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Research Article

A Quasi-Experimental Study to Assess the Effectiveness of Electronic Messaging Support Service Program on Adherence of Lipid-Lowering Therapy among Patients of Acute Coronary Syndrome at Cardiac Out Patient Department, KGMU, Lucknow

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Abstract

Aim: The objective of the study was to assess the effectiveness electronic messaging support service program (EMSSP) on adherence of lipid-lowering therapy among cardiac outpatient department (OPD) patients of acute coronary syndrome (ACS). **Materials and Methods:** The research approach was quantitative and quasi-experimental with nonrandomized control group design was applied in the study. Samples of the study were outdoor patients attending cardiac OPD, who met the inclusion criteria and agreed to participate in the study. In this study, 90 patients of ACS (45 in each, experimental and control group) within 48 h of diagnosis are included. The intervention, EMSSP was given for 2 months. Tools used for data collection were Modified Morisky, Green and Levine Medication Adherence Scale (MAS), pill count, and serum lipid profile. Collected data were analyzed by descriptive (frequency distribution and percentage) and inferential statistics using the SPSS vesion16. **Results:** There was significant change in mean and Standard deviation (SD) score of Modified Morisky, Green and Levine Medication Adherence Scale (MAS) and pill count in experimental group than in control group with P = 0.00001. Similarly, there was a significant decrease in mean SD of total cholesterol and low-density lipoprotein level (P < 0.05) in the experimental group than the control group at 2 months of EMSSP. **Conclusion:** Reminding and supporting patients in taking the medication seems the most promising intervention in treating un-intentional non-adherence of medication.

Key words: Acute coronary syndrome, adherence of lipid-lowering therapy, electronic messaging support service program

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Background of the Study

Coronary artery disease (CAD) is a clinical condition characterized by atherosclerosis in the coronary arteries. Atherosclerotic plaques are the hallmark of atherosclerosis; it progressively narrows the coronary artery lumen and further impair sante grade myocardial blood flow. The decreased blood flow in coronary artery can be symptomatic or asymptomatic, occur maybe with exertion or at rest, and leads to myocardial infarction, depending on obstruction severity of the disease develops.^[1]

Acute coronary syndrome (ACS) is an umbrella term that is used to describe many of the complications

associated with CAD. These include unstable angina (USA), non-ST-elevation myocardial infarction (NSTEMI), and ST-elevation myocardial infarction (STEMI).^[2]

In a study of Rajeev Gupta et.al dyslipidaemias, smoking, diabetes, hypertension, abdominal obesity, psychosocial stress, unhealthy diet, physical inactivity are some recurrent cardiovascular events. The essential medication therapies used are: lipid-lowering agent, antihypertensive, and antiplatelet agentsand non-medication therapy includes healthy life style that consist of regular physical activities, balanced diet, avoiding smoking, alcoholism and consumption of junk food.

Lipid-lowering therapy is necessary to decrease LDL cholesterol to a target level of less than 100 mg/dL, and physicians should consider a goal of less than 70 mg/dL for very high-risk patients. Statins are very much beneficial in reducing morbidity and mortality as the secondary prevention of coronary artery disease. [3]

European Society of Cardiology Guidelines for the management of ACSs recommended to initiate high-intensity statin therapy (i.e., statin regimens reduces LDL cholesterol by 50%) as early as possible after admission of patient of non-ST-segment elevation-ACS patients (in the absence of contraindications).^[4]

Dyslipidemia is a major cause of CV diseases and strokes, and it is responsible for one-third of mortality worldwide. [5] It has been reported that 10% increase in serum cholesterol could cause a 20–30% escalated risk of coronary heart diseases. [6]

The effectiveness of statin therapies in reducing lipid levels and prevention of CV events has been widely recognized, as it can safely decrease the 5-year incidence of CV events and absolute CV risks irrespective of the initial lipid profile. Use of statins could also decrease overall mortality.^[7]

Babu stated that the common intentional non-adherence factor is dose omission. Maximum patients forget to take the prescribed medications, due to busy schedule, poor memory, fear to take too many drugs, and confusion in dosing schedule.^[8]

Managing dyslipidemia is a serious challenge to ensure optimal medication adherence in clinical practice, and the scope of the problem could not easily be identified. It has been suggested that reminding and supporting patients in taking the medication seem the most promising intervention, while it is equally important to adopt a patient-centered and shared decision-making approach.^[9]

Need of the study

In the light of above facts and personal experience of the investigator, it has been observed that the patient does not show much concern about their health condition until and unless it leads to a major problem. There are various

reasons for non-adherence of medication. Hence, to make the patient conscious about medication adherence and its benefit there is need to conduct this research study.

Problem statement

A study to assesses the effectiveness of electronic messaging support service program (EMSSP) on adherence of lipid-lowering therapy among patients of ACS at Cardiac Outpatient Department (OPD), KGMU, Lucknow.

