

## Clinical outcomes and cost effectiveness of two aftercare models provided by general physicians and nurses to patients with severe mental illness

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### Abstract

**Background:** Implementing community-based psychiatric services is one of the priorities of the WHO/EMRO mental health programs. This study presents an aftercare service, as a community based-service, for patients with severe mental illness (SMIs).

**Methods:** In this randomized controlled clinical trial design, 176 patients, who attended selective hospitals with SMI, were allocated into three groups: clinical case managers provided by general practitioners, nurses and the control group (usual treatment). The clients and their caregivers received monthly home visits (education and treatment supervision). The effectiveness of the intervention was measured by indicators of psychopathology such as scores of YOUNG, caregivers' knowledge and satisfaction with the services. Health-related quality of life (SF-36) was considered as the primary outcome variable. Data were collected at baseline and at 12 months follow-up. Direct and indirect medical costs were obtained through a periodic completion of questionnaires and interviews by caregivers. Cost effectiveness ratio was estimated as cost per QALY gained in each group. SPSS 16.0 was used in this survey and statistical methods were chi-square, ANOVA, Scheffé as post-Hoc test and paired sample t-test with 95% confidence interval and 0.05 significance level.

**Results:** The results of our study revealed that the score of YOUNG, caregivers' knowledge and satisfaction with service were improved in both intervention groups after 12 months. Improvement in health-related quality of life was observed in the general practitioner and nurse group. The incremental cost effectiveness ratio was 5740807 IRR and 5048459 IRR per QALYs gained in the general practitioner and nurse groups, respectively.

**Conclusion:** The model of aftercare services provided by trained nurses is the most cost-effective and feasible model for Iran's socio-economic conditions with low resource allocations.

**Keywords:** Severe Mental Illness, Aftercare, Service, Mental Health, Community.

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### Introduction

The establishment and expansion of

community-based services in WHO/EMR countries sprung out of a different require-

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ment: shortage of acute psychiatric beds. However, shortage of community-based facilities (such as outreach services) is an important issue which is generally considered in developing countries such as Iran. (1-3). Assertive Community Treatments (ACT) have been introduced and proven effective in maintaining and improving patients' mental health and quality of life (4-11). However, implementing the ACT system requires certain substructures in the society and allocation of enough budgets in which the intensive services could be provided.

Although case management services are not promising (12-13), clinical case management services provided by different professionals such as trained nurses (14) psychologist and family members (15) or with minor differences "less intensive home-care service" in our social-economic setting (16) have revealed remarkable results with the main aim of reducing hospitalization rates. We need to evaluate different models of the clinical case managers, particularly their

cost-effectiveness, and eventually introduce the best practices with the least resource demands for outreach services to the policy makers.

The aim of this study was to compare the effectiveness and cost-effectiveness of home-visit clinical case-management services provided by trained nurses and general practitioners (GPs). The main focus of the study was set on rates of re-hospitalization and clinical outcomes in patients with severe mental illness.

## Methods

### Study Design and Sample

This study was registered in Iranian Registry of Clinical Trials under the reference number of IRCT138807251959N3. The study design was a double blind, multi center, randomized controlled trial. The study participants were selected from patients who attended selective hospitals according to the study criteria and were randomly allocated into three groups by block randomization method and using random numbers

