

Influence of Patient Counseling (By the Pharmacist) on Adherence to Medication in People with Mental Illnesses

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Abstract— Non-adherence to antipsychotic medication is common in people with mental illnesses forming major obstacles to long term maintenance of treatment contributing to high relapse rate. Pharmacists can play a vital role in improving adherence to medication of this population. The study aimed to examine whether patient oriented counseling session (POCS) by the pharmacist can improve the adherence to medication in people with schizophrenia, bipolar affective disorder (BAD), and depression. A single-blind, experimental comparative study was performed at an out-patient mental health clinic at a hospital in Colombo district, Sri Lanka. 250 participants who met the inclusion criteria were randomly divided into two groups (125 each). Pre-adherence was measured for both control and intervention groups using the modified version of Medication Adherence Rating Scale (MARS). The intervention group underwent a POCS on medication which was supported with the Daily Activity Diary (DAD) over four months of follow up. Then both groups were reassessed for adherence with MARS. The DAD scores and pill count ratio were compared with MARS scores for the intervention group. The intervention group showed a significant improvement in adherence to medication ($p < 0.05$). DAD scores showed a significant positive relationship with the MARS scores (0.503). Continuous POCS at out-patient clinics using DAD as a supportive tool, can improve adherence to medication among people with Schizophrenia, BAD and Depression.

Keywords:- Adherence to Medication, Schizophrenia, Bipolar Affective Disorder, Depression, Patient Oriented Counseling on Medication.

I. INTRODUCTION

Adherence to medication is one of the most complex behaviours and a challenging problem demonstrated across people with many disease conditions. It is defined as the extent to which a person's behaviour of taking medication, following a diet, executing lifestyle changes and/ or corresponds with recommendations from a healthcare provider[1]–[3]. The behaviour of non-adherence among these people with illnesses ranges from refusing to take medication due to lack of acceptance regarding the necessity of having them, to non-adherence due to forgetfulness, lack of insight or financial difficulties, although they have recognised the need of taking medication [4], [5]. In addition, for some people the perception regarding illness and medication to be taken has become a key factors affects the adherence[6].

Non-adherence encompasses a wide range of behaviours (such as delaying or not filling a prescription, not re-filling a prescription, stopping medication early, forgetting, lack of understanding) both active and passive, leads to either underuse or overuse of prescribed medication [3]. It may be due to either a patient related factor such as their psychological disturbances, physical disabilities or therapy related factors such as complexity of medication, unpleasant side effects and duration of therapy. Poor adherence may also cause by social and economic factors; medication cost, lack of family or social support, language barrier and the gaps in existing health care system. For example, not having access to care, confusion of patient education materials, stress of health care visits [3], [7]. Misbelieves about treatments, cultural influences, poor symptom control and poor physician – patient relationship may also influence non-adherence among people with mental illnesses [8], [9].

Non-adherence is marked especially among long-term management of conditions such as asthma, cancer, hypertension, TB, depression, epilepsy and also smoking and tobacco cessation [3]. Among those conditions, non-adherence is prevalent in people with mental illnesses [10]–[12] perhaps due to lack of insight of some conditions. Evidence shows that most people with schizophrenia or schizoaffective disorders who are on medication take less than 70% of prescribed doses even in developed countries such as USA [3], [9], [13] and comparable numbers in the countries such as Ethiopia with under-resourced health care system [14]. In the management of mental illnesses, the first line treatment is medication and it requires adjunctive supportive measures to adhere patients for treatment regimens[15]. Many mental illnesses require long term medication adherence perhaps entire life time[16]. Effectiveness of the treatment, long term management of mental illnesses and the maximum benefit to affected people are highly dependent on their adherence [17], [18]. Therefore, adherence is the driving force of the success of the treatment to mental illnesses [19]–[22].