Objectives of the study

The objectives are as follows:

- 1. To assess the baseline adherence of lipid-lowering therapy among patients of ACS
- 2. To assess the effectiveness of EMSSP on adherence of lipid-lowering therapy.

Operational definitions

EMSSP on lipid-lowering therapy

In this study, an electronic program used to send short messages about lipid-lowering therapy. Lipid-lowering therapy includes lifestyle modification (smoking/alcoholism abstains, diet modification, exercise and controlling weight, and avoiding stress), disease awareness, and medication adherence (Tab. atorvastatin).

Adherence of lipid-lowering therapy

Adherence of tab. atorvastatin means subjects is taking one tablet daily after dinner. Adherence will be measured using tool modified standardized structured questionnaire: Modified Morisky, Green and Levine Medication Adherence Scale (MAS) in which 8 questions has been prepared and pill count.

Adherence to lifestyle modification will be measured by serum lipid profile. It is biochemical test of fasting blood that includes total cholesterol, LDL cholesterol, triglycerides, and high-density lipoprotein (HDL) cholesterol.

Patients of ACS

Patients newly diagnosed with ACS and admitted in cardiac ICU at the time of enrolment of subjects. It includes patients of STEMI, NSTEMI, and USA.

Hypothesis

 $\rm H_1$ – There will be a significant difference of medication adherence in post-test of the experimental group as compared to the control group, as measured by MAS and pill count at significant level of P < 0.05.

Materials and Methods

Research approach

The quantitative approach was selected for the present study.

Research design

This was a quasi-experimental, and nonrandomized control group design. Table 1 shows that pre-test was done before given any intervention. After providing intervention to experimental group and usual care to control group post-testing was done.

Variables

Independent variable

EMSSP regarding lipid-lowering therapy.

Dependent variable

Adherence of lipid-lowering drug and serum lipid profile level.

Demographic variables

Age, gender, education, occupation, income, diet, lifestyle (smoking/alcoholism status), duration of smoking/

alcoholism, current exercise behavior, and oil were used in cooking.

Clinical variables

Diagnosis.

Setting

LARI Cardiac OPD, KGMU is an autonomous tertiary care hospital located in Lucknow, Uttar Pradesh and one of the largest Government funded research centers with the main hospital that receives 7000–8000s of patients from all over Uttar Pradesh on daily basis.

KGMU has a specialized division, the LARI Cardiac OPD, which provides specialized care to patients with CV problems. The cardiology department of KGMU has both medical and surgical wards (cardiology and cardiothoracic

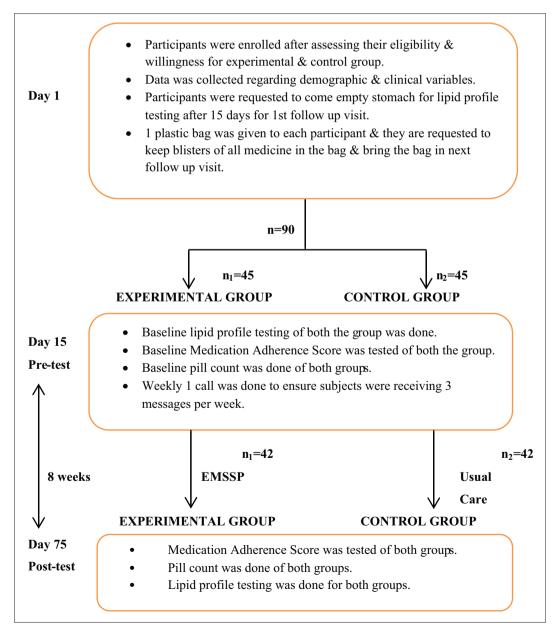


Figure 1: Data collection procedure

Table 1: Diagrammatic representation of research design

Nonrandomized control group	At baseline visit	Intervention	At 2 months follow up
Experiment group	01	EMSSP	O2
Control group	O1	Usual Care	O2

O1: Observation at baseline visit, O2: Observation at 2 months follow-up, EMSSP: Electronic messaging support service program, EMSSP along with telephonic call to reinforce lipid-lowering therapy in experimental group

vascular surgery) fully equipped with ancillary facilities required for cardiac patients. The LARI also has OPDs which runs on a daily basis from Monday to Saturday.

Population

The accessible population of this study was outdoor patients who have been diagnosed with ACS and getting lipid-lowering drug (Atorvastatin) attending Cardiac OPD, KGMU, Lucknow, during the period of data collection.