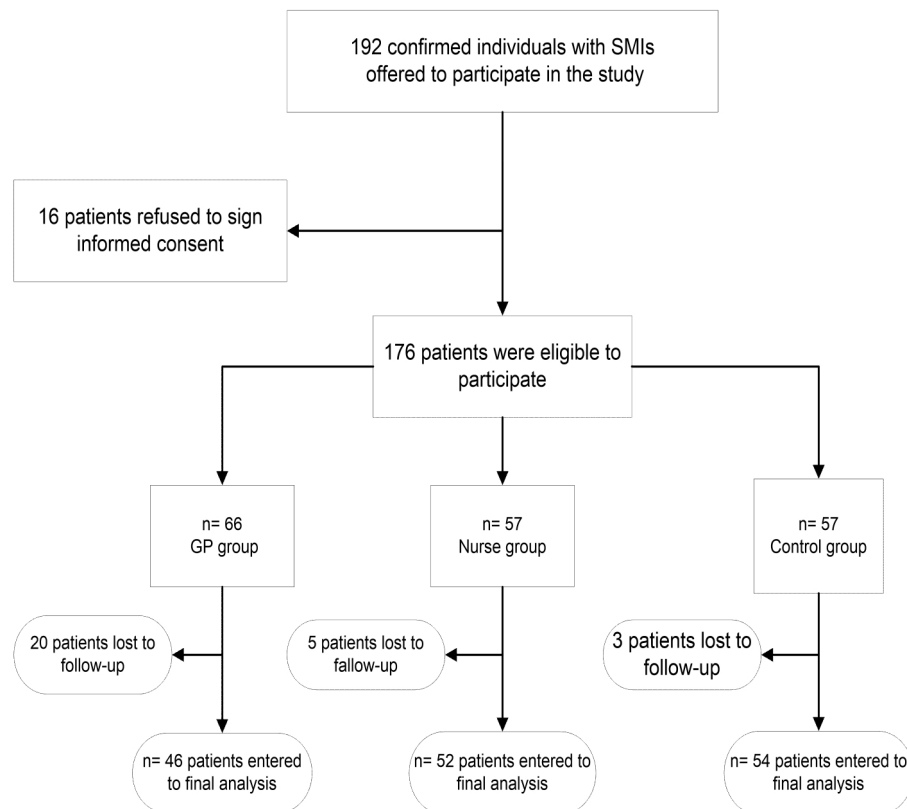


Fig.1. the selection and allocation of study subjects in three groups

table.

The inclusion criteria were as follows: having a diagnosis of bipolar or schizophrenia spectrum disorders (as severe mental illnesses), and being hospitalized at least twice in the past two years and not having good compliance according to the caregiver(s). The exclusion criteria included being in the acute phase of the illness, having mental retardation, suffering from organic brain problem, addiction to psychoactive substances and receiving the same services contemporarily from other sources. We measured baseline variables at the index point in the beginning of the enrollment in the study and after a 12-month follow-up period. The study participants were randomly allocated into three groups: GPs, nurses (trained clinical case managers) and control group (receiving the usual treatment available in the community). In total, 176 individuals were enrolled in the study (Fig. 1).

The study participants were recruited from four psychiatric centers, and the response rate was 85%. Sixty participants were from Tehran (from different psychiatric hospitals) and 92 were from the city of Karaj; of whom, 45% (n= 82) had bipolar mood disorder and 55% (n= 90) had spectrum diagnosis of schizophrenia. The patients were enrolled between December 2007 to March 2008 from outpatient clinics or immediately after discharge from the hospital.

#### *Selection and Training the Case-Managers*

Six registered nurses with a bachelor's degree were trained for 33 hours.

Five GPs for the other case-managers group were trained in multiple courses for 24 hours. A training manual was provided to trainees to familiarize them and update their knowledge about schizophrenia and mood disorders (15). After obtaining a written and oral evaluation, 3 trainees were selected from each group to provide clinical case-management (CM) services to the patients. Pre and post tests were performed to

evaluate the training outcomes on trainees. Wilcoxon Signed Ranks Test revealed that the mean of the score before the training was 42.7 (SD= 4.7) which was improved to 77.4 (3.9) (p= 0.06) after training in the nurse group. The scores before and after the training were 60.6 (14.2) and 73.6 (5.3), respectively (p= 0.04) in the GPs group. The selected CMs received supervision sessions regularly by the main investigator every two weeks for the first 3 months and then once every month till the end of the survey. The technical and implementing problems were discussed in each session.