Non-adherence to medication has a huge impact on the affected people, their families, society and health care system. For example, lack of adherence to medication is associated with negative or undesired clinical outcomes such as increasing relapses; suicidal thoughts and attempts, clinical and functional deteriorations and further undesirable side effects on the affected person. It may also increase the caregiver burden, incidents of hospitalisation and also increase the healthcare cost and social burden [23]–[26]. Moreover, reviews on medication compliance and schizophrenia in developed countries such as United States and Australia indicate that the people who showed non-adherence have an average of 6-months to 2-year risk of relapses. This relapse rate is 3.7 times higher than the adhered patients [27], [28].

The pharmacist has to play a key role in the case of improving adherence to medication of people with mental illnesses as in all other diseases [29]. There are several interventions found in empirical literature to improve adherence to medication, such as pill boxes, pill cards, pill organizers, reminder charts, information leaflets, and motivational interviewing. It has been recognised that patient education is one of the mainstays of interventions that are used to improve adherence to medication [30]. Further, patients who have used pharmacy-based interventions including unit dose prescriptions of medication for psychiatric and medical conditions, medication education in packaging and refill reminders, information leaflets and counselling about drug treatment have made significant promotion of the adherence [31], [32].

The patient-oriented counseling style has been proven effective in improving adherence to medication in patients with Schizophrenia, BAD and Depression [33]–[37]. The counseling session for prescribed medicines should be a one-to-one interaction between a pharmacist and the person with mental illness and/or their caregiver in interactive nature [38]. It should include an assessment of whether or not the

information was received as intended and that the patient understands how to use the information to improve the probability of positive therapeutic outcomes [38]. Information in medicine can be provided orally or in written form to the patient or their representative on proper direction of use, advice on side effects, storage and diet and lifestyle modifications. Further, the strength of the therapeutic alliance is known to improve adherence related to medication and therefore pharmacists should help patient to identify the expected therapeutic goals and should also direct them towards achieving them. Thus it is necessary to design the patient counseling sessions in a way ensuring those outcomes and should be developed as a client centered approach [30]. In this study, counseling sessions were conducted exclusively regarding their medication and it does not have any involvement in counseling the patients by a psychiatrist for their well-being.

Based on estimates from the global health research center at the University of Washington; Institute of Health Metrics & Evaluation (IHME) Global Burden of Disease (GBD) in 2017, around 1-in-10 people (10.7%) have one or more mental or substance use disorders. The values show 3.4% of Depression, 0.6% of BAD and 0.3% of Schizophrenia as a share of global population[39]. These values are compatible with Sri Lanka as 3.44 % for Depression, 0.57% for BAD and 0.24% for Schizophrenia as a proportion of total population of the country [40]. According to the WHO statistics (2016) the prevalence of psychiatric disorders in the Sri Lankan population is 11.5%, which is a substantial proportion of the total population [41]. As this population is under mental deterioration, only directions on the label or instruction at the pharmacy counter will not be adequate to make them adhere to the regimen.

The WHO adherence meeting in June 2001 highlighted that the relationship between patient and the health care provider is very important in improving adherence to medication. However, in Sri Lankan context, the chance of receiving focused and individual counseling on medication by the pharmacist is less. In the case of people with mental illnesses this is even less as frequently their prescriptions are carried by a family member and directions are not given to the patient himself directly. There are also situations where medication is provided without informing the patient due to lack of insight and tendency to refuse because of the symptoms such as delusions, hallucinations, and also side effects of the medication. There is a dearth of evidence in the existing literature regarding POCS on medication by the pharmacist in Sri Lankan context and therefore, it is doubtful whether this population has been actually exposed to such an organised patient counseling session. Accordingly, the current study was concerned on the people with **schizophrenia**, **depression** and **BAD** depending on the high frequency of encountering in the out-patient mental health clinic, in Colombo Sri Lanka.

A. *Aim and Objectives*

Aim of the current research was to assess the level of adherence to medication in people with schizophrenia, BAD and depression through monitoring them towards proper and

rational use of medicine by providing patient oriented counselling session (POCS). The primary objective is to determine whether the POCS by the pharmacist can improve adherence to medication in this group.