Variables	Total (n=90)	Experiment $(n_1=45)$	Control (n ₂ =45)	<i>P</i> -value
	f (%)	f (%)	f (%)	
Age (in years)				
31–40	8 (8.89)	3 (6.67)	5 (11.11)	0.15^{a}
41–50	23 (25.56)	14 (31.11)	9 (20.00)	
51–60	27 (30.00)	13 (28.89)	14 (31.11)	
61–70	24 (26.67)	14 (31.11)	10 (22.22)	
71–80	8 (8.89)	1 (2.22)	7 (15.56)	
Gender				
Male	68 (75.56)	34 (73.91)	34 (73.91)	0.1^{a}
Female	22 (24.44)	11 (26.09)	11 (26.09)	
Education				
High school	26 (28.88)	12 (26.67)	14 (31.11)	0.1^{a}
Intermediate	15 (16.66)	6 (13.33)	9 (20)	
Graduation	30 (33.33)	16 (35.56)	14 (31.11)	
Postgraduation	19 (21.11)	11 (24.44)	8 (17.77)	
Occupation				
Government employee	8 (8.89)	7 (15.56)	1 (2.22)	0.75^{b}
Home maker	17 (18.89)	8 (17.78)	9 (20.00)	
Private employee	47 (52.22)	20 (44.44)	27 (60.00)	
Retired	15 (16.67)	10 (22.22)	5 (11.11)	
Unemployed	3 (3.33)	0 (0)	3 (6.67)	
Monthly income				
<rs. 5000<="" td=""><td>18 (20.0)</td><td>8 (17.78)</td><td>10 (22.22)</td><td>1ª</td></rs.>	18 (20.0)	8 (17.78)	10 (22.22)	1ª
Rs. 5001–Rs. 10,000	20 (22.22)	7 (15.56)	13 (28.88)	
Rs. 10,001–Rs. 20,000	22 (24.44)	10 (22.22)	12 (26.66)	
>Rs. 20,000	30 (33.33)	20 (44.44)	10 (22.22)	
Dietary pattern				
Non-vegetarian	50 (55.56)	25 (55.56)	25 (55.56)	1ª
Vegetarian	40 (44.44)	20 (44.44)	20 (44.44)	
Smoking/tobacco/alcoholism status				
None	43 (47.78)	23 (51.11)	20 (44.44)	1 ^b
Smoking	17 (18.89)	7 (15.56)	10 (22.44)	
Smoking+alcohol	3 (3.33)	3 (6.67)	0 (0)	
Smoking+tobacco	8 (8.89)	1 (2.22)	7 (15.56)	
Tobacco	18 (20.00)	11 (24.44)	7 (15.56)	
Alcohol	1 (1.11)	0 (0)	1 (2.22)	

(Contd...)

Table 2a: (Continued)

Variables	Total (n=90)	Experiment (n ₁ =45)	Control (n ₂ =45)	<i>P</i> -value
	f (%)	f (%)	f (%)	
Duration of Smoking/tobacco/alcoholism (in years)				
0–10	14 (15.56)	4 (8.89)	10 (22.22)	0.87^{b}
11–20	15 (16.67)	9 (20.00)	6 (13.33)	
21–30	10 (11.11)	6 (13.33)	4 (8.89)	
31–40	6 (6.67)	2 (4.44)	4 (8.89)	
41–50	2 (2.22)	1 (2.22)	1 (2.22)	
0	43 (47.78)	23 (51.11)	20 (44.44)	
Exercise				
Yes	62 (68.89)	30 (66.67)	32 (71.11)	1ª
No	28 (31.11)	15 (33.33)	13 (28.89)	
Type of oil used				
Butter	1 (1.11)	1 (2.22)	0 (0)	0.83^{b}
Mustard	59 (65.55)	26 (57.78)	33 (73.33)	
Refined	30 (33.33)	18 (40.00)	12 (26.67)	

^aChi-square test, ^bKruskal-Wallis test, *P<0.05

Table 2b: Clinical characteristics of subjects. *n*=90

Variables	Total (n=90)	Experiment $(n_1=45)$	Control (<i>n</i> ₂ =45)	<i>P</i> -value ^b
	f (%)	f (%)	f (%)	
Diagnosis				
NSTEMI	23 (25.56)	11 (24.44)	12 (26.67)	0.551
NSTEMI+HTN	4 (4.44)	2 (4.44)	2 (4.44)	
NSTEMI+DM	2 (2.22)	1 (2.22)	1 (2.22)	
NSTEMI+DM+HTN	3 (3.33)	3 (6.67)	0 (0)	
STEMI	21 (23.33)	6 (13.33)	15 (33.33)	
STEMI+HTN	7 (7.78)	4 (8.89)	3 (6.67)	
STEMI+DM	2 (2.22)	1 (2.22)	1 (2.22)	
STEMI+HTN+DM	2 (2.22)	1 (2.22)	1 (2.22)	
USA	17 (18.89)	11 (24.44)	6 (13.13)	
USA+HTN	4 (4.44)	2 (4.44)	2 (4.44)	
USA+DM	3 (3.33)	2 (4.44)	1 (2.22)	
USA+HTN+DM	2 (2.22)	1 (2.22)	1 (2.22)	

^bKruskal-Wallis test, *P<0.05. NSTEMI: Non-ST-elevation myocardial infarction. STEMI: ST-elevation myocardial infarction, USA: Unstable angina, DM: Diabetes mellitus

Sample

The samples of the study were outdoor patients of cardiac OPD who have been diagnosed with ACS and getting lipid-lowering drug (Atorvastatin), meeting the designated set criteria and agreed to participate in the study.

