The effect of a care plan based on the Roy adaptation model on general health in hemodialysis patients; a randomized controlled clinical trial

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A B S T R A C T

Introduction: Evidence suggests that end-stage renal disease (ESRD) significantly affects general health in the patients, causing their general health to be poorer compared to the general population. The Roy adaptation model (RAM) is the best one for ESRD patients.

Objectives: The present study aimed to determine the effect of a RAM-based care plan on general health in hemodialysis patients.

Patients and Methods: This randomized controlled clinical trial conducted on 60 hemodialysis patients in Iran. The data collected using a demographic questionnaire and the general health questionnaire-28 (GHQ-28). In the intervention group, the Roy assessment form was completed and the RAM-based care plan was then trained in four group sessions over 4 weeks. Individual sessions were also held if required and patients followed-up for 2 weeks. The control group received only routine care. At the end of the follow-up, general health was re-assessed in the patients. The findings were analysed using t test, the chi-square test and the McNemar test.

Results: Despite observing no significant differences between the two groups in terms of general health levels before the intervention (P=0.530), the difference was significant after the intervention (P=0.028), since the mean score of general health decreased by 4.07 in the intervention group compared to before the intervention (P=0.003). The intervention significantly affected the subscales of somatic symptoms (P=0.013), anxiety and insomnia (P=0.006), social dysfunction (P=0.016) and depression (P=0.031).

Conclusion: The findings suggested the positive effects of using the RAM on general health in hemodialysis patients. The RAM is therefore recommended that be used as a holistic care approach to improving general health in these patients.

Trial Registration: The trial protocol was approved by the Iranian Registry of Clinical Trials (identifier: IRCT20141119865N4; https://irct.ir/trial/9154).

Implication for health policy/practice/research/medical education:
The findings of present study suggested the positive effects of using the Roy adaptation model (RAM) on general health in hemodialysis patients. Given the chronic trend of hemodialysis, the RAM is recommended that be consistently utilized for promoting general health in hemodialysis patients.

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Evidence suggests that ESRD significantly affects general health in the patients (10), and causes general health to be lower in these patients compared to in the general population (11). The World Health Organization defined general health as physical, mental, social and spiritual well-being (12). General health in these patients is affected by numerous factors, including the disease, family conditions and their attitudes and cognitions (13). Moreover, sleep disorders, anxiety, depression and social isolation reduce general health in ESRD patients (14-18).

To maintain their general health, these patients need to change their diet, medication of regimen and lifestyle and commit themselves to attending hemodialysis sessions (19). The results obtained by some studies suggested poor general health in hemodialysis patients (10,11). The study conducted by Czyżewski et al showed a poorer general health in hemodialysis and peritoneal dialysis patients than in transplant patients (20). Similarly, in Germany, Overbeck et al also found a poor general health in hemodialysis patients (21). Given their poor general health, paying attention to their general health problems is crucial (6), since maintaining positive attitudes and functioning in these patients requires their adaptation to ESRD (22).

The Roy adaptation model (RAM) is a practical, safe, non-invasive, non-medicinal and cost-effective model for promoting adaptation (23). Reviewing ten studies using the RAM as a research framework in different designs, Sosha and Al Kaladeh found this model to be effective in explaining adaptation in humans (24). Frazao et al also introduced RAM as the best adaptation model in ESRD patients (25). According to this model, manipulating the focal, contextual and residual stimuli can improve adaptation (26,27). These stimuli can be therefore identified in the patients’ non-adaptive behaviours through their assessments to lay plans to develop their healthy behaviours (28). According to this model, the individual can achieve adaptation in physical (physiologic) mode and psychological dimension, i.e. self-concept, role function and interdependence modes (26,29,30). Hay suggested that adaptation in psychophysical dimension reduces the debilitating complications of the disease and improves quality of life in the patients (23).

The RAM has been addressed in literature in terms of its contribution to increase the ability of hemodialysis patients to perform different dimensions of their daily life activities; i.e. social and personal activities and household affairs management, reducing fatigue and its behavioural, emotional, sensory and cognitive dimensions. Additionally, the RAM has been detected to change paraclinical findings such as reducing urea and potassium and increasing serum albumin (22,25).