B. Inclusion and Exclusion criteria

People who had diagnosed with schizophrenia, depression or BAD, were on medication for at least 4 months and at the age of 18 years or above were included. Patients who visited the out-patient mental health clinic during the data collection period were recruited for the study. Those who had poor insight (e.g. delusions and hallucinations) and people with visual and hearing impairments were excluded. The recruitment procedure illustrates in Figure I.

II. METHODOLOGY

A single-blind, experimental comparative study was performed among randomly selected group of people with depression, schizophrenia and BAD ($n=250$). They were randomly divided into 2 groups (intervention group and control group, 125 participants in each group). The research team provided POCS for the intervention group after issuing medication at the clinic for four months. A Daily Activity Diary (DAD) was given to each participant in the intervention group (four counselling sessions at each monthly clinic visit and four diaries). Pill counts were taken for each participant of the intervention group from their second clinic visit onward (three pill counts). The control group only received medication for their prescriptions.

Consent was obtained from all participants before the data collection. When the mental capacity was considered adequate (for example, mild depression), the informed consent was obtained. Informed proxy consent was obtained from the guardian in other cases. The permission to conduct the study at the psychiatric clinic setting was obtained from the particular district hospital. Researchers were well trained to conduct counselling sessions by role plays before commencing the data collection.

A. Interventions

POCS and patient administered medication activity diary (DAD) were used as interventions to improve the adherence to medication.

B. The counseling session

One-to-one counseling sessions were conducted for approximately 10 minutes at a convenient area arranged in the clinic upon issuing their prescribed medication. A topic guide was used to maintain a common flow of each counselling session for each participant and/ or their caregivers. POCS were conducted by trained four (04) pharmacy undergraduates who were also the members of the research team. Training included practice of topic guide by role plays. If there was a guardian or family members attended the session with the participants they were also instructed how to guide, help, and encourage the participants to take medicine regularly at home. The counselling sessions were mainly designed based on the United States Pharmacopoeia (USP) medication counselling behaviour guidelines which consisted of four main stages: (1)

Medication information transfer, (2) Medication information exchange, (3) Medication education and (4) Medication counseling [42], [43]. The investigators maintained a friendly and comfortable relationship with the participant throughout each counselling sessions in order to establish a strong trustworthiness towards the counsellor. Participants were allowed to ask questions and clarify the things related to their medicines and especially they were advised on how to minimize the influence of bad side effects they experience with some medicines without interrupting their day-to-day activities. Further, the counselors tried to make them feel free during counseling sessions while explaining the important facts about medicines they were using in very simple manner, resolving their problems related to their medication, explaining and encouraging them to fill the DAD given by the study team, helping in improving their health-related behaviour, showing genuine empathy, accepting them and helping them in changing negative thoughts about medicines.