#### *Defining Groups and Intervention* *Home Visit Groups*

Each patient in the home visit group had a face-to-face session every month by his/her assigned case manager. The duration of each session was 45 minutes on average. The case manager tasks were as follows: 1) To complete the checklists for symptoms and drug side effects and share the list with the patient's psychiatrist if necessary; 2) Educating the patients and their family members by providing hand outs and educational material; 3) Being in touch with the patients or their family in case of an emergency situation; 4) Contact the patient's psychiatrist or study supervisors in case of necessary or emergency conditions; 5) Injection of the depot antipsychotic if prescribed.

Some patients were prescribed psychotherapeutic medicine by GPs if they needed new medication or needed their prescription to be refilled. This was unique to GPs group only. The patients were encouraged to visit their psychiatrist to avoid the eventual replacement of the psychiatrist with CMs services.

#### *Control Group (The Usual Treatment)*

The control group received "the usual treatment" in which patients receive the services by referring to an outpatient clinic (private or governmental). The interval visits was based on the patients and/or their caregiver decision. In this group, the pa-

tients were only looked after by their families. In case of exacerbation, they were referred to psychiatrist hospitals/wards to be admitted if any empty bed was available.

### *Evaluators*

Each study participant was evaluated using study instruments twice: first immediately after signing the informed consent form, and second at the end of the 12-month follow-up. The study instruments were completed by trained psychiatric residents or clinical psychologists with master's degree who were blind to the randomization of the participants before and after the intervention.

### *Study Instruments*

1. Kohlman Evaluation of Living Skills - KELS (17). In a pilot study, the Kappa coefficient between the two raters for five subscales were 0.86 to 0.99 (15).

2. Knowledge questionnaire for caregivers. The modified version of the questionnaire was developed by Khazaeilie (18) and is comprised of 31 items (true/false) including symptoms, treatment and family's awareness and behavior toward the patients. The reliability of this questionnaire via test-retest within a week was acceptable ( $r=0.83$ ).

3. Family Experience Interview Schedule (FEIS). In this study, the short-form with 41 items was developed. Test-retest reliability within a week was 0.89, and Cronbach's alpha coefficient was 0.89 for this instrument (15).

4. The Persian version of the General Health Questionnaire-28 (GHQ-28). This questionnaire has 28 items and 4-point likert scale. A higher score indicates a possible case of mental disorder (19).

5. Client Questionnaire Satisfaction (CQS). This is a self-administered questionnaire with 8 items on a 4-point likert scale. For the overall score, the sum of the item responses ranges from 8-32, with a higher score indicating higher satisfaction (20).

6. Positive and Negative Symptoms Scale

(21). In this scale, the positive and negative symptoms of mental disorder, usually psychosis, are quantified. In this scale, 7 items evaluate positive symptoms subscale, 7 items evaluate negative symptoms subscale and 16 items evaluate the general symptoms subscales and three supplementary items. Each item is reported on a scale of 0 to 7 with higher score reflected more severe symptoms. The Farsi translated version of this scale has been used in this study.

7. Young Mania Rating Scale. This scale is used to evaluate the severity of symptoms of BMD. Cronbach's alpha coefficient for the Persian version of this questionnaire was 0.72 (22).

8. In order to examine the utility, the QALY index was measured using the SF-36 questionnaire (23). Information was collected through standard interviews with participants and caregivers, and the response rate was 75%. The outcome is presented as a mean difference (95% CI).

9. Cost questionnaire. This questionnaire consists of the costs of prescriptions, outpatient treatment, hospitalization services, telephone calls, case managers' payments and the cost of training as direct costs. The indirect costs included in this study were patients' transportation, case managers' transportation and the loss of income of caregivers due to taking care of their patients. The cost of any services was calculated based on 2008 tariffs.

10. The demographic questionnaire included age, gender, education, job, marital status, age of disease onset, duration of marriage, duration of illness and frequency of hospitalization (Tables 1 and 2).

### *Monitoring Program*

The following activities were performed to monitor the program progress:

1. Obtaining written confirmation from the patients' caregivers for every home-visit made by the case managers

2. Providing an Ambulatory Medical Document (AMD) for each patient in intervention groups

3. Filling out the symptoms and drug side

effects checklist and updating medical AMD

4. Providing a data sheet to register the collected data for each patient and tracking them

5. Having the AMD reviewed by the supervisor in every supervision session

6. Having the patients' data sheets reviewed by the main investigator periodically

7. Contacting the participants or their caregivers every 2 to 3 months to trace the activities being performed regularly by each case manager.

#### *Cost Evaluation Method*

In this study, the costs consisted of the costs of outpatient visit, hospitalization, transportation, drugs and the cost of time allocated by caregivers to care for the patient, case managers' transportation and the cost of home visit for one year. The cost of each home visit for the GPs and nurses were 125,000 and 10,5000 Iranian Rials (IRR), respectively.

To evaluate the cost effectiveness of the interventions, the primary health outcome was quality-adjusted life years (QALYs). These were calculated for each group using HRQoL scores from the SF-36 and were converted to utility scores using OLS formulae (24).

#### *Ethical Consideration*

The study protocol was approved by the Ethical Committee of the Mental Health Research Center of Iran. The participants and their main caregivers were fully informed of the study design and were asked to sign a consent form. The study questionnaires were numbered and entered in the data sheet identified by codes for each study sample without revealing the name of the participants. There were no known conflicts of interest.

#### *Statistical Analyses*

All analyses were done using SPSS software package version 16.0 (SPSS, Inc. Chicago, IL). In order to compare demo-

graphic and clinical variables between the three groups, we used chi-square for nominal data and analysis of variance (ANOVA) for numeric variables. ANOVA was used to compare the mean score of the questionnaires between the groups. We calculated two by two comparisons of groups by Scheffe as a post-Hoc test. Paired sample t-test was used to compare the mean score of the questionnaires before and after interventions among each group. Odds ratio with 95% confidence interval was calculated for independent effect of each intervention on rehospitalization rate using logistic regression. Because all demographic variables were the same across groups, we just entered groups as an independent variable and re-hospitalization as a dependent variable in the applied model. The level of significance was set at 0.05 for all analyses.

## **Results**

### *Participants*

The three groups were similar in all demographic features (Tables 1 and 2), but the educational level of the participants in the GP and nurse groups were higher than the control group. More participants in the GP and control groups were employed or had a job compared to the nurse group. The mean ( $\pm$ SD) duration of illness for the participants was 12.74 ( $\pm$ 9.8) years and the mean of hospitalization frequency was 2.7 ( $\pm$ 3.3). In other words, the mean frequency of hospitalization was once every four years.

### *Number of Hospital Admissions*

Seven participants in the GP group (15.2%), 9 in the nurse group (17.3%) and 20 in the control group (37%) were hospitalized during the 12 months of the intervention ( $p=0.01$ ,  $\chi^2=8.32$ ). The risk of hospitalization was calculated between groups using regression analysis. The results revealed that the risk of re-hospitalization in the control group was OR= 3.3 (CI= 1.23-8.69) and it was OR= 1.16 (CI= 0.39-3.4) in the nurse group.

Table 1. Demographic features of the study sample in three groups

	Groups	N	Mean	SD	95% Confidence Interval for Mean		F	Pv
					Lower Bound	Upper Bound		
Patients age	GP	46	35.3	10.02	32.31	38.30	0.30	0.70
	Nurse	52	34.5	9.31	31.88	37.12		
	control	52	36.2	12.90	32.62	39.84		
Disease duration	GP	37	11.6	7.74	9.06	14.25	0.52	0.59
	Nurse control	38	12.4	10.42	9.01	15.88		
Number admission	GP	47	13.8	10.80	10.65	17.0	0.29	0.75
	Nurse	37	2.8	3.21	1.77	3.9		
	control	40	2.9	3.73	1.76	4.19		
		49	2.4	2.86	1.67	3.27		

GP: general physician

Table 2. Demographic features of the study sample in three groups

		GP group (N=46)		Nurse group (N=52)		Control group (N=54)		$\chi^2$	df	Pv
		No.	%	No.	%	No.	%			
Sex	Male	29	63.00	29	55.77	30	55.55	0.71	2	0.73
	Female	17	37.00	23	44.23	24	44.45			
Marital status	Single	26	56.52	26	50.00	26	48.15	4.82	4	0.32
	Married	17	36.96	17	32.69	24	44.44			
	Other	3	6.52	9	17.31	4	7.41			
Job	Unemployed	26	56.52	39	75.00	29	53.70	5.88	2	0.05
	Employed	20	43.48	13	25.00	25	46.30			

*Outcome Measures*

The psychological status was not significantly different among the three groups before the intervention, validating the randomization of the participants. The evaluation of the effects of the intervention revealed that after 12 months of the follow up, the scores of YOUNG, caregivers'

knowledge and satisfaction with the services were improved in both intervention groups (Table 3). The social skills (KELZ), caregiver's burden, the general health of the caregivers, and PANSS of the study participants in the GP and nurse groups were improved after the intervention, but the differences were not significant. The

Table 3. the clinical features of the study subjects in three groups

	Group	Baseline		After the intervention		Pv within group	Pv between group
		Mean	SD	Mean	SD		
Young	GP	17.2	12.3	13.2	6	0.001	0.03
	Nurse	22.5	16.4	11	6.5		
	control	18.8	15.2	17.5	11		
Panss Total	GP	94.6	32.5	84.9	124	0.004	0.30
	Nurse	106.7	33.8	68.2	30.3		
	control	104.9	35.9	80.6	40.3		
KELZ	GP	8.79	4.8	6.92	4.47	0.006	0.09
	Nurse	9.64	4.53	7.23	3.31		
	control	9.45	4.89	9.58	4.39		
Knowledge	GP	18.9	3.81	24.12	8.36	<0.001	0.05
	Nurse	19.54	4.35	22.07	2.96		
	control	18.56	4.04	20.95	6.70		
Burden Total	GP	120.1	22.77	98.66	20.23	<0.001	0.08
	Nurse	119.08	19.71	1.01	20.07		
	control	116.07	21.46	1.05	19.36		
general health of caregivers	GP	63.54	18.47	54.92	10.47	<0.001	0.20
	Nurse	59.37	18.7	53.55	10.85		
	control	56.36	16	53.98	10.33		
Consumer satisfaction with services	GP	24.3	4.9	26.32	3.02	0.100	0.01
	Nurse	24.16	5.41	25.63	3.53		
	control	24.96	4.73	23.72	5.38		
QALYs	GP	0.90	0.4	0.95	0.4	<0.001	0.01
	Nurse	0.84	0.3	1	0.4		
	control	1.01	0.4	0.95	0.4		

Cost of services

Table 4. Cost effectiveness rates in three groups

	Nurses	GP	Control
Mean cost (IRR)	6,123,741	5,733,031	5,017,813
Mean Effect (QALYs gained)	0.15	0.05	-0.06
Cost-Effectiveness ratio	40,571,370	101,541,472	-73,655,971
ICER	5,048,459	5,740,807	NA

mean difference of the utility score at baseline and after 12 months was 0.056 (95% CI: -0.13-0.24), 0.15 (95% CI: -0.01-0.32) and -0.068 (95% CI: -0.24-0.10) in the general practitioner, nurse and control groups, respectively. Improvement in the utility score after intervention was observed in the GP and nurse groups.

