



The Effect of a Drug Adherence Enhancement Program on the Drug Adherence Behaviors of Patients With Major Depressive Disorder in Thailand: A Randomized Clinical Trial



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ABSTRACT

This study aimed to compare drug adherence behaviors during the sixth week between patients with first diagnosed major depressive disorder who received the Drug Adherence Enhancement Program and those who received only the usual care. A randomized clinical trial, post-test only design was conducted in the outpatient-unit of a medical school hospital in Bangkok, Thailand. The experimental and control groups consisted of 30 and 26 participants respectively. Participants in the experimental group exhibited significantly higher drug adherence behaviors than the control group. This is important for nurses in promoting adherence to antidepressant drugs for patients with first diagnosed major depressive disorder.

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Patients with major depressive disorder (MDD) can have their depressive symptoms relieved by taking antidepressant drugs continuously according to a treatment protocol. Clinical practice guidelines strongly recommend using antidepressant medication as an initial modality for at least 6–12 weeks to induce remission of symptoms during the acute phase of treatment (American Psychiatric Association, 2010). However, patients with MDD tend to be uncooperative regarding medication intake when antidepressant drugs are first prescribed. Study findings have revealed that the lack of cooperation of patients with MDD is commonly found within the first three months of treatment (Nemeroff, 2003), and about 70% of patients with MDD discontinue their medications by themselves during the course of treatment (Demyttenaere et al., 2008; Haynes, Ackloo, Sahota, McDonald, & Yao, 2008; Pampallona, Bollini, Tibaldi, Kupelnick, & Munizza, 2002). Of Thai patients with MDD who sought treatment at a medical school hospital as many as 64% did not follow up on treatment within the first month (Vannachavee, Pakdeejit, & Seeherunwong, 2008). On the other hand, approximately four out of 10 US patients (42.4%) who initiated antidepressant treatment for depression discontinued their antidepressant medication during the first 30 days of treatment.

BACKGROUND

There are many reasons for drug non-adherence during the first diagnosis of MDD. The major reasons are erroneous beliefs about the disease and its pharmacological treatment. The other reasons are physical and mental suffering from the adverse drug effect occurring after their use (Bollini, Pampallona, Kupelnick, Tibaldi, & Munizza, 2006; Chakraborty, Avasthi, Kumar, & Grover, 2008; Demyttenaere, 2001; Nabeel, 2008). People who have been diagnosed with MDD have perceived that they were insane and could not accept their abilities as a normal person (Seeherunwong, Boontong, Sindthu, & Nilchaikovit, 2002). As a result, they refused and neglected taking medication because it is a symbol of having mental illness (Sirey et al., 2001). Regarding the treatment, patients believed that medication cannot solve their mental sufferings, and assume that continuous medication intake will make them become dependent on antidepressant drugs for the rest of their lives (Aikens, Nease, & Klinkman, 2008). Patients also incorrectly think that antidepressant drugs are like symptomatic treatment that should be discontinued when the symptoms are lessened or should be taken only when they have the symptoms (Chakraborty et al., 2008). Regarding drug adverse reactions, patients were unable to tolerate the undesirable reactions of the drugs such as dizziness and drowsiness, which are most likely to occur in the early course of treatment (Lin, Korff, & Katon, 1995; Maddox, Levi, & Thompson, 1994). Furthermore, during delivery services in an outpatient clinic, health care providers did not have enough time to create a relationship and provide individualized information to the patients, which led to the patients' continued misunderstanding and erroneous beliefs. All of these reasons cause patients to terminate their medication in the early days of treatment.

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Table 1
Topic and Implementation of Each Session of the DAEP.

Session	Implementation
#1 Motivation to comply with the treatment plans	Build the nurse–patient relationship and conduct comprehensive assessment for understanding the patient's problems and care needs Find out the participant's goal for visiting psychiatric clinic Explore patient's attitude, perceptions, and feelings toward depressive disorder and its impact Find out the patient's erroneous attitudes toward becoming a patient with depressive disorder and its treatment Provide information about MDD and its treatment Encourage participants to present their concerns and intention to adhere to the regime Use trigger questioning to make the patients aware of their problems, provide information or useful options for making decisions regarding self-care and to perceive the situation as manageable, leading them to have hope, set goals, and make plans for their mental health Assign homework to record drug taking on worksheet every day
#2 Enhancement of confidence and strengthening the commitment to take medication	Explore the experience of medication taking, its benefit, and barriers to adhering to drug taking Search for feelings of ambivalence toward drug use Elicit attitudes, perceptions, and feelings about drug taking that made the patients have ambivalence concerning adherence Modify erroneous automatic thought toward drug taking, symptoms of adverse effects, and their illness Provide information tailored to the patient regarding the illness, reasons for using antidepressant drugs, and how to manage adverse effects Modify their behaviors that did not facilitate drug taking or recovery Record a plan to change specific behavior Assign homework to make them have a sense of success
#3 Monitoring and evaluation of the actual situation	Help the patients manage problems related to adverse effects of drugs and other problems Anchor drug adherence Assign homework to record change in perceptions and feelings in the worksheet
#4 Planning for continuing adherence	Prepare for solutions to drug taking problems for a long time Rehearse alternative options when forgetting to take drugs Provide information related to problems in discontinuing the regimen Encourage continuous medication intake after the end of the program Revision and summarization