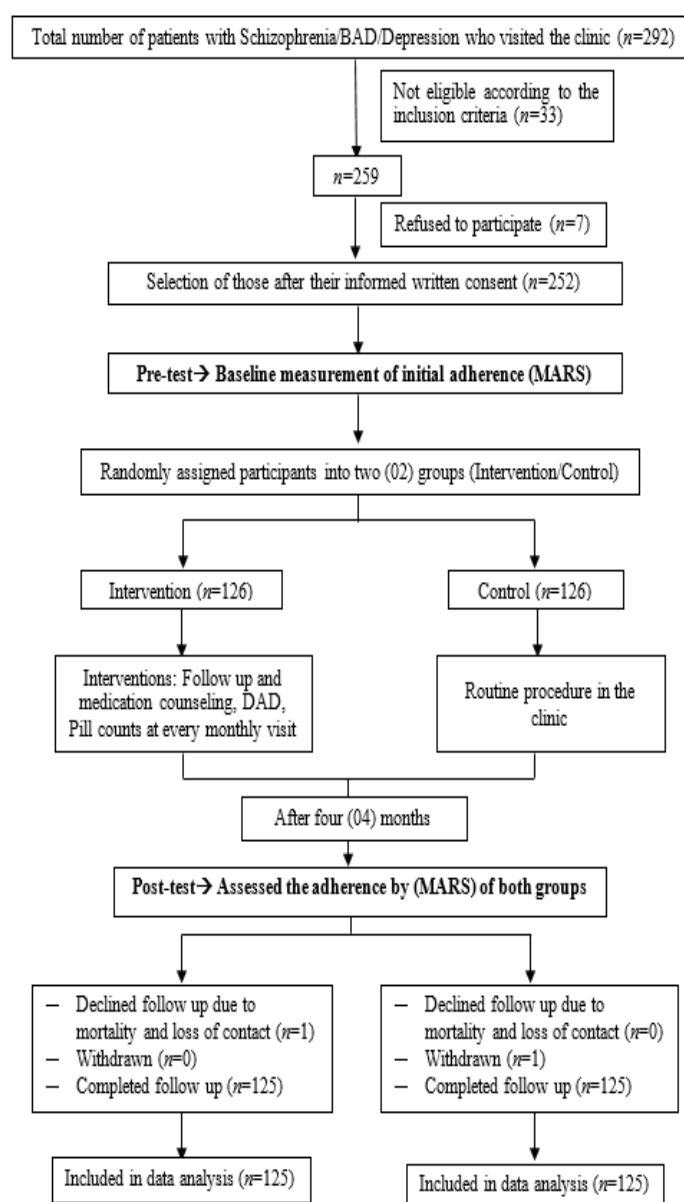


Fig. I. Study design

III. ANALYSIS

Descriptive and analytical data analysis were performed using SPSS (version 21) software. Comparison between the two groups was performed using the *t* test. Paired- samples *t* test and independent samples *t* test, were adopted to test the heterogeneity of data. Bivariate correlation statistics were used to understand the bivariate relationships between continuous variables (Figure 3 ; $P < 0.05$ for all tests).

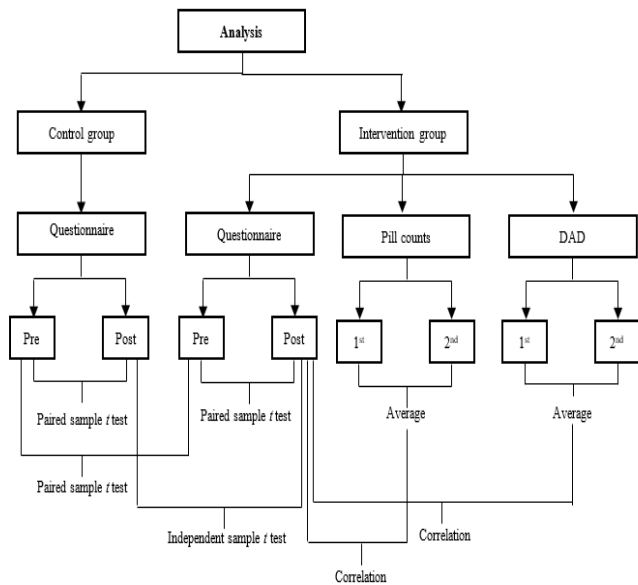


Fig. 3. Data analysis plan

IV. RESULTS

Table 1 summarizes the demographic and clinical data of the two groups. About 42.8% of the participants in the study were males and 57.2% of the participants were females and the mean age of the patients was 45.19 (12.90) years in the study. 38% of the participants were people with Schizophrenia, 34% of the participants were people with BAD and people with Depression was 28% of the total study population.

TABLE 1. DESCRIPTION OF DEMOGRAPHIC AND CLINICAL DATA OF THE ENTIRE SAMPLE

Variable	Frequency	Percentage (%)	M	SD
Gender				
Male	107	42.8	-	-
Female	143	57.2		
Age	-	-	45.19	12.90
Disease				
Schizophrenia	95	38	-	-
BAD	85	34	-	-
Depression	70	28	-	-

Analytical data are presented in three sub-headings as illustrated in the Figure 3.