Sampling technique

Non-probability and purposive sampling technique were used to select the subjects.

Sample size

Patients of ACS were assessed for eligibility, and the consenting patients were included in the sample. A target of total 90 subjects was decided based on statistical analysis of a similar study at estimated proportion (P) = 0.58, desired

precision of estimate(e) was 10%, at confidence interval (CI) 0.95 with Z = 1.96. Out of 90 subjects, 45 subjects were in each group, six subjects did not complete the study because three subjects were died and three subjects started taking treatment from other hospital so, 42 subjects in each group had completed the study.

$$n = \frac{Z^2 P(1-P)}{e^2}$$

Sample selection criteria

Inclusion criteria

The following criteria were included in the study:

Patients of ACS who are on lipid lowering therapy

Table 3a: Question wise comparison of pre-test scores of modified Morisky, Green and Levine Medication Adherence Scale between experimental and control group. *n*=90

S. No.	Questions	Response	Exp $(n_1 = 45)$	Control (<i>n</i> ₂ =45)	<i>P</i> -value ^a
			f (%)	f (%)	
1.	Do you ever forget to take your medicine?	YES	3 (6.67)	3 (6.67)	1
		NO	42 (93.33)	42 (93.33)	
2.	Are you careless at times about taking your	YES	19 (42.22)	18 (40.00)	1
	medicine?	NO	26 (57.78)	27 (60.00)	
3.	Do you mostly fail to take your medicine daily at the	YES	31 (68.89)	25 (55.56)	0.1745
	same time?	NO	14 (31.11)	20 (44.44)	
4. Do you	Do you take two doses of medicine after missing a	YES	10 (22.22)	7 (15.56)	1
	dose?	NO	35 (77.78)	38 (84.44)	
5.	Do you sometimes stop taking your medicine when	YES	6 (13.33)	2 (4.44)	0.43
	you feel better?	r? NO	39 (86.67)	43 (95.56)	
6.	Do medications make you feel tired and sluggish?	YES	25 (55.56)	27 (60.00)	0.83
		NO	20 (44.44)	18 (40.00)	
7.	Sometimes if you feel worse when you take the	YES	7 (15.56)	.56) 7 (15.56)	0.57
	medicine, do you stop taking it?	NO	38 (84.44)	38 (84.44)	
8.	When you travel or leave home, do you sometimes	YES	15 (33.33)	12 (26.67)	0.47
	forget to carry your medicine?	NO	30 (66.67)	33 (73.33)	_

^aFischer exact test, *P<0.05

Table 3b: Comparison of the level of adherence of pre-test score of modified Morisky, Green and Levine Medication Adherence Scale between experimental and control group. n=90

Level of adherence	Adherence score	Experimental (n ₁ =45)	Control (<i>n</i> ₂ =45)
		f (%)	f (%)
High adherence	<4	36 (80)	41 (91.11)
Medium adherence	4–6	9 (20)	4 (8.89)
Low adherence	7–8	0 (0)	0 (0)

Table 3c: Comparison of pre-test score mean and SD of modified Morisky, Green and Levine Medication Adherence Scale between experimental and control group. n=90

Group	Experimental group	Control group
Mean±SD	2.6±1.38	2.27±1.02
Unpaired t-test value	1.44	
<i>P</i> -value	0.152	

P<0.05. SD: Standard deviation

(Atorvastatin 80 mg)

- Those who are willing to participate in the study
- Patient who are recently diagnosed with ACS (within 48 h of diagnosis)
- Patient with hypertension and diabetes mellitus (DM) along with ACS.

Table 4a: Comparison of pre-test score of pill count percentage between the experimental and control group. n=90

Adherence	Pill count percentage	Experimental (n ₁ =45)	Control (n ₂ =45)
		f (%)	f (%)
Poor adherence	<85	15 (33.33)	14 (31.11)
Good adherence	85–100	30 (66.67)	31 (68.89)

Table 4b: Comparison of pre-test score of mean and SD of pill count percentage between Experimental and control group. n=90

Group	Experimental group	Control group
Mean±SD	86.34±56.7	86.98±51.44
Unpaired <i>t</i> -test value	-0.4	1
P-value	0.68	5

P<0.05. SD: Standard deviation

Exclusion criteria

The following criteria were excluded from the study:

- Those who are not willing to participate
- Patient of ACS who is not on lipid-lowering therapy
- Patient of ACS who is critically ill
- Patient more than 80 years of age
- Patient of an old case of ACS (more than 48 h of diagnosis)
- Patient who cannot use mobile
- Patient who is illiterate.

Table 5a: Question wise comparison of post-test scores of Modified Morisky, Green and Levine Medication Adherence Scale between experimental and control group. *n*=84

S. No.	Questions	Response	Exp $(n_1 = 42)$	Control (n ₂ =42)	P-value ^a
			f (%)	f (%)	
1.	Do you ever forget to take your medicine?	YES	4 (9.5)	25 (59.5)	0.0001*
		NO	38 (90.5)	17 (40.5)	0.10
2.	Are you careless at times about taking your	YES	17 (40.5)	24 (57.1)	0.19
	medicine?	NO	25 (52.5)	18 (42.9)	
3.	Do you mostly fail to take your medicine daily at the	YES	30 (71.4)	22 (52.4)	0.12
	same time?	NO	12 (28.6)	20 (47.6)	
4.	Do you take two doses of medicine after missing a	YES	3 (7.1)	10 (23.8)	0.067
	dose?	NO	39 (92.9)	32 (76.2)	0.19 0.12
5.	Do you sometimes stop taking your medicine when	YES	3 (7.1)	19 (45.2)	0.0001*
	you feel better?	NO	39 (92.9)	23 (54.8)	
6.	Do medications make you feel tired and sluggish?	YES	23 (54.76)	27 (64.3)	0.23
		NO	19 (45.24)	15 (35.7)	
7.	Sometimes if you feel worse when you take the	YES	5 (11.9)	25 (59.5)	0.0001*
	medicine, do you stop taking it?	NO	37 (88.1)	17 (40.5)	
8.	When you travel or leave home, do you sometimes	YES	2 (4.76)	36 (85.7)	0.0001*
	forget to carry your medicine?	NO	40 (95.24)	6 (14.3)	

^aFischer exact test, *P<0.05

Table 5b: Comparison of the level of adherence of post-test score of modified Morisky, Green and Levine Medication Adherence Scale between experimental and control group. *n*=84

tentrol group. It o						
Level of adherence	Adherence score	Experimental (n ₁ =42)	Control (<i>n</i> ₂ =42)			
		f (%)	f (%)			
High adherence	<4	41 (97.61)	20 (47.61)			
Medium adherence	4–6	1 (2.38)	21 (50)			
Low adherence	7–8	0 (0)	1 (2.38)			

Table 5c: Comparison of post-test mean and SD of modified Morisky, Green and Levine Medication Adherence Scale between the experimental and control group. *n*=84

Group	Experimental	Control		
	group	group		
Mean±SD	2.57±1.27	3.93 ± 1.87		
Unpaired t-test value	-5.04			
P-value	0.0000	1		

^{*}P<0.05. SD: Standard deviation

Tools used for data collection

- 1. Structured demographic and clinical profile data.
- 2. Modified Morisky, Green and Levine Medication Adherence Scale (MAS):

Morisky, Green and Levine MAS was developed by Donald E. Morisky, Lawrence W. Green, David M. Levine. This scale includes four items. Items in the scale

address barriers of medication adherence and permits health-care providers to reinforce positive adherence behavior. Reliability of the tool was calculated by Cronbach alpha = 0.61. The researcher has included four more items in the original scale. Now there are eight items in this scale to assess the adherence of lipid-lowering drug. Items are related to forgetfulness and carefulness to take medicine, feeling worse or better after taking medicine. Cronbach alpha for Modified Morisky, Green and Levine Medication Adherence Scale (MAS) is 0.89. The reliability of the tool was computed using test-retest technique after administering it on 18 patients.

Interpretation

Adherence level	Scores
High adherence	<4
Medium adherence	4-6
Low adherence	>6

Development of tool

Tool modification was done by the researcher under the supervision of guide and coguide.

Permission for tool modification

Permission to modify the tool was obtained.

3. Pill counts of lipid-lowering drug: Pill counts are often used to measure medication adherence. A plastic bag was given to all participants and they were instructed to keep blisters of all drug in that plastic bag. Participants were instructed to bring plastic bag at each follow-up visit so that pill count can be done.

Table 6a: Comparison of post-test pill count percentage between the experimental and control group. *n*=84

	1	<i>U</i> 1		
Adherence	Pill count percentage	Experimental (n ₁ =42)	Control (n ₂ =42)	
		f (%)	f (%)	
Poor adherence	<85	7 (16.67)	25 (59.52)	
Good adherence	85–100	35 (83.33)	17 (40.47)	

Table 6b: Comparison of post-test mean and SD of pill count percentage between experimental and control group groups. *n*=84

Group	Experimental group	Control group	
Mean±SD	87.94±28.25	82.55±28.25	
Unpaired t-test value	4.65		
P-value	0.000013*		

^{*}P<0.05. SD: Standard deviation

Pill counts would be done using standard formula¹⁰:

No. of dosage units dispensed -Pill count = $\frac{\text{No. of dosage units remained}}{\text{Prescribed No. of dosage unit per day} \times \text{No. of days between two visits}$

Interpretation of pill count

Adherence	Percentage		
Good adherence	85 and above		
Poor adherence	84 and below		

Serum Lipid Profile level:
 National Cholesterol Education Program (NCEP)
 Guidelines for interpretation of lipid values (Adult Treatment Panel III 2001; updated 2004).[11]

EMSSP regarding lipid-lowering therapy

The experimental group received the EMSSP and control group received the usual care.

EMSSP includes messages regarding lipid-lowering therapy. Mobile-based Way2 short-message service (SMS), application was used to deliver SMS to the participants. The application was freely available. Lipid-lowering therapy consists of messages related to lifestyle modification, information about ACS and drug reminder (Atorvas).

Development of intervention

EMSSP was developed by the researcher under the guidance of guide and coguide. Message layout was prepared to maintain the consistency of the EMSSP.

Content validity of the tool

To ensure validity, the tool along with the blueprint, objectives, and criteria checklists was given to 12 experts. The experts were chosen from among the best in their clinical expertise. The experts were requested to give their opinion and verify the items for relevance, organization, and measurability. Modifications were done according to expert suggestions.

Reliability of tool

To ensure the reliability of the instrument, pilot study was done and it was administered on 18 outdoor patients of ACS (nine from the experimental group and nine from the control group). The reliability of the tool was computed using test-retest technique. The reliability coefficient was 0.89 (for MAS). This indicates that the tool which was used in the study was reliable.

Ethical considerations

Institutional ethical approval obtained from the Ethics Committee of King George's Medical University. After that permission was taken from the concerned department. Informed consent was taken from the subjects.

Data collection procedure

On day 1 the patients who are admitted in cardiac ICU are enrolled in experimental and control group on the basis of their eligibility and willingness. Information regarding demographic and clinical variable are gathered. Subjects were instructed to come for 1st follow up visit after 15 days of discharge from hospital and they have to come empty stomach for lipid profile testing. They were also given 1 plastic bag to keep blister of all medicines and bring the bag in next visit.

On day 15th, this was 1st follow up visit on which pre-test was done. Baseline lipid profile testing done. Baseline medication adherence was checked by using MAS Scale and pill count method. From now intervention was started for experimental group (text messages regarding diet, life style modification and medication reminders). Both experimental and control group were called after 8 weeks for next follow up visit Figure 1.

On day 75th, subjects were called for post-test. medication adherence score and pill count was checked for both the group. Lipid profile testing was also done for both the groups. In post-test on 84 subjects came for follow up visit i.e., 42 in each group. Out of 6 subjects 3 was died and 3 started taking treatment from other hospital.

Plan for data analysis

Collected data were analyzed by descriptive (frequency distribution and percentage) and inferential statistics using the SPSS vesion16.

Results

• Section I: Demographic characteristic and clinical profile of the subjects

Table 7a: Comparison of pre-test and post-test score of lipid profile within the experimental group. n=42

Variable	Pre-test	Post-test	Change from pre to post test	Paired t-test	<i>P</i> -value	% change
	Mean±SD	Mean±SD	Mean±SD			
Total cholesterol	152.37±45.67	126.66±31.89	-25.71±38.46	4.33	0.001*	16.9
LDL	93.59 ± 48.38	73.69±30.40	-19.31 ± 35.23	3.55	0.001*	20.63
Triglyceride	145.55 ± 62.06	113.49±38.89	-32.05 ± 44.21	4.69	0.001*	22.01
HDL	40.56±11.45	44.84±2.27	+4.28±11.18	2.48	0.017*	6 0.15

^{*}P<0.05. LDL: Low-density lipoprotein, HDL: High-density lipoprotein

Table 7b: Comparison of pre-test and post-test score of lipid profile within control group. n=42

Variable	Pre-test	Post-test	Change from pre- to post-test	Paired t-test	<i>P</i> -value	% change
	Mean±SD	mean±SD	mean±SD			
Total cholesterol	136.95±36.16	129.55±30.22	-7.34±29.34	1.62	0.11	5.4
LDL	78.47 ± 44.43	73.52±33.06	-4.95 ± 30.70	1.04	0.30	6.3
Triglyceride	155.29±151.73	137.83±120.51	-17.46 ± 51.34	2.20	0.033*	11.24
HDL	40.62 ± 10.85	43.52±9.50	+2.90±9.20	2.04	0.04*	7.1

^{*}P<0.05. LDL: Low-density lipoprotein, HDL: High-density lipoprotein

Table 7c: Comparison of change from pre-test to post-test of lipid profile between experimental and control groups. *n*=84

Variables	Experimental	Control	<i>P</i> -value ^a
	Mean±SD	Mean±SD	
Total cholesterol	-25.71±38.46	-7.34±29.34	0.016*
LDL	-19.31 ± 35.32	-4.95 ± 30.70	0.049*
Triglyceride	-32.05 ± 44.21	-17.46 ± 51.34	0.16
HDL	+4.28±11.18	+2.90±9.20	0.53

^aUnpaired *t*-test, *P<0.05. LDL: Low-density lipoprotein,

HDL: High-density lipoprotein

 Section II: Analysis for the effectiveness of EMSSP on adherence of lipid-lowering therapy among patients of ACS – As per protocol.

Section I: Demographic characteristics and clinical profile of subjects

This section describes the demographic characteristics and clinical profile of subjects in the experimental and control group.

On comparison, there was no statistically significant difference between experimental and control group with regard to the demographic variables (gender, educational qualification, monthly income, occupation, dietary pattern, smoking/tobacco/alcoholism status, duration of smoking/tobacco/alcoholism, exercise, and type of cooking oil used). It is concluded that both groups were comparable in terms of demographic variables [Table 2a].

On comparison, there was no statistically significant difference between experimental and control group with regard to the clinical profile (NSTEMI, STEMI, USA with comorbidities of hypertension, and DM), *P*-value was not

significant (P = 0.551). It is concluded that both groups were comparable in terms of clinical profile [Table 2b].

Section II: Analysis for effectiveness of EMSSP on adherence of lipid-lowering therapy among patients of ACS – As per protocol

Objective 1

To assess the baseline adherence of lipid lowering therapy among patients of Acute Coronary Syndrome.

Table 3a shows the comparison of Pre-test scores of Modified Morisky, Green and Levine Medication Adherence Scale (MAS) between the experimental and control group. On comparison, *P*-value was not significant in any of the eight questions in MAS.

Table 3b shows the comparison of the level of adherence of pre-test score of Modified Morisky, Green and Levine Medication Adherence Scale (MAS) in experimental group and control group. In experimental group, 80% subjects were highly adherent and 20% subjects were medium adherent to medication. In control group, 91% were highly adherent and 9% were medium adherent to medication.

Table 3c shows the comparison of pre-test score mean and standard deviation (SD) of Modified Morisky, Green and Levine Medication Adherence Scale (MAS) in between experimental group and control group. On comparison, *P*-value was not significant.

Table 4a shows the comparison of pre-test score of pill count percentage in experimental group and control group. In experimental group, 33% subjects were poor adherent and 67% subjects were good adherent to medication. In control group, 31% subjects were poor adherent and 69% were good adherent to medication.

Table 4b shows comparison of pre-test score of mean and SD of pill count percentage in the experimental group and control group. On comparison, *P*-value was not significant.

It is concluded that the experimental and control groups were comparable in terms of the pre-test scores of Modified Morisky, Green and Levine Medication Adherence Scale (MAS) and pill count percentage.

Objective 2

The objective of the study was to assess the effectiveness of EMSSP on adherence of lipid-lowering therapy.

Table 5a shows Question wise comparison of post-test scores of Modified Morisky, Green and Levine Medication Adherence Scale between experimental and control group.

In question no.1 "Do you ever forget to take your medicine?" 'Yes' response was significantly increased in control group Post test score 25(59.5%) than experimental Post test score 4(9.5%) and 'No' response was significantly decreased in control group Post score 17(40.5%) than experimental group Post test score 38(90.5%) with a p value of 0.0001. Therefore it can be concluded that frequency of "forgetting to take medicine" was less in experimental group after 2 months of intervention as compared to control group.

In question no.5 "Do you sometimes stop taking your medicine when you feel better?" 'Yes' response was significantly increased in control group Post test score 19(45.2%) than experimental Post test score 3(7.1%) and 'No' response was significantly decreased in control group Post score 23(54.8%) than experimental group Post test score 39(92.9%) with a p value of 0.0001. Therefore it can be concluded that frequency of "stop taking medicine when felt better" was less in experimental group after 2 months of intervention as compared to control group.

In question no.7 "Sometimes if you feel worse when you take the medicine, do you stop taking it?" 'Yes' response was significantly increased in control group Post test score 25(59.5%) than experimental Post test score 5(11.9%) and 'No' response was significantly decreased in control group Post score 17(40.5%) than experimental group Post test score 37(88.1%) with a p value of 0.0001. Therefore it can be concluded that frequency of "stop taking medicine after feeling worst" was less in experimental group after 2 months of intervention as compared to control group.

In question no.8 "When you travel or leave home, do you sometimes forget to carry your medicine?" 'Yes' response was significantly increased in control group Post test score 36(85.7%) than experimental Post test score 2(4.76%) and 'No' response was significantly decreased in control group Post score 6(14.3%) than experimental group Post test score 40(95.24%) with a p value of 0.0001. Therefore

it can be concluded that frequency of "forgetfulness related to carrying medication while traveling" was less in experimental group after 2 months of intervention as compared to control group. There was no significant difference in other questions.

Table 5b shows comparison of level of adherence of post-test score of Modified Morisky, Green and Levine Medication Adherence Scale(MAS) in between Experimental and Control Group. In the experimental group, maximum subjects 98% were highly adherent and 2% were medium adherent. In control group, maximum subjects 51% were medium adherent and 48% were highly adherent to the medication

Table 5c shows comparison of post-test mean and standard deviation of Modified Morisky, Green and Levine Medication Adherence Scale (MAS) in between Experimental and Control Group. On comparison, the significant mean difference was found with P = 0.00001.

Table 6a shows comparison of post-test pill count percentage in between Experimental and Control Group. In the experimental group, most of the subjects 83% were good adherent and 17% were poor adherent to the medication. In control group, most of the subjects 60% were poor adherent and 40% were good adherent to the medication.