A program that can enhance patients' cooperation in the treatment of MDD, increase their medication adherence, and reduce their depressive symptoms has been developed based on the concept of motivational interviewing of Miller and Rollnick (2002), together with the strategies of the cognitive therapy of Beck, Rush, Shaw, and Emery (1979). It has been reported that such a program is effective in adjusting patients' attitudes toward medication intake (Tay, 2007) and their motivation to continue drug taking to 12 weeks is 2.7 times that of those who received the usual care (OR 2.7, 95% CI 1.6–4.8), resulting in significantly improvement in depressive symptoms during the follow-ups at 12 weeks (Peveler, George, Kinmonth, Campbell, & Thompson, 1999) and six months after the medication treatment (Sirey et al., 2001). In Thai psychiatric clinics, there is no nursing intervention to improve the drug adherence of patients with MDD. Therefore, the researcher developed the Drug Adherence Enhancement Program (DAEP) based on the concept of motivational interviewing (MI) proposed by Miller and Rollnick (2002), implemented together with the concept of cognitive therapy of Beck et al. (1979). The DAEP was utilized for patients with first episodes of MDD who were still receiving pharmacological treatment for the first time. According to MI, the program provides counseling which emphasizes to the patients the problems caused to them by non-adherence and manages their hesitation in becoming motivated to take antidepressant drugs. Regarding the cognitive approach, the program placed its emphasis on negative automatic thinking and erroneous beliefs associated with the disease and its treatment, which directly affected patients' motivation and hesitation in appropriately adhering to the treatment plan and taking antidepressant drugs. In addition, the DAEP emphasized the establishment of a good relationship between nurses and patients, encouraged patients to accept their illness and treatment with medications, reduced their anxiety and concern about the undesirable side effects of the prescribed antidepressant drugs, and provided information regarding the benefits of antidepressant drugs. Therefore, the specific aim of the current study was to determine the effect of the DAEP on the drug adherence behaviors of patients with MDD. The secondary aim was to explore the lessons learned from the clinical implementation. We hypothesized that patients with MDD who received the DAEP together with usual care would exhibit better drug adherence behaviors during the sixth week after the initial treatment than those who received only the usual care.

METHODS

Design

A randomized controlled trial with two parallel-group posttest-only designs was used in this study. As a result of the patients visiting the clinic for the first time, there was no pre-test score for drug adherence behavior. The study was carried out from October 2009 to January 2010. The experimental group received the DAEP for four weeks plus the usual care, while the control group only received the usual care.

Sample and Setting

The target population was outpatients first diagnosed with MDD at the psychiatric unit of a medical school hospital, in Bangkok, Thailand. The patients were recruited based on the inclusion criteria as follows: 1) male or female patients aged 18 or over, 2) receiving a first diagnosis of MDD based on the DSM-IV TR criteria by psychiatrist, 3) starting treatment with antidepressant drugs, 4) Thai language ability and 5) no psychosis. The participants who met the inclusion criteria and who were willing to participate in the study were randomly assigned into the experimental group and the control group, with 30 participants in each group, using block randomization performed using a statistical computer program. Participants were excluded if they had any additional psychotic symptoms and/or had attempted suicide.

Sample sizes were calculated on the basis of medium effect size ($ES = 0.5$) of the intervention on the outcome of the drug adherence (Cohen, 1988), using a one-sided 5% significance level. The sample sizes are sufficient to have about 90% power to detect a difference between experimental and control groups of 30 in *t*-test analysis.

The hospital where this study took place is a leading medical school. The hospital provides general tertiary health care services having 1200 beds for inpatients. Bangkok is the capital of Thailand, and a major commercial city, with a population of 10,000,000 and an estimated MDD prevalence of 3.2% in males and 4.8 in females aged over 15 (data from national survey of Department of Mental Health, Ministry of Public Health, Thailand 2008). From the monthly record of the psychiatric unit, the number of new patients with first episode MDD averages 29 per month.

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