Adherence according to the MARS questionnaire

Test adherence of both control and intervention group at baseline

The baseline values obtained for intervention group and control group (mean values 6.33 vs 6.7, $p = 0.148$) were approximately equal and there were no statistically significant differences between the two groups in terms of adherence to medication at baseline (Table 2).

Test pre and post adherence in control group

No statistically significant differences were found in the control group in terms of adherence to medication at pre-test and post-test of MARS. According to significant (2-tailed) value, ($p= 0.730$) and there was no significant difference after four months.

Test pre and post adherence in intervention group

A statistically significant difference was found in the intervention group in terms of adherence to medication at pre-test and post-test of MARS. In accordance with significant (2-tailed) value, ($p=0.000$) there is a significant difference in adherence after four months with respect to MARS scores before and after counseling.

Post adherence between intervention and control groups

However, we did obtain statistically significant results in post scores of MARS questionnaires between the Intervention and the control groups in terms of adherence to medication at the end of four months. Mean value obtained for intervention group was greatly higher than mean value of control group (5.95 vs 7.86, $p= 0.000$) (Table 2). Thus, there is a statistically significant difference between two groups following intervention.

TABLE 2. INDEPENDENT SAMPLE T-TEST RESULTS FOR MARS SCORE OF CONTROL AND INTERVENTION GROUPS

Group	M		SD		SEM		P
	C	I	C	I	C	I	I
Pre-adherence	6.74	6.33	2.226	2.217	0.198	0.199	0.148
Post-adherence	5.95	7.86	2.459	1.857	0.166	0.220	0.000

Part I. Correlation of DAD and pill counts with MARS questionnaires.

The significant (2-tailed) value is 0.000. Therefore, it shows a significant relationship between MARS questionnaire and DAD of 0.503 is the correlation density.

TABLE 3. BIVARIANT CORRELATION TEST FOR MARS (POST) AND DAD

Tool	Correlation Coefficient		Sig. (2-tailed)	
	MARS	DAD	MARS	DAD
Correlation	1.000	0.503**	-	0.000

According to the significant (2-tailed) value ($p=0.148$), there is no significant correlation with average pill count and MARS questionnaire.

TABLE 4. BIVARIANT CORRELATION TEST FOR MARS (POST) AND AVERAGE PILL COUNT

Tool	Correlation Coefficient		Sig. (2-tailed)	
	MARS	Pill count	MARS	Pill count
Correlation	1.000	0.130**	-	0.148

Part II. Disease wise adherence in before and after counseling upon MARS scores

According to the results, all three diseases have shown a significant difference in MARS value before and after the counseling. Each significant 2-tailed value 0.024 (Schizophrenia), 0.003 (BAD) and 0.033 (Depression) was less than 0.05.

TABLE 5. DESCRIPTION OF ANALYTICAL DATA OF PRE AND POST MARS QUESTIONNAIRES ACCORDING TO THE DISEASE

Disease	Mean (Pre-test MARS)	Mean (Post-test MARS)	T	Sig. (2-tailed)
Schizophrenia	7.10	7.90	- 2.336	0.024
BAD	6.80	7.91	- 3.164	0.003
Depression	6.73	7.70	- 2.234	0.033

In addition to above statistical results, we could obtain some favorable facts regarding DAD. It has been found that, by marking the DAD it avoids having repeated doses due to forgetfulness. Its simplicity, attractive format made easy to understand to the users and they were interested in using it as an aid of following their dosing frequencies properly. Further, it encourages the users to take medicines and they were enthused once they completed the diary and submitted to investigators.

