine

Introduction

Background

Depression become one of the commonest mental illness that needs early screening and intervention [1]. There are different modalities to treat depression which are divided mainly in to three categories, these categories are: Medication, Psychotherapy and Electroconvulsive therapy [2-4]. Psychotherapy treatment includes interpersonal therapy and cognitive behavioral therapy (CBT). Behavioral activation is a part of CBT that does not need an expert in psychotherapy, requires less time, and has proven efficacy. Psychotherapy can work alone or in combination with pharmacotherapy. There is a low risk of recurrence with psychotherapy [5]. The theory of BA is to work from the outside in instead of from the inside out. Usually, a depressed patient stops doing important activities and waits for his/her emotional status to improve before resuming those activities. BA helps the patient recognize pleasurable and valuable activities and start scheduling the easiest and effective activity that will help to improve the patient's status. The number of session varies from 12-24 sessions weekly, according to the patient's status. Every session lasts 50-60 minutes, and in every session, the therapist focuses on activation. In every session, the therapist reviews the progress since the last contact, sets an agenda, attends to the patient's understanding, solicits feedback, and assigns homework [5-7].

Methodology

This Randomized Controlled Trial (RCT) conducted to assess the effectiveness of BA therapy among females over 18 years of age, living in KFRCNGJ with confirmed depression. A "CONSORT Statement" for Consolidated Standards of Reporting Trials has been used throughout this study. Depressed patients were recruited through a community screening using the Beck Depression Inventory II (BDI-II) questionnaire. There was an Arabic version of (BDI-II) that had been

tested and validated [8]. Positive patients were interviewed according to the DSM-V and recruited for the RCT. There were 16 participants volunteered and randomize for the RCT stage in a ratio of intervention to control (1:1). Due to the limited sample size the study could not assign the randomization regarding to the depressive episode subtype. The reasons for small sample size was patient refusal to show in the clinic after the initial screening due to many reasons like: stigma, lack of interest and cannot reach the clinic.

The intervention planned to be 10 sessions for each patient but was finished only for 3 patients and the rest received less than 10 sessions. Initially all patients attend to the clinic to confirm the diagnosis and conduct the randomization. Those who's identify as an intervention cases receive the behavioral activation intervention. Every session was about 50-60 minutes. During the first session the concept of behavioral activation was explain to the patients and given a recording sheet to recognized the suitable activity for the patient to be planned in the next session. During the next session the therapist start to schedule in the cooperation with the patient the most suitable activities for the patient to be accomplished during the week.

In the next follow up after a week the therapist discuses with the patient if the activity is done or not and if not why and work on the problem solving with the patient. The same will be done in the next sessions until the patient understand the hypothesis of behavioral activation. Post intervention assessment conducted by (BDI-II). Behavioral activation working sheets used during the intervention. The study period was three months for the intervention. The study Setting was at KFRCNGJ represents the major residential city for the National Guard military personnel and dependent's in the city of Jeddah. The intervention was carried out at Iskan Jeddah Primary Health Care (Iskan Jeddah-PHC, WR).

Inclusion criteria for the RCT

- Not diagnosed previously.
- Diagnosed with depression but not on any antidepressant medication.
- Diagnosed with depression and taking antidepressant medication for less than six weeks [9].
- Diagnosed with depression but not adherent to the medication regimen when assessed at six months after the initiation of treatment [10,11].

Exclusion criteria for the RCT

- Diagnosed with depression and taking an antidepressant regularly for more than six weeks.
- Current substance abuse or dependence.
- Diagnosed with a psychotic disorder or bipolar disorder.
- Currently receiving any psychotherapy.

This RCT repeated measures design consisted of two groups of subjects, each measured at two time points: before and after the intervention. In this case, the primary goal of the study was to compare the change over time for the intervention group versus the control group. The procedure of randomization was held by letting the positive confirmed participants with depression to pick up an opaque envelope in an allocation concealment format.

This study design used a ratio of one intervention to one control (1:1) (Figure 1). A staff member from the Preventive Medicine Department of KFRCNGJ, who was not involved in the study, conducted the randomization procedure.

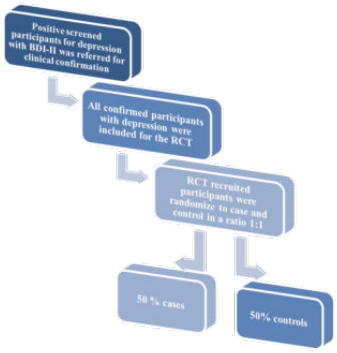

Figure 1: Recruitment, screening, and confirmation of depression, RCT conducted at KFRCNGJ, Jeddah, 2016-2017.

The main researcher had training in the Psychiatric Department – KAMC, under supervision of psychiatric consultant for three months, also the researcher passing through many courses and conference to be qualified to do the research. This stage carried out at the Family Medicine at Iskan Jeddah-PHC, WR under supervision of a family medicine consultant. Regarding the data Entry and Statistical Analysis, a qualified person in the Preventive Medicine Department of KFRCNGJ entered the data through excel software. SPSS software version 24 used for the analysis by a specialized statistician in the Preventive Medicine Department of KFRCNGJ.