Table 6b shows comparison of post-test mean and standard deviation of pill count percentage in between Experimental and Control Group. On comparison, the significant mean difference was found with P = 0.000013.

With regard to the above findings, research hypothesis was accepted. It is concluded that after electronic messaging support service system implementation there was significant difference in medication adherence between experimental and control group.

Table 7 shows the comparison of change from pre-test to post-test of lipid profile between the experimental and control group.

Post-test of experimental and control group showed that total cholesterol level was more decreased in the experimental group -25.71 ± 38.46 than in control group -7.34 ± 29.34 with P=0.016.

Post-test of experimental and control group showed that LDL level was significantly decreased more in experimental group -19.31 ± 35.32 than in the control group -4.95 ± 30.70 with P = 0.049.

Post-test of experimental and control group showed that there was no significant difference in triglyceride level between experimental group and control group, but more decrease in experimental group -32.05 ± 44.21 than control group -17.46 ± 51.34 from baseline triglyceride level.

Post-test of experimental and control group showed that there was no significant difference in HDL level between experimental group and control group, but more increase in experimental group +4.28±11.18 than control group +2.90±9.20 from baseline HDL level.

Discussion

Effectiveness of EMSSP on adherence of lipid-lowering therapy

In the present study, in the experimental group, maximum subjects 98% were highly adherent and 2% were medium adherent. In control group, maximum subjects 51% were medium adherent and 48% were highly adherent to the medication. On comparison significant mean difference was found with P = 0.00001.

The present study is congruent with the study of Khonsari *et al.* (2014),^[12] an interventional study was conducted at a tertiary teaching hospital in Malaysia. A total of 62 patients with ACS were equally randomized to receive either automated SMS reminders before every intake of cardiac medications or only usual care within 8 weeks after discharge. There was a higher medication adherence level in the intervention group rather than the usual care group, (χ^2 (2)= 18.614, P < 0.001). The risk of being low adherent among the control group was 4.09 times greater than the intervention group (relative risk =4.09, 95% CI 1.82–9.18).

Effectiveness of EMSSP on pill count

In the present study, most of the subjects 83% were good adherent and 17% were poor adherent to the medication in the experimental group and control group showed that most of the subjects 60% were poor adherent and 40% were good adherent to the medication. On comparison, significant mean difference was found with P = 0.000013.

The present study is supported by Ershad Sarabi *et al.* (2016) [13] systematic literature search, using the five electronic bibliographic databases: PubMed, Embase, PsycINFO, CINAHL, and the Cochrane central register of controlled trials. Studies were included on the basis of whether they examined the benefits and effects of SMS interventions on medication adherence. The result of the study indicated that text messaging interventions have improved patients' medication adherence rate (85%, 29.34).

Effectiveness of EMSSP on lipid profile

In this study, total cholesterol level, LDL level, triglyceride level, and HDL level were significantly decreased in posttest score within experimental group (P = 0.001).

The post-test of the experimental and control group showed that total cholesterol level (P = 0.016) and LDL level (P = 0.049) were more significantly decreased in the experimental group than in control group. Post-test of the experimental

and control group showed that there was no significant difference in triglyceride level between experimental group and control group, but more decrease in experimental group -32.05 ± 44.21 than control group -17.46 ± 51.34 from baseline triglyceride level. Post-test of experimental and control group showed that there was no significant difference in HDL level between experimental group and control group, but more decrease in experimental group $+4.28\pm11.18$ than control group $+2.90\pm9.20$ from baseline HDL level.

The present study findings are in line with Bosworth et al. (2017)[14] a study to evaluate a simple, scalable, and affordable medication packaging method for improving cholesterol medication adherence and subsequently lowering LDL-C levels. This mixed-method study involved US military veterans with LDL-C levels >130 mg/dL and/or <80% refill adherence of cholesterol-lowering medication in the past 12 months; they were randomized to an education-only (control) group or an adherence packaging intervention group. Adherence packaging group participants' statin medication was provided in special blister packaging labeled for daily use that included written reminder prompts. Two hundred forty individuals (120 interventions, and 120 controls) were enrolled. Overall, 54.2% of the adherence packaging intervention group was adherent per medication possession ratio (MPR) over 12 months compared with 46.6% of the educationonly group (difference = 7.6%; 95% CI, -5-20%; $P \le$ 0.24). Both arms reported improvements in self-reported cholesterol adherence at 12 months and decreases in LDL-C, HDL-C, and total cholesterol were observed, but differences in change between arms were not statistically significant. Qualitatively, patients reported high levels of satisfaction with the blister package.

Conclusion

The electronic messaging support system program was effective in improving medication adherence and pill count as well as it was reminding the subjects to take their medication on time regularly and motivating them for lifestyle modification.

The study has shown a significant reduction in total cholesterol and LDL level in experimental group but other parameters of lipid profile, i.e., triglycerides and HDL were not showing significant changes between experimental and control group.

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