Analysis of the cost data showed that the total cost of the nurse group was higher than the GP and control groups and that there was no significant difference between the GP and control groups with respect to cost. The total costs of the study participants in the GP group was 263,719,451 IRR, it was 318,434,542 IRR in the nurse group and 270,961,905 IRR in the control group. The major difference in the costs among the different groups was the cost of hospitalization.

#### *Cost Effectiveness Analysis*

The economic evaluation of the two aftercare models was made using cost-effectiveness methods. The mean difference of the utility score index was calculated before and after a 12-month period in each group, and the quality adjusted life years (QALYs) for each group were calculated by taking into account the length of each period. We estimated the mean cost in each group, and the following formula was used to obtain the ratios for incremental cost-effectiveness (ICER):

$$\text{ICER} = (\text{Cost Intervention} - \text{Cost Control}) / (\text{Effect Intervention} - \text{Effect Control})$$

The incremental mean cost was 715218.4 IRR and 1105928.1 IRR for the GP and the nurse groups to control group, respectively and the incremental effectiveness was 0.12 QALYs and 0.21 QALYs for the GP and the nurse groups to control group, respectively. The incremental cost effectiveness

ratio (ICER) of the GP group, compared to the control group, was 5740708 IRR and 5048459 IRR for the nurse group compared to the control group (Table 4).

#### **Discussion**

The Impact of Clinical Case-Management Service on Hospitalization Rate

The program implemented in this study was in accordance with the clinical model of case-management (7). With respect to hospitalization rates, studies conducted in western countries have shown that classic case-management services may increase the hospitalization rate (OR= 1.84) (24-25), but a variety of these services were actually effective in three domains of family burden, family satisfaction with services and cost of care and other clinical features (26-27).

The result of this study revealed that hospitalization rate in patients in the control and nurse groups were 3.3 and 1.2 folds higher compared to those in the GP group. In a previous study in Iran (Ahebbba study), trained psychologists were utilized as clinical case-managers and non-professional family members, and the results showed that hospitalization rates were 17 and 14 percent, respectively compared to the control group (15). Comparing our results to another study carried out in Roozbeh hospital (16), the re-admission rates were similar in the control group; however, it was rather lower in our study. One reason could be visiting and monitoring patients by psychiatrists, but the costs of psychiatrist case managers' have to be taken into account compared to the other two studies. The main difference is that in our study, case managers acted as a clinical manager and their main task was to look after patients' drug treatment, help them to continue their

current medications and link them to a psychiatrist to manage their problems in a more appropriate way. Family education and providing advice for their social skills were mainly in accordance with the above role. In our model of clinical case-manager and home visit services, the case managers were only trained nurses, who could function effectively to reduce hospitalization rate. This is very crucial for Iran's society where the available acute psychiatric beds are only one thirds of the needed beds in psychiatry.

#### *Clinical Outcomes of Providing Home Visit Services*

The study results revealed that among the six clinical features, the caregivers' knowledge, satisfaction with the services and the severity of BMD psychopathology were improved in the both case managers' groups compared to the control group.

Against the general belief of conducting home visit with only one person as a case manager, the result of this study showed that it is safe and feasible. the following preparations such as calling the patients' families in advance to set the home-visit of the case managers and the mandatory presence of the family members of the patients at the time of the visit, could increase the safety of the interventions and reduce the unnecessary expenses even further.

#### *Cost effectiveness*

The clinical case manager model defined in this study is a cost-effective model for both GP and nurse case managers. However, the nurse group was the most cost effective intervention due to the lower incremental cost effectiveness ratio in this group than the GP and the control group. In this study, the difference of the cost for each home visit between the GP and nurse case managers was 25,000 IRR.

#### *Implication for Behavioral Health*

According to the aim of this research, the model of aftercare services provided by trained nurses is the most cost effective and

feasible model which could be more appropriate for Iran's socio-economic conditions with low resource allocations.

#### *Conflict of interest*

This research did not have any sponsors.

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