Recently, Agustiyowati et al in Indonesia demonstrated the effectiveness of the RAM in improving physiological adaptation responses of CKD patients regarding fluid intake and serum creatinine level, and their psychological responses regarding role function, self-concept and interdependency. These researchers recommended the model to be disseminated and applied in nursing care for CKD patients in pre-dialysis period (28). Yodchai et al also suggested that RAM improved physiological and role function types of adaptation responses in hemodialysis patients (31). Accordingly, the study on the efficiency of group cognitive behavioural treatment with mindfulness in hemodialysis individuals conducted by Sohn et al showed the effectiveness of mindfulness in reducing physical and anxiety symptoms, quality of life, stress and depression symptoms. They recommended this program to be applied as a complementary therapy to improve general health levels in hemodialysis patients (32).

Given the poor general health status in ESRD patients, taking supportive and care measures to promote their general health is crucial (33). Improving general health is a key goal of nursing measures, and various studies suggest that the RAM is a non-invasive and non-medicinal method that can be implemented by nurses (22,34).

**Objectives**

A review of the literature suggests that the effect of the RAM on all dimensions of general health in hemodialysis patients has not been addressed in either Iran or other countries, since only one or two dimensions of general health, including fatigue, daily life activities and physiological and psychological responses have been investigated. The present study was therefore conducted to determine the effect of a RAM-based training/care plan on the dimensions of general health in hemodialysis patients.

**Patients and Method**

**Study population**

Convenience sampling was conducted to select the subjects in April to September 2015 from eligible patients in the hemodialysis wards of Semnan hospitals (Iran). The sample size was calculated as at least 60 in two groups of 30 for each using a preliminary investigation. The patients were assigned to these groups using permuted block randomization. Allocation concealment was conducted using closed envelopes with letter A (intervention group) and B (control group). The present study investigated 78 patients, of whom 12 were excluded due to ineligibility (n=7), unwillingness to participate in the study (n=4) and kidney transplant (n=1). According to Figure 1, six patients were excluded during the follow-up due to death (three in the control group and one in the intervention group) and transfer to other hemodialysis centres (two in the intervention group).

The inclusion criteria comprised signing written
informed consent form, the age of 40-80 years, history of hemodialysis for at least six months and undergoing hemodialysis three times per week. The exclusion criteria consisted of physical disabilities, psychological disorders, addiction to opioids, cancers, hearing or visual impairments preventing proper communication, experiencing stressful events in the previous six months, undergoing kidney transplantation during the study and unwillingness to regularly participate in the training sessions according to the designed program.

The data collection tools comprised demographic questionnaires, including age, gender, occupation, marital status, level of education and history of hemodialysis, the general health questionnaire-28 (GHQ-28) and the Roy assessment form. The GHQ was developed by Goldberg and Hillier in 1979. Different versions of the GHQ contain different numbers of items ranging from 12 to 60 (35). The GHQ-28 comprises four 7-item subscales, and the items are sequential and respectively associated with somatic symptoms (items 1-7), anxiety and insomnia (items 8-14), social dysfunction (items 15-21) and depression symptoms (items 22-28). The items are scored on a Likert scale including zero (never), one (usually), two (more than usual) and three (far more than usual). A score of at least six in each subscale denotes symptoms of the disease (26). The total score of 0-84 equals the sum of the scores of all the items, and shows general health in the subject, with higher scores suggesting lower levels of general health (36). The psychometric properties of this scale have been confirmed in 15 populations of different cultures and languages across the world (37). This scale was translated to Persian in Iran, since the face validity, content validity and internal consistency of this version and its subscales were confirmed (38).

The GHQ-28 has been used by Theofilou, Katayama et al and Overbeck et al in their studies on hemodialysis patients (21,39,40). Overall, the GHQ questionnaire items showed good internal consistency across all countries as reflected by Cronbach’s alpha; Chile (0.86), Ethiopia (0.83), Peru (0.85), and Thailand (0.82). The comparative fit index (CFI) values for Chile, Ethiopia, Peru and Thailand were 0.964, 0.951, 0.949, and 0.931, respectively. The corresponding root mean square errors of approximation (RMSEA) values were 0.051, 0.050, 0.059, and 0.059 (41). Moreover, a Cronbach’s alpha of >0.7 calculated in a study on the stroke population confirmed the reliability of this
questionnaire (42).

Roy assessment forms are used to investigate the patients in physiologic, self-concept, role function and interdependence dimensions. The 25-item physiologic dimension comprised nine subcategories, i.e. circulation and oxygenation, nutrition, excretion, rest and activity, protection, senses, water and electrolytes, neurologic status and endocrine glands status. The 10-item self-concept dimension comprised five subcategories, i.e. physical self, personal self, ideal self, moral self and spiritual self. The 8-item role function dimension included three subcategories, i.e. primary role, secondary role and tertiary role. The 6-item interdependence dimension comprised two subcategories, i.e. other important people and supportive system. Questions associated with different dimensions were asked from the patients during their interviews, and their responses were investigated based on the RAM. This form, which is extracted from reliable scientific resources, is confirmed in terms of validity, while its reliability was confirmed with a Cronbach's alpha of 0.75 (43).

After introducing himself to the subjects and their accompaniments, the researcher briefed them on the study objectives and procedure, the voluntary participation and confidentiality of their information, and then obtained their written consent. The study began by completing the demographic questionnaire and the GHQ, which was performed by the researcher for illiterate patients. The subjects were then randomly assigned to the intervention and control groups.

In the intervention group, after providing routine nursing care during hemodialysis, the Roy assessment form was completed and investigated by the researcher. Then the RAM-based training program was administered. The focal, contextual and residual stimuli related to each patient and their maladaptive behaviours in each dimension were also identified. In addition, after developing the nursing diagnosis, all the subjects in this group participated in individual training and counselling sessions according to their needs and maladaptive behaviours. Furthermore, each patient received nursing care at their bedside depending on their necessities. The majority of maladaptive behaviours in this group were comprised two subcategories, i.e. primary role, secondary role and tertiary role. The 6-item interdependence dimension comprised two subcategories, i.e. other important people and supportive system. Questions associated with different dimensions were asked from the patients during their interviews, and their responses were investigated based on the RAM. This form, which is extracted from reliable scientific resources, is confirmed in terms of validity, while its reliability was confirmed with a Cronbach's alpha of 0.75 (43).

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Upon completing the group sessions, educational pamphlets on the cited subjects were distributed among all the patients in the intervention group, and they were followed up face to face or on the phone for two weeks. In fact, to answer their questions, the researcher was given a telephone number, asking them if their problems had been resolved and their questions answered. If their problem had not been solved, they referred to a specialist, i.e. a psychologist or nutritionist. According to Figure 2, general health was reassessed in the patients at the end of the follow-up.

In the end, the GHQ-28 was concurrently completed in both the intervention and the control group, who had only received routine care with no additional interventions.

Ethical issues
The research followed the tenets of the Declaration of Helsinki. The Ethics Committee of Semnan University of Medical Sciences approved this study (Approval No.: 93/529209 dated 25 November 2014). Additionally, this study was registered as a clinical trial at Iranian Registry of Clinical Trials (identifier: IRCT201411198665N4; https://irct.ir/trial/9154; registration date 2014-11-30), and written informed consent was taken from all participants before any intervention. Sampling began after obtaining permission from the Ethics Committee of Semnan University of Medical Sciences and the authorities of the hospital and the hemodialysis ward. This work has been conducted as part of MSc of critical care nursing thesis of second author (M.S.) in Semnan University of Medical Sciences, Semnan, Iran.

Statistical analysis
Descriptive statistics were used to analyse the demographic data of the subjects. The distribution normality of the data was investigated using the Shapiro-Wilk test. The chi-square test was also used to test the independence of qualitative traits between the two groups. The independent t test was used for investigating between-group differences in the numerical variables, including the scores of general health and its subscales, and the paired t test for within-group comparisons. Furthermore, the two groups were compared in terms of contracting the disease at the beginning and end of the study using the McNemar test. The data were analysed in SPSS 16, and \( P < 0.05 \) was set as the level of statistical significance.

Results
Males accounted for 46.7% of the patients in the control group and 66.7% in the intervention group. The mean age of the patients was 61.97 ± 10.93 years in the control group and 61.33 ± 9.2 years in the intervention group, suggesting no significant differences according to the \( t \) test \((P = 0.809)\).

The study subjects were 43-80 years old and had a mean age of 61.65 ± 10.02 years. A total of 73.3% of the patients in the control group and 90% in the intervention group were married, and level of education was below high school diploma in 66.7% of the controls and 43.3% of the
intervention group. Moreover, 83.3% in the controls and 76.7% in the intervention group were unemployed, since 63.3% in the controls and 70% in the intervention group had a history of dialysis of at most 40 months. According to Table 2 and statistical comparisons, the two groups were not different in terms of the distribution of demographic variables. Furthermore, the mean duration of history of hemodialysis was 33.70 months in the intervention group and 46.97 months in the controls, which suggested a statistically-insignificant difference ($P = 0.211$).

Maladaptive behaviours were also observed in the intervention group patients in different dimensions. In the physiologic dimension, these behaviours were observed in the subscales of activity (50%), rest (40%), nutrition (60%), protection (40%), senses (86.6%), excretion (66.6%), circulation (66.6%), water and electrolytes (66.6%), neurologic status (60%) and endocrine glands status (50%). Maladaptive behaviours were also observed in the dimensions of self-concept (66.6%), role function (46.6%) and interdependence (36.6%) (Table 1).

Before the intervention, the mean score of general health was 25.17 in the intervention group and 24.20 in the controls, suggesting no significant differences between the two groups according to the $t$ test results ($P = 0.530$). The post-intervention difference between the two groups was significant regarding the mean score of general health ($P = 0.028$), while this score decreased in the intervention group by 4.07 compared to before the intervention, which
showed improvements in general health in this group with significant statistical differences ($P = 0.003$; Table 3).

Comparing the mean scores of dimensions of general health suggested no statistically significant differences between the two groups in any dimensions. After the intervention, significant differences, however, were observed within the intervention group before and after the intervention, and also between the two groups in terms of all the dimensions. Significant changes were also observed in the mean scores of all the dimensions, except for somatic symptoms, between before and after the intervention in the two groups (Table 4).

In the intervention group, comparing the mean scores of dimensions of general health between after and before the intervention using the McNemar test showed the significant effects of the intervention on the subscales of somatic symptoms ($P = 0.013$), anxiety and insomnia ($P = 0.006$), social dysfunction ($P = 0.016$) and depression symptoms ($P = 0.031$), whereas these effects were insignificant on all these subscales in the control group.

**Discussion**

To the best of the authors’ knowledge, the present study pioneered the investigation of the effect of training/care interventions based on the RAM, as the best model in the care of ESRD patients, on different dimensions of general health in patients undergoing hemodialysis in the hemodialysis wards of Semnan hospitals.

The present findings showed no differences in the pre-intervention general health between the intervention group and the control group. This difference was, however, significant, since the mean post-intervention score of general health in the intervention group decreased by 4.07 compared to the pre-intervention score, which showed improvements in general health in this group.

Comparing the mean scores of dimensions of general health suggested no statistically significant differences between the two groups in any dimension. However, after the intervention, significant differences were observed between the two groups in terms of all the dimensions, such as somatic symptoms, anxiety and insomnia, social dysfunction and depression symptoms. In addition, significant changes were observed in the mean scores of all the dimensions, except for somatic symptoms, between before and after the intervention in the two groups.

In line with the present findings, the results obtained by Dickson et al in the United States showed significant differences between the mean scores of general health...
before and after six months motivational interviews and improved compliance to hemodialysis schedules and treatment times (44).

