*J Caring Sci*. 2025;14(1):5-13
doi: 10.34172/jcs.025.33604
https://jcs.tbzmed.ac.ir

Original Article

# A Randomized Controlled Clinical Trial of Individualized Patient Education on Hemodialysis Adequacy and Interdialytic Weight Gain

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**Article Info**

**Article History:**
**Received:** July 1, 2024
**Accepted:** September 18, 2024
**ePublished:** October 22, 2024

**Keywords:**
Individualized education, Hemodialysis adequacy, Kt/V, Interdialytic weight gain (IDWG), Hemodialysis

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**Abstract**

**Introduction:** Today, there is an emphasis on considering the individual needs and preferences of the patient in education and care. This study aims to assess the effect of individualized education on hemodialysis adequacy (Kt/V) and interdialytic weight gain (IDWG) in patients undergoing hemodialysis (HD).

**Methods:** 102 HD patients were randomly assigned to the intervention or control groups. Patients in the intervention group (n=51) received individualized education. The control group (n=51) received routine education. The patients' dialysis adequacy (Kt/V) and IDWG were assessed before the intervention, immediately, and three months after the last session of individualized education. Data were analyzed using SPSS software.

**Results:** A significant increase in Kt/V was found in the intervention group compared with the control group immediately and three months after the intervention ($P<0.05$). Moreover, the mean total score of IDWG in the intervention group was significantly lower than the control group immediately and three months after the intervention ($P<0.05$).

**Conclusion:** The results highlighted the importance of individualized education for improving HD adequacy and lowering IDWG in HD patients. Moreover, it is recommended to tailor the patients' education based on their own needs, rather than a one-size-fits-all approach.

## Introduction

Chronic kidney disease (CKD) as a common chronic disease is increasing globally. It ranked as the 18th leading cause of death in 2010.[1] It is projected that by 2030, more than 70% of individuals with end-stage kidney disease (ESKD) will reside in lower-middle-income nations like Iran.[2] These patients require life-sustaining renal replacement therapies. Hemodialysis (HD) is the most common treatment for ESKD in Iran and worldwide.[2,3]

Compliance with dietary guidelines and fluid restrictions is essential for effective management of HD treatment.[4,5] Failure to adhere to these recommendations can lead to various health complications like hypertension, edema, left ventricular hypertrophy, congestive heart failure, acidosis, or pulmonary edema.[6,7]

Studies have indicated that many HD patients have problems with following these restrictions due to diminished self-care capabilities and disabilities.[8] About 10%-60% of HD patients do not comply with fluid restrictions.[9] In a study on HD patients conducted by Kara et al 68.1% of patients did not adhere to diet and 58.1% of them did not adhere to fluid restrictions.[10] Factors such as loss of motivation and inadequate self-assessment contribute to non-adherence.[11-13] Also, factors such as being male, younger, and educated predict noncompliance to fluid restrictions.[14] Biochemical and physiological measurements such as Kt/V and Interdialytic Weight Gain (IDWG) are used as measures of adherence in dialysis patients.[15,16]

Adequate delivery of HD dose as measured by Kt/V is a crucial determinant of clinical outcomes for chronic HD patients. The adequacy of HD refers to how effectively waste products and toxins are eliminated from the patient's blood, significantly influencing their overall health. Dialysis delivery should be adequate to improve quality of life and to prolong survival.[17] Patients with inadequate dialysis have an increase in mortality and morbidity rates.[18] Gender, hemoglobin, dialyzer surface area, and nutritional adherence are significantly associated with dialysis adequacy.[19,20]

Also, high IDWG is linked to an increased risk of

cardiovascular mortality and morbidity, including ventricular hypertrophy and adverse cardiac and cerebrovascular events.[21-23] It can lead to additional HD sessions, impacting quality of life and imposing higher costs. The primary cause of high IDWG is excessive fluid and/or food intake. Non-compliance with dietary and fluid restrictions is prevalent, with over 60% of assessments showing non-adherence.[24]

Improving adherence to restricted nutrition/fluid intake in HD patients is challenging in routine clinical practice.[25] A multidisciplinary healthcare team comprising physicians, nurses, and dialysis technicians is crucial for ensuring patient adherence to treatment, with nurses playing a pivotal role.[26] Research by Vijay & Kang has demonstrated that nurse-led interventions can effectively reduce non-adherence to fluid restrictions.[27] Nurses are responsible for providing education on adhering to fluid, diet, and salt restrictions to HD patients. Continuous and person-specific education plans are essential for the effectiveness of the training programs.[28,29]

The educational materials given to patients are typically presented in the form of printed brochures or booklets. These materials do not take into account the differences in patients' characteristics and preferences, as they are presented to all patients using the same format and wording. As a result, limited literacy or lack of motivation among patients may compromise the effectiveness of these educational materials. For example, a patient may have difficulty or misconceptions in understanding medical terms, or graphs.[30]

Nurses should assess and identify patient needs and try to provide them with the most suitable method of education by considering the preferences of each patient.[31] Providing individualized education is the main solution to overcome these concerns, which emphasizes providing tailored education based on the specific learning needs and health literacy status of each patient.[32] Studies have shown that individualized education significantly increases knowