Impact of Pharmacist Intervention Using MEDS-UOD on Medication Adherence among Schizophrenia Patients

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Abstract

Introduction: About 80% of patients with schizophrenia were found non-adherent towards antipsychotic medications at some stage of their illness. Medications-Unit of Dose (MEDS-UOD) was an intervention by the pharmacists to improve medication adherence among schizophrenia patients.

Objective: To evaluate the impact of pharmacist intervention using MEDS-UOD on medication adherence in schizophrenia patients.

Method: This study was conducted using quasi-experimental study design. Patients with schizophrenia who received treatment at the Psychiatric Clinic of Hospital Melaka between January to December 2018 were recruited. Patients were divided into Control Group (CG) and Intervention Group (IG). CG patients received usual care, standard communication and standard counselling, while IG patients received MEDS-UOD booklet, refill reminder through phone call, and standard counselling. MEDS-UOD was a new packaging intervention in which individually packed medications were arranged according to prescribed dose and frequency in a booklet. Medication-adherence were measured using validated Medication Adherence Rating Scale (MARS) score and pill count (%) method at baseline, and three and five months after interventions.

Results: A total of 60 subjects had completed five months of follow ups (n=33 in CG versus n=27 in IG). Compared with CG, the pill count percentage significantly improved in IG at 3 and 5 months after intervention ($p<0.001$). However, no significant changes in MARS score were recorded between the two groups at all time of follow ups. In IG, the mean differences in both pill count percentage and MARS score between baseline and five-month post-intervention was statistically significant ($p<0.001$ and $p=0.020$ respectively).

Conclusion: MEDS-UOD could be a useful intervention to improve medications adherence among schizophrenia patients and could be recommended for schizophrenia patients with compliance issues.

Keywords: Medication adherence, pharmacist, schizophrenia, packaging intervention

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Introduction

Schizophrenia stands as a prevalent mental ailment, ranking among the top fifteen contributors to global disability, impacting around 21 million individuals (1). Those afflicted by schizophrenia encounter instances of hallucinations, delusions, disorganized speech, unpredictable behaviour and also exhibit negative symptoms. The middle occurrence rate of schizophrenia was recorded at 15.2 per 100,000 individuals (with a range of 7.7 to 43.0 per 100,000) (2). In Malaysia, the National Mental Health Registry for Schizophrenia which was established in 2003, documenting a total of 7351 cases that had been registered from year 2003 to 2005. This chronic and debilitating disease severely disrupts psychosocial functioning across various aspects of life. Thus, leading to significant economic burden due to reduced employability, productivity and escalating expenses linked to illness management (3).

Continued utilization of antipsychotic medications over an extended period is a crucial element of treatment for individuals diagnosed with schizophrenia (5). Unfortunately, those suffering from schizophrenia frequently exhibit incomplete adherence to the prescribed medication. According to the Malaysia Psychiatric Association, there were about 80% of patients with schizophrenia were found non-adherent towards the antipsychotic medications at some stage of their illness (4). Non-adherence towards antipsychotic medications is often divided into intentional and unintentional, though both can occur in the

same individual. Intentional non-adherence occurs when a patient deliberately decides not to take medication as prescribed. Examples of unintentional non-adherence include forgetting to take a dose of medication, misunderstanding medication directions, losing medication, and environmental barriers such as transportation issues (6). The consequences of non-adherence include relapse, treatment failure, increased morbidity, hospitalization, and increased healthcare costs (7). Hence, improved adherence may reduce relapse rates, decrease the length of hospital stay, and reduce healthcare costs (6).

Several specific interventions have been used to improve antipsychotic adherence, including psychosocial interventions, service interventions, education, integrated care, packaging and daily reminders and financial incentives. The distinction between these interventions is not absolute, and some studies use a combination of strategies (6, 8). These interventions needed an active engagement of healthcare resources due to their complexity and labour intensive nature, thereby resulting in increased costs (8). Recommendations for enhancing medication adherence have long involved packaging interventions that include various packaging formats. These formats aim to improve medication adherence by physically organizing medications in a manner that indicates the specific day and/or time for administration. Common examples of packaging interventions include professionally prepared blister packs, unit-packaging, unit-of-use systems and unit-of-dose packaging which provide correct medications in containers. . Meanwhile, medication interventions involving pill boxes may not demand professional involvement as patients, informal caregivers or healthcare providers can fill these pill boxes (9).

A study which implemented unit-of-use packaging medications had found positive finding to improve patient adherence that included all patient's medication for psychiatric and general medical conditions. In addition to the intervention, they providing educational sessions and timely refill reminders two weeks before scheduled refill dates where this approach offers a means for patients to independently monitor their medication intake. This methodology is particularly effective for medications that require consumption at distinct times throughout the day, as it eliminates the need for patients to decide which medications to take at different intervals (10). Despite being widely studied within Western countries, the inconsistency in the methodologies and outcomes still exists across studies, with varying approaches to the same interventions. These factors have hindered the attainment of conclusive evidence that could be directly applied to the healthcare context in Malaysia.On top of that, no data regarding impact of packaging intervention toward medication adherence among psychiatry patient in Malaysia. Thus, our objective of this study is to investigate patients' adherence towards antipsychotic medication through a pharmacist intervention using MEDS-UOD to compare the mean pill counts percentage and MARS score between different groups and to compare the mean differences of pill count percentage and MARS score in different time periods in Hospital Melaka setting.

Method

Recruitment

This study was conducted using a quasi-experimental design at Psychiatric Clinic Hospital Melaka between January to December 2018. Screening and recruitment of the patients was carried out at the Outpatient Pharmacy Department. Inclusion criteria were patients aged between 18 to 60 years, stable schizophrenia according to Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV), who started antipsychotic drugs at least four weeks of treatment and those who took tablet preparations only. There were four features for exclusion criteria include those schizophrenia patients who were new to drug treatment, had cognitive impairment that may hinder the assessment, patients who received antipsychotic medications outside from Psychiatric Department Hospital Melaka and patient who had syrup or solution antipsychotic only. Participants who able to comprehend the study's objectives and expressed a willingness to provide their consent were enrolled.

Patients were alternately grouped into two groups which are the Control Group (CG) and the Intervention Group (IG) by order of recruitment. Patients in the control group received usual care which are the standard communication regarding their medications at the pharmacy and standard medication counselling. Any questions directed to the pharmacist were responded to in accordance with the standard procedures followed in the pharmacy. Meanwhile, intervention group patients received the MEDS-UOD intervention and standard medication counselling. All patients received standard medication counseling which followed the psychoeducation module established by the Ministry of Health Malaysia (11).

Sample size

Sample size was calculated using EpiCalc 2000 software. Based on a power of 80% (β=0.2), alpha of 0.05, an expected mean difference of MARS score is 10% and standard deviation of 4% between the 2 study interventions. The margin of error is 20% of the mean difference. Calculated sample size (N) for each group is 30 patients. Allowing for 10% dropout, a final sample size of 35 per group will be used.

MEDS-UOD

MEDS-UOD (Medications-Unit of Dose) was a new packaging intervention in which individually packed unit of dose (UOD) medications were arranged in a booklet according to the prescribed dose and frequency (Figure 1). For instance, the medication strips were cut into UOD and filled in a plastic zipper bag and stapled at the MEDS-UOD sheet according to the intake time and date. All sheets were compiled into a patient's booklet, which consists of a front page, patient medication summary and MEDS-UOD sheet for one month or until the next appointment. The booklet also has refill reminder. Each patient has to take one packed medication at one time according to the date written in the booklet. MEDS-UOD can be prepared early, before the patient's appointment at pharmacy, except during the recruitment phase.

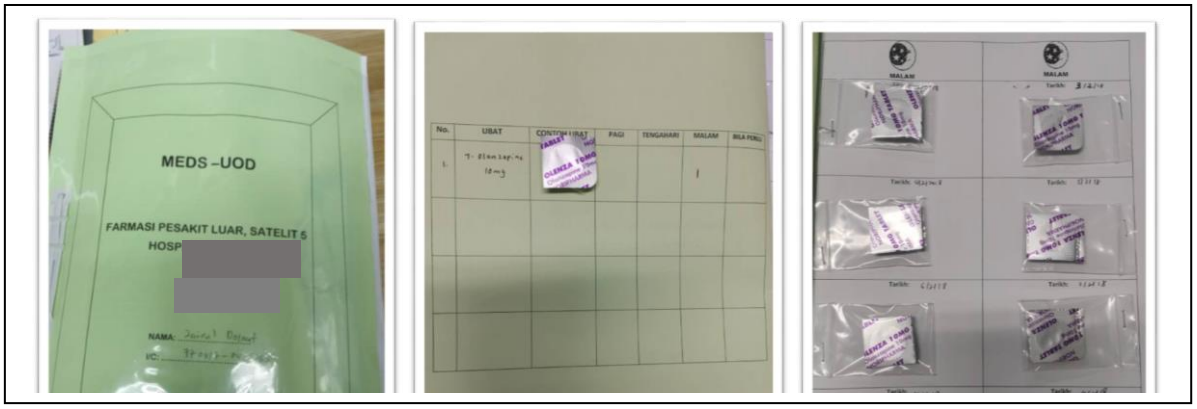

Figure 1: MEDS-UOD booklet

During the recruitment phase for the intervention group, patients were explained regarding the MEDS-UOD booklet. Those patients in the intervention group were called a week before refill dates to ensure patients came at scheduled appointment dates every month. Patients were asked to bring the MEDS-UOD booklet in an empty zipper plastic bag. All zipper plastic bags were recycled for next appointment at the pharmacy. The cost of MEDS-UOD booklet for each patient for once-daily dosing was RM3.60 over six months study; meanwhile, cost for twice-daily dosing was RM7.20 over six months.

Data Collection

The information was collected using a data collection form. Part A consisted of demographic data such as age, gender, race, marital status, education level, duration of illness, number of medications and employment status. Part B consisted of medication adherence assessment using the pill count method (%) and the validated Medication Adherence Rating Scale (MARS) score (12). The MARS score consisted of ten questions Yes/No scale which evaluated both attitudes about the medication and actual medication taking behavior. The total score ranges from zero (low likelihood of medication adherence) to ten (high likelihood of medication adherence). The questionnaires were self-administered. The pharmacist will answer the patient's queries when clarification is needed.

Both the English and Malay versions of the MARS were used in this study. Permission of using MARS in this study has been obtained from the authors. Medication adherence using MARS score and pill count (%) were assessed at baseline, three and five months after interventions. To measure pill count, the patient required some initial preparation, including asking patients to keep all empty medication blisters and empty zipper plastic bags. Equations of medication adherence measure using pill count used in this study as mentioned below (13).

$$PILL\ COUNT = \frac{(Number\ of\ dosage\ unit\ dispensed - number\ of\ dosage\ unit\ remained)}{(Prescribed\ number\ of\ dosage\ unit\ per\ day \times number\ of\ days\ between\ 2\ visits)} \times 100$$

Analysis

All data were analysed by using SPSS® program version 23.0 software. Descriptive statistics such as mean and standard deviation (SD) were used for continuous demographic variables. Categorical variables were summarised in frequency (n) and percentage (%). Kolmogorov Smirnov test showed the data were normally distributed, thus Repeated Measure ANCOVA was applied to compare the mean of MARS score and pill count (%) between groups. This method was used to identify which group has given a positive impact to improve medication adherence. Pairwise comparison (Bonferroni) of repeated measure ANOVA was applied to measure the mean differences of MARS score and pill count (%) between different time periods. This analysis was conducted to explore the time effect between these two groups and identify whether this measurement has changed in that duration. P-values less than 0.05 were considered statistically significant.

Ethics Statement

This study was registered in the National Medical Research Registry (NMRR) (NMRR-17-2766-36795) and approved by the MOH Medical Research and Ethics Committee (MREC). Informed consents were obtained from patients before enrolment into the study.

Results

A total of 112 patients were assessed for eligibility. After exclusion, only 69 patients were enrolled. However, only 60 of them completed the five-month follow-up period. There were 33 patients in the CG and 27 patients in the IG (Figure 2). The demographic characteristics of the subjects are shown in Table 1. The mean age of CG and IG was 41.5 (SD 8.8) and 36.9 (SD 8.7) years old, respectively. The majority of the subjects in CG were male (72.7%) and Malay (57.6%), while the majority of the subjects in IG were female (59.2%) and Chinese (55.6%).The duration of illness was similar for CG and IG, which were 12.5 (SD 10.6) and 13.0 (SD 9.1) years, respectively.

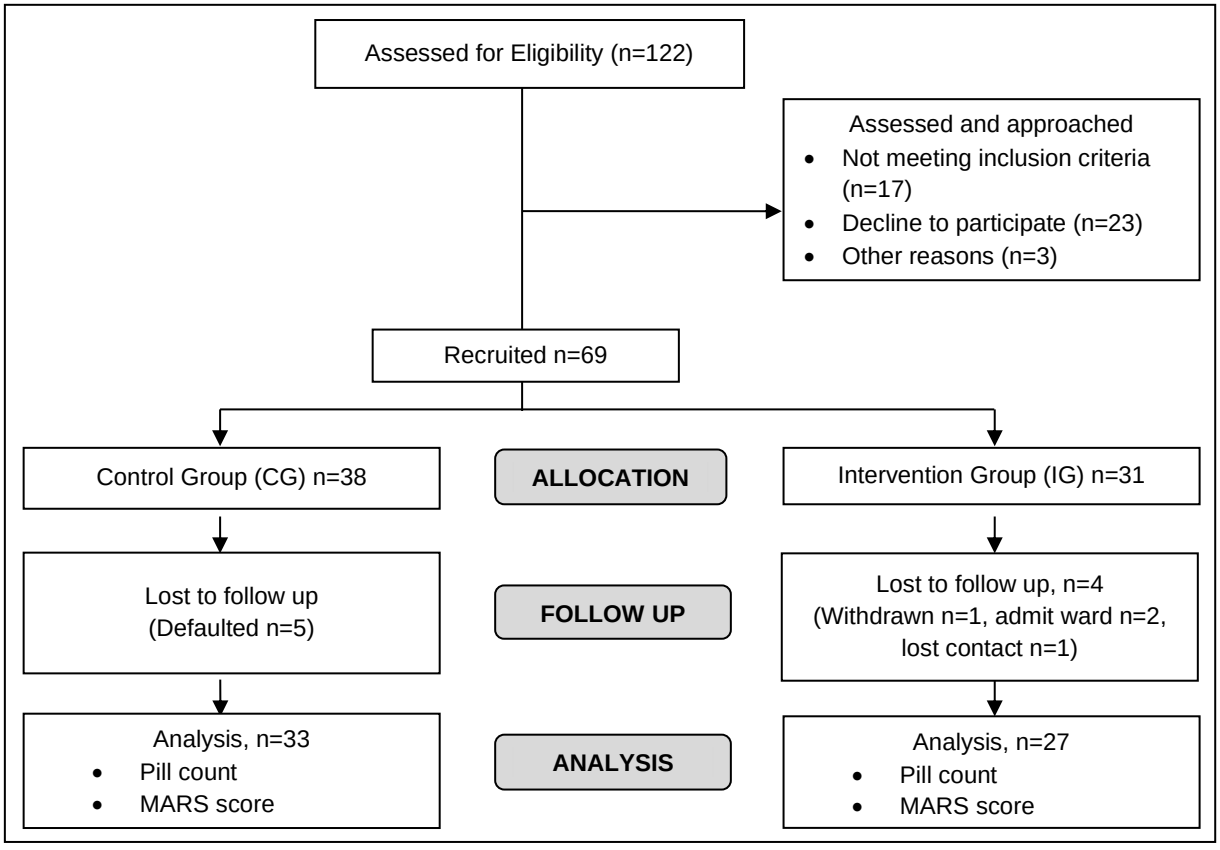

Figure 2: Flow chart of recruitment of the study population

Table 1: Demographic characteristic of the study population

Characteristic	Control Group (n= 33)	Intervention Group (n= 27)
Age (mean ± SD)	41.5 (8.8)	36.9 (8.7)
Gender		
Male	24(72.7)	11(40.7)
Female	9(27.3)	16(59.2)
Race		
Malay	19(57.6)	11(40.7)
Chinese	13(39.4)	15(55.6)
Indian	0	1(3.7)
Others	1(3.0)	0
Marital status		
Married	11(33.3)	5(18.5)
Single	20(60.6)	22(81.5)
Widow/widower	2(6.1)	0
Number of medication		
1	19(57.6)	15(55.6)
2	9(27.3)	8(29.6)
≥3	5(15.2)	4(14.8)
Employment		
Employed	14(42.4)	18(66.7)
Unemployed	19(57.6)	9(33.3)
Duration of illness (mean ± SD)	12.5(10.6)	13.0(9.1)

Abbreviation: SD = Standard deviation

Compared with CG, the mean (95%, Confidence Interval (CI) of pill count percentage was significantly higher in IG at 3 and 5 months after intervention [3 months:(97.5%(93.5-101.5) vs 89.5%(85.9-93.1)]; and 5 months:[100.2%(97.9-102.5) vs 92.3%(90.2-94.4); p<0.001] (Table 2). However, no significant changes in the mean (95%CI) MARS score were observed between both groups at all times of follow up (Table 3).

Table 2: Comparison of adjusted mean of pill count percentage between groups with adjustment of baseline

Month after intervention	Adjusted mean (95% CI)		F-statistics (df)	p-value
	Control Group (CG)	Intervention Group (IG)		
Baseline	87.9 (84.9, 90.9)	93.2 (89.8, 94.3)		
3 months	89.5 (85.9, 93.1)	97.5 (93.5, 101.5)	17.1 (1,57)	<0.001
5 months	92.3 (90.2, 94.4)	100.2 (97.9, 102.5)		

Repeated Measure ANCOVA [baseline adjustments] F(df) = 17.1 (1,57); p<0.001
Abbreviation: CI = Confidence interval; df = Degrees of freedom

Table 3: Comparison of adjusted mean of MARS score between Groups with adjustment of baseline

Month after intervention	Adjusted mean (95% CI)		F-statistics (df)	p-value
	Control Group (CG)	Intervention Group (IG)		
Baseline	8.5 (8.1, 8.8)	8.3 (7.4, 8.7)		
3 months	8.7 (8.3, 9.0)	8.9 (8.5, 9.3)	2.2 (1,57)	0.141
5 months	8.3 (7.9, 8.7)	9.1 (8.6, 9.5)		

Repeated measure ANCOVA [baseline adjustments] F(df) = 2.2 (1,57) ; p=0.141
Abbreviation: CI = Confidence interval; df = Degrees of freedom

In IG, the mean difference (95%CI) between baseline and 5 months intervention of pill count percentage [-7.6(-11.2 -4.0); p<0.001] and MARS score [-0.7(-1.4 -1.0); p=0.020] was found statistically significant (Table 4 & 5). No significant improvements were observed in CG group after 5 months.

Table 4: Comparison of changes in pill count percentage at different study time points

Comparisons (month after intervention)	Control Group (CG)		Intervention Group (IG)	
	Adjusted mean difference (95% CI)	p-value	Adjusted mean difference (95% CI)	p-value
Between baseline and month 3	-1.5 (-7.7, 4.6)	>0.95	-4.3 (-8.2, -0.4)	0.029
Between baseline and month 5	-3.8 (-8.2, 0.7)	0.127	-7.6 (-11.2, -4.0)	<0.001

Pairwise comparison (Bonferroni) of repeated measure ANOVA for each CG and IG.
Repeated measure ANCOVA [baseline adjustments] F (df) = 4.3 (1.5, 86.3), p=0.026)
Abbreviation: CI = Confidence interval

Table 5: Comparison of changes in MARS score at different study time points

Comparisons (month after intervention)	Control Group (CG)		Intervention Group (IG)	
	Adjusted mean difference (95% CI)	p-value	Adjusted mean difference (95% CI)	p-value
Between baseline and month 3	-0.1 (-0.6, 0.4)	>0.95	-0.7 (-1.3, -0.1)	0.023
Between baseline and month 5	0.2 (-0.3, 0.7)	0.886	-0.7 (-1.4, -1.0)	0.020

*Pairwise comparison (*Bonferroni) *of repeated measure ANOVA for each CG & IG.*
Repeated measure ANCOVA [baseline adjustments] F (df) = 2.4 (2,114), p=0.092
Abbreviation: CI = Confidence interval

Discussion

Medication adherence in mental health treatment is very important (14). Hence, intervention such as the MEDS-UOD was implemented as an adherence aid to educate schizophrenia patients about their antipsychotic treatment and emphasize compliance. The MEDS-UOD packaging utilized in our study differs slightly compared to one study where the packaging consisted of a seven-day supply of medications organized on a strip, which was prepared by pharmacists and featured medication-specific instructions. It also included designated times of the day (morning, noon, evening, and night) for dose administration (10). In contrast, our study employed a simpler MEDS-UOD packaging designed for a month with medication-specific instructions and specific morning and night dosing times. This packaging was prepared by pharmacists without requiring special skills and included the specific dates for dose administration. It offered a continuous visual record of the daily doses to be taken and facilitated the monitoring and tracking of missed doses on a monthly basis by patients, pharmacists, clinicians and caregivers. Therefore, the design of the MEDS-UOD packaging may have played a role in guiding patients to self-administer their medications punctually and gradually cultivate a habit of adherence to their prescribed treatments.

A significant improvement in medication adherence by using pill count after five months of intervention was seen in intervention group. This clearly demonstrated that the packaging intervention approach was significantly better compared to the conventional care approach. Similar finding was made in a Malaysian study where the implementation of calendar packing interventions by pharmacists for hypertensive patients found to an enhancement in medication adherence as indicated by the Medication Possession Ratio (MPR). The intervention group have higher MPR compared to the control group (p<0.05) (8). Another study highlighted the positive impact of packaging interventions using the Meds-Help approach showing statistically significant increases in MPR at 6 and 12 months among schizophrenia, schizoaffective, or bipolar patients (p<0.0001) which consisted of unit of use packaging, medication and packaging education session, refill reminders and clinician notification (10).

In another study, it was discovered that the intervention groups utilising PharmCAT and Med-eMonitor (MM) found statistically significant enhancements in medication adherence as measured by pill counts during the 9-month follow-up period in comparison to the control group (p<0.001). Nevertheless, the average treatment cost per patient per month for each of these interventions was higher in comparison to our study. This increased cost included expenses such as mileage for home visits, the cost of the monitoring

device along with web support, as well as the need for home visits for PharmCAT and refilling the monitor for MM (15). While we cannot compare the outcomes of our intervention directly because of the differences in methodology and approach, the cost of MEDS-UOD is cheaper and easier to be implemented. Thus, MEDS-UOD could be considered to improve the adherence to antipsychotics.

The difference in MARS score between CG and IG was not-statistically significant at five months of study. This outcome is similar to one study which used medication schedules and pillboxes as adherence aids in their pharmacist-assisted psychiatric clinic (14). However, when comparing the mean differences of both pill count percentage and MARS score between baseline and three months, and between baseline and five months, statistically significant improvements was observed = in the intervention group. Similar improvement was not observed in the control group. This may reflect indicate that MEDS-UOD may improve antipsychotic medication adherence. A similar result was found in a study conducted in Malaysia which uses MARS score as one of the tools to evaluate medication adherence among schizophrenia patients after giving pharmacist's intervention (Home Medication Review program). The mean MARS score at study baseline and end study was significantly improved throughout six months of study ($p<0.001$) (16).

There were several limitations in this study. The main limitation of this study was the differences in baseline characteristics between the control group and intervention group. This may potentially impact the study outcomes. Besides that, this study was only conducted in a single setting. Hence, the findings may not represent the Malaysian population of schizophrenia patients. Also, the results may not apply to elderly patients and/or those with cognitive impairment that may hinder their assessment.

The present study was conducted using pill counts method, which may lead to the Hawthorne effect. There is a possibility that patients may have discarded their pills before their visits because they worried the pharmacist might count them. Our study had no mechanism to measure this possibility. Therefore, the data collected was assumed to be accurately reported by the patient. Despite this concern, we believed that the pill counts method is an easy and cost-effective method to measure patient's medication adherence in a resource-limited setting.

Conclusion

Pharmacist intervention using Meds-UOD showed improvement in medication adherence among stable schizophrenia patients. Hence, the positive impact of introducing MEDS-UOD in pharmacist service can be considered for schizophrenia patients with compliance issues and could be implemented in other hospitals or clinics throughout Malaysia that provide psychiatric services for better patient care and aim to reduce treatment failure, rate of hospitalization and morbidity. As MEDS-UOD is still novel in our hospital setting, there is room for improvement to improve patient care and quality of life. Future studies should conduct with a larger sample size and a longer intervention period.

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Conflict of Interest Statement

This research received no grant from any funding agency in public, commercial or not-for-profit sectors. The authors declare that there is no conflict of interest.

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