The results of a study conducted by Moser et al in North Carolina (USA) also showed that motivational interviewing in patients on maintenance hemodialysis improves nutritional status measurements after the one-month intervention period. These findings also support the benefits of recurrent counselling sessions (on a weekly schedule) as it helps build rapport and promote monitored change in behaviours (45). Although their results are consistent with the present findings, they did not administer a care program and their training encompassed only the nutrition dimension in four group sessions, whereas the present study performed the RAM-based training individually and in groups coupled with referrals and follow-up. Training and counselling in the present study focused on all the dimensions of general health and maladaptive behaviours of the patients, whereas Moser et al focused only on nutrition in the patients during four sessions, which provided them with more time to address a specific dimension of problems as a common problem in the patients. Different results could have been obtained depending on the number of individual counselling and training sessions.

Alikari et al observed increase of knowledge, adherence and quality of life (QoL) levels as an outcome of general health in the intervention group after educational intervention. In addition, a significant positive correlation was found between the change in the overall QoL and the changes in the total adherence score as well as the adherence to the fluids and dietary behavior. They concluded that educational intervention could improve knowledge, adherence and QoL among HD patients (46), which is consistent with the present findings suggesting improvements in general health in the intervention group. The present research administered the RAM-based care plan as individual and group trainings and counselling by a psychologist, a nurse and a nutritionist, whereas the implementation of the nursing educational intervention and the administration of the booklet applied only by

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### Table 2. Between groups comparisons with respect to participants' demographic characteristics

| Characteristics                      | Group                  | Intervention (n=30) | Control (n=30) | P value* |
|--------------------------------------|------------------------|--------------------|---------------|---------|
|                                      | No. (%)  | %                 | No. (%)  | %     |
| Age (y)                              |           |                   |             |        |
| ≤60                                  | 13 (43.3) | 14 (46.7)         | 17 (56.7) | 16 (53.3) | 0.795   |
| >60                                  | 20 (66.7) | 14 (46.7)         | 10 (33.3) | 16 (53.3) | 0.118   |
| Gender                               |           |                   |             |        |
| Male                                 | 21 (70)   | 19 (63.3)         | 9 (30)     | 11 (36.7) | 0.584   |
| Female                               | 3 (10)    | 8 (26.7)          |            |         | 0.095   |
| Hemodialysis duration (month)        |           |                   |             |        |
| ≤40                                  | 27 (90)   | 22 (73.7)         | 3 (10)     | 8 (26.7)  | 0.069   |
| >40                                  | 13 (43.3) | 20 (66.7)         | 17 (56.7) | 10 (33.3) | 0.003*  |
| Marital status                       |           |                   |             |        |
| Married                              | 7 (23.3)  | 5 (16.7)          | 23 (76.7) | 25 (83.3) | 0.519   |
| Single                               | 23 (76.7) | 25 (83.3)         |            |         |        |

*Chi-square test.

### Table 3. Distribution of mean scores of the general health according to intervention and control groups

| Variables                  | Group                  | Intervention (n=30) | Control (n=30) | P value |
|----------------------------|------------------------|--------------------|---------------|---------|
|                            | No. (%)  | Mean ± SD         | No. (%)  | Mean ± SD |         |
| General health scores      |           |                   |             |         |
| Before                     | 25.17 ± 6.58 | 24.20 ± 5.2       | 0.530*     |
| After                      | 21.10 ± 3.60 | 23.67 ± 5.08      | 0.028*     |
| Difference                 | 4.07 ± 6.97 | 0.53 ± 6.31       | 0.044   |
| P value                    | 0.003**    | 0.647**           |         |

* t test, ** Paired t test.

### Table 4. Distribution of mean scores of the general health subscales according to the intervention and control groups

| General health subscales        | Group                  | Intervention (n=30) | Control (n=30) | P value* |
|--------------------------------|------------------------|--------------------|---------------|---------|
|                            | No. (%)  | Mean ± SD         | No. (%)  | Mean ± SD |         |
| Somatic symptoms             |           |                   |             |         |
| Before                       | 6.83 ± 3.01 | 6.80 ± 2.70       | 0.964   |
| After                        | 5.17 ± 1.89 | 6.53 ± 2.43       | 0.018   |
| Difference                   | 1.66 ± 3.28 | 0.26 ± 3.54       | 0.118   |
| P value**                    | t= 2.78, P = 0.009  | t= 0.41, P = 0.683 |         |
| Anxiety and sleep disorder   |           |                   |             |         |
| Before                       | 6.03 ± 3.95 | 7.07 ± 3.34       | 0.279   |
| After                        | 3.70 ± 2.18 | 6.70 ± 3.05       | <0.001  |
| Difference                   | 2.33 ± 3.72 | 0.36 ± 3.52       | 0.040   |
| P value**                    | t= 3.43, P = 0.002 | t= 0.56, P = 0.574 |         |
| Social dysfunction           |           |                   |             |         |
| Before                       | 8.93 ± 4.15 | 7.00 ± 3.57       | 0.058   |
| After                        | 11.45 ± 3.46 | 7.70 ± 3.07       | <0.001  |
| Difference                   | -2.48 ± 4.05 | -7.00 ± 2.84      | 0.055   |
| P value**                    | t= -3.30, P = 0.003 | t= -1.34, P = 0.188 |         |
| Depression symptoms          |           |                   |             |         |
| Before                       | 3.43 ± 3.52 | 3.33 ± 2.51       | 0.900   |
| After                        | 0.90 ± 1.09 | 2.77 ± 2.16       | <0.001  |
| Difference                   | 2.53 ± 3.56 | 0.56 ± 2.60       | 0.018   |
| P value**                    | t= 3.89, P = 0.001 | t= 1.19, P = 0.244 |         |

* t test, ** Paired t test.
nurses in the study by Alikari et al (46). The relative strength and weakness of the present research compared to their study include the higher number of educational sessions in the present study (4 versus 1), but using a two-week follow-up with referral to specialist, which was 2-8 months in their study.

Numerous studies have confirmed the effect of the RAM on one dimension of general health in hemodialysis patients (22,28,31,34). Regarding the present study, main hypothesis suggested that administration of the RAM-based training/care program improves general health in hemodialysis patients. The results of the student t-test showed significant differences in the mean score of general health between the intervention and control groups in a way that this score was higher in the group receiving the RAM-based care compared to the group receiving only routine care. Lingerfelt and Thornton reviewed the benefits of training ESRD patients in the disease, diet, treatment and medication for improving self-therapy, and found improvements in the patients’ knowledge from 66% before the training to 90% afterwards (47). However, the effect of demographic characteristics on the patients should not be disregarded. Theoﬁlou investigated the effect of demographic and social characteristics on anxiety and depression in CKD patients and found older patients to score higher in the social dysfunction subscale of the GHQ. The patients with low-literacy also received high scores in anxiety/insomnia and depression subscales, while the divorced/widowed patients scored higher in the severe depression subscale. The findings suggested sociodemographic variables such as old age, low literacy and divorce/widowhood are damaging factors to mental health in the patients (39).

Conclusion
The present findings generally confirmed the positive effects of applying the RAM on general health in hemodialysis patients. As a holistic care approach, the RAM is therefore recommended that be used for improving symptoms and dimensions of general health in these patients. More comprehensive studies are also recommended that be conducted on the RAM as a supplementary or auxiliary method in the nursing care for patients. Given the chronic nature of the disease, patients’ problems, the ineffectiveness of hemodialysis in completely solving these problems and the need for consistent care, the RAM can be used to improve the adaptation of hemodialysis patients to the numerous problems and complications caused by hemodialysis.

Limitations of the study
The present study limitations mainly comprised the poor cooperation of the patients and their accompaniments, the patients’ disabilities such as painful legs, weakness, lethargy and fatigue caused by hemodialysis and their impatience with participation in the counselling sessions. Given that the present study was conducted with a small sample in two teaching hospitals, further similar studies are recommended that be conducted with larger samples in larger health centres.

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Authors’ contribution
At designed the experiment. MN, HB and NS supervised the project. MS involved in collecting data, MM involved in data analysis and all authors discuss the results and commend on the final manuscript.

Conflicts of interest
The authors declare that they do not have any conflict of interest.

Ethical considerations
Ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

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