The analysis was as intention to treat. Inference statistics including a Wilcoxon signed-rank test were used for comparisons. The Signed Rank Test was used to determine if there was a significant association between the BDI-II score before and after the intervention. The Signed Rank Test was used to see the difference in pre- and post-treatment BDI-II score between the intervention and control group to test the effect of intervention and the improvement between the two groups. Both groups were similar in each factor, including factors related to depression, because both groups were recruited from the same community and were assigned randomly. P value $\leq$ 0.05 was considered as a statistically significant in the analysis. All of the study participants were received detailed information regarding the purpose and nature of the study and an informed written consent for inclusion in the study in the RCT stage were taken from each participant. The study was approved by the Joint Program of Family and Community Medicine IRB in Jeddah city and the King Abdullah International Research Center. This study used BA and supportive counseling, and this type of intervention would not cause harm to the participants. Privacy and confidentiality were completely protected, no identifiers nor personal information were collected nor stored, including participant's name, IDs, results and others.

Result

out of 32 interviewed participants 21 were true positive, out of the 21-true positive for depression 16 (76.2%) of the 21 patients volunteer

to be recruited for the RCT (Figure 2). By using the DSM-5 the classification of the intervention group had eight participants (severe depression: zero participants, moderate depression: one participant, and mild depression: seven participants) and the control group had eight participants (severe depression: one participant, moderate depression: Three participants, and mild depression: four participants). The assessment and evaluation of the participants at the end of the study was done using the BDI-II and comparing the pre-intervention and post-intervention score between the intervention and control groups (Figure 3). The Correlation between the BDI-II score pre and Post-intervention for the Intervention group and the control group: A Wilcoxon signed-rank test showed that the intervention did elicit a statistically significant change in decreasing the BDI-II score in the intervention group (Z=-2.38, P=0.017). Indeed, the median BDI-II score pre-intervention decreased from 23 into 11 on post-intervention (Table 1).

Whereas, a Wilcoxon signed-rank test showed that the intervention did not elicit a statistically significant change in the BDI-II score in the control group (Z=-1.472, P=0.141). However, there was a little change in the median BDI-II score of the control group, where the first measurement was 28 and the second measurement decreased to 26 (Figure 3). So, the behavioral activation is effective and simple intervention with significant P value among the interventional group (P=0.017).

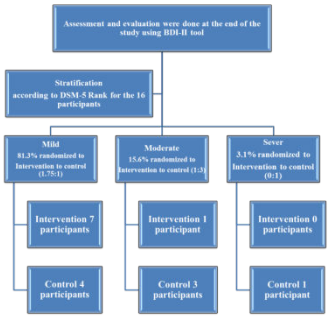

Figure 2: Stratification and randomization of participants, RCT conducted at KFRCNGJ, Jeddah, 2016-2017 (n=16).

		Mean ± SD	Median	Min	Max	*P value
Intervention group (n=8)	Total BDI-II score (pre)	24 ± 5	23	19	33	**0.017
	Total BDI-II score (post)	13 ± 10	11	4	36	
Control group (n=8)	Total BDI-II score (first)	30 ± 11	28	20	55	***0.141
	Total BDI-II score (second)	25 ± 9	26	10	38	

*The significance level (a) was set at p<0.05. A paired sample Wilcoxon Signed Rank Test was used to determine if there was a significant association.
**P value <0.05; There was a significant difference in the pre- and post-intervention median of BDI-II score among the intervention group (P=0.017).
***P value >0.05; However, no significant difference was found in the first and second median of BDI-II score in the control group (P=0.141).

Table 1: The significant difference of the BDI-II score regarding the severity pre-and post-intervention among the intervention and the control group, RCT conducted at KFRCNGJ, Jeddah, 2016-2017 (n=16).

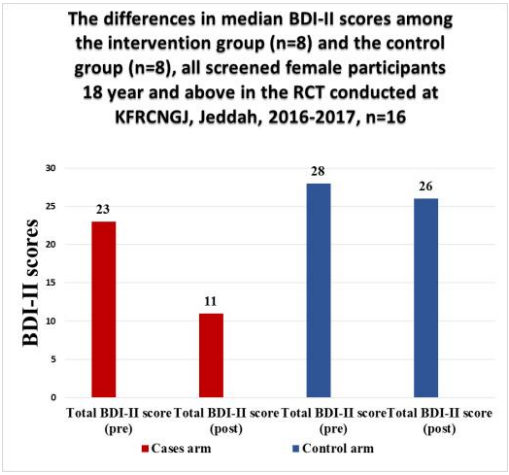

Figure 3: There was a different in the median BDI-II score pre-and post the interventional group and less change in the control group, n=16.

Discussion

It is noticed in this study the drop out was large and the reasons for the drop out are false positive for depression, moving from the compound, stigma, no interest, no response to any type of communication. Some factors that are noticed during the study and contributed to the drop out are under estimation of the important of mental health and the value of BA therapy by the participants, redundancies and time inefficiency, husbands play a major role for the recruiting and follow up of the participants, health status of the participants and commitment of the participants with their kids. Many strategies done to overcome the drop out ratios like increase the sample size of the screened participants, different types of communications as mentioned before, flexible appointments for participants and using non-parametric test in the analysis.

Although the sample size for the RCT was less than expected, this study proved the effect of BA among KFRCNGJ female depressed participants. BA is an effective treatment for depression [5,6,12,13].

Conclusions

The result also showed that the acceptant to participate in the BA therapy was lower than expected, due to moving from KFRCNGJ,

stigma and not interested to complete the RCT stage. However, it is believed that the BA therapy prove it is effectiveness among the cases in the comparison with the control group and it might be simple effective intervention for depression management. Some patients experience improvement in their relationships with others like family and some patients dose not notice any improvement.

Recommendations

Periodic Training Program among primary health care physicians and nurses in the BA therapy concepts and technique to improve the quality of health of depressed patient.

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