V. DISCUSSION

This study explored how the POCS by pharmacist could change the level of adherence to medication of people with Schizophrenia, Depression and BAD. The findings indicated that the adherence to medication among the selected group improved after being subjected to regular counseling sessions over four months. Similar studies from high income countries such as Germany, Singapore, Hong Kong and upper middle income countries such as Iran and China have shown various patient-centered educational interventions such as motivational interviews have positive effects on increasing insight and adherence to medication in people with mental illness including Schizophrenia, BAD and Depression [33], [34], [52]–[55]. In contrast, evidence given in some reviews

indicate that the educational and interviewing interventions do not show consistent success for long term mental illnesses such as Schizophrenia[56], [57]. That is because of the variability in adherence measures used and the limited number of sessions conducted. In contrast, combined interventions and longer duration of interventions have found to be associated with favorable outcomes. Motivational interviewing interventions were conducted for duration of 3 weeks to 12 weeks, and single session to more than 9 sessions in the studies conducted on medication adherence found in the literature, [34], [56], [58]–[60] whereas, four POCS sessions were conducted over four months and used combined interventions; POCS and DAD in the current study.

Findings of the current study indicated that the POCS could significantly improve the medication adherence of the participants who showed poor adherence at the beginning. It was also noted that during these counseling sessions most participants were willing to talk, share their experiences and discuss their concerns and issues related to long-term medication with the research team. Findings revealed that the limited time with the medical officers in an over-crowded clinic hindered the opportunity of them having adequate discussions with the patients and their caregivers and this affected negatively with the adherence to medication. Findings also showed that the pharmacists can play a vital role in providing such counseling with training. Moreover, existing evidence suggests that effective counseling on medication require more time spent with the patients and pharmacists are more equipped and accessible to patients over other healthcare providers in an out-patient clinic setting [20], [43], [61].

However, in the existing health care system, healthcare professionals face several challenges such as work overload, burden of preventable medical errors, limited staff, and limited or not enough access to technology [61]. Health literacy problems, limited appointment availability, office hours and economical barriers are also identified issues experienced by the patients and the caregivers. Further, it was recognised that there is a timely need of bridging the gap exists between the patient and the healthcare provider in terms of time, personalised care and communication to produce better health outcomes [62]–[64]. In addition to improving the hospital sector facilities strengthening the home-based care delivery and reinforce the family and social support would be important to combat with such challenges.

The positive results obtained in the current study provides a new understanding and direction for further investigations on improving patient adherence to medication, involvement of pharmacists in that and practicing the same in the clinical set up. It is a challenge for the same pharmacist who dispenses medicines, to carry out counseling sessions for each patient in the Sri Lankan hospital setup with the increased number of patients and the pharmacies operated with minimum staff. Some studies conducted in the USA and Netherlands report that pharmacists often were hindered by time constraints and work load that impeded patient counselling [20], [61]. Therefore, involvement of a trained pharmacist for medication counseling at the clinic would be

more beneficial in Sri Lankan context when educating patients.

The new adherence measuring tool, the Daily Activity Diary (DAD) was found to be very useful in measuring patient's adherence to medication. It also increased the patients' responsibility, active engagement and involvement in treatment planning and their own treatment regime. For example, most of the participants expressed that they had a positive experience and feedbacks of advantages, practicality and usability of DAD were very much positive. The DAD entries prevented the patients having repeated doses and was also considered as a 'good solution' for their forgetfulness. They also stated that the symbols used in DAD were easy to understand, and therefore interested in using it as an aid of adherence to medication. This tool can be used in the existing clinic settings and therefore suggest further studies to validate this tool. However, there can be disadvantages of this tool such as forgetting to mark the DAD and one can mark without taking the pills.

Using the pill count ratio in measuring adherence to medication was not effective as expected, perhaps because of several participants were reluctant to bring the remaining pills with them to the clinic. Similar studies on medication adherence have shown the issues and limitations in use of pill counts [49], [50], [65]. However, a review from USA on psychiatric treatment adherence methods and measures shows the importance of traditional pill count method of asking the patient to bring the remaining pills [50]. Evidence indicates that there is a chance of dumping pills to pretend adherence and such misleading practices by the least adherent patients may lead to dissimulation and inaccuracy of the therapeutic outcomes [50]. This method can be improved with electronic monitoring devices though it does not confirm whether the patient has actually ingested the medication [51]. Therefore, along with other attempts, encouraging the patient and their family caregivers with the support of the healthcare professionals in order to improve their adherence to medication.

Even though MARS questionnaire was used as the main tool of measuring adherence in the current study, it also comprises of some drawbacks. Such as, scoring requires some interpretation, "yes" response does not necessarily indicate a positive attitude or behavior. Some patients' opinions might change the response to questions despite of the actual answer. As an example, a clear symptom of a co-current disease can be misinterpreted by the patient as a side effect of a medication. As same as in above tools discussed, here also patient might tend to hide their poor adherence and sometimes they may get forget [51]. However, MARS questionnaire can be recognised as a self-report measure, which evaluates both attitudes about medications and actual medication-taking behavior.

Furthermore, findings of this study indicated that the counselling sessions helped the participants to understand the nature of their illness, improve the importance of regular treatments and adherence to medication and to identify and manage the barriers to adherence of medication. Several

studies conducted using motivational interviewing methods including counseling sessions also shown that its impact to various secondary outcomes such as improve the insight to treatment and perception on medication [20], [33], [66]. In the current study, most of the participants complaints were regarding the side effects of medicines such as sedation, dizziness, and weight gain. According to participants' personal experiences, such side effects hindered their activities of day-to-day life and had a strong negative impact on poor adherence. Findings also indicated that with increased awareness of possible side effects of medicines and the ways of overcoming difficulties caused by them on their daily activities enhances the adherence to medication.

VI. LIMITATIONS

The current study was conducted in small scale, only three kind of disorders were selected upon the base of the prevalence in the selected study setting. Generalizability of the results is limited due to the small population and the selected study setting. The Randomized Control Trial is the golden choice for these types of studies.

VII. CONCLUSION

Patient oriented counseling sessions on medication by the pharmacist were successful and had a positive impact on improving adherence to medication of the people with schizophrenia, BAD and depression over a four-month follow-up period. When compared to MARS, the DAD was a useful and simple tool to measure and improve medication adherence among people with mental illness. POCS by the pharmacists can be recommended for practice in the hospital or clinic settings to improve the treatment success of people with chronic mental illnesses.

The DAD can be implemented in the current clinic system as a supportive tool for improving the medication adherence and home-based long-term management of care of people with chronic mental illnesses. The current study also highlights the importance of the role and responsibility of pharmacists to refresh and update their skills and understanding of working with people with mental illnesses and their family caregivers. Counseling on medication, which is a structured and self-empowering intervention used in conjunction with daily activity diary and other psychiatric treatments, has explicit benefits to patients with schizophrenia, bipolar affective disorder, and depression and deserves further research into its suitability for a wider implementation in community for diverse psychiatric patient groups.

ABBREVIATIONS

MARS; Medication Adherence Rating Scale, DAD; Daily Activity Diary, Patient Oriented Counseling Session; POCS, WHO; World Health Organisation, BAD; Bipolar Affective Disorder, USP; United States Pharmacopoeia, DAI; Drug Attitude Inventory, SPSS; Statistical Package for Social Sciences, MAQ; Morisky Medication Adherence, M; Mean value, SD ; Standard Deviation, SEM; Standard Error Mean,

P; *p* value, Sig: Significant value, USA; United States of America.

COMPETING INTERESTS

All authors declare that they have no competing interests.

ETHICS APPROVAL AND CONSENT

Ethical approval was obtained from the Ethical Review Committee (ERC) of the Faculty of Medicine, Kotelawala Defence University, Ratmalana, Sri Lanka (reference no: RP/S/2016/04 on 25/02/2016). The purpose and method of the research were described for the participants. Also, the participants' informed, written consent to voluntarily participate in the study was obtained from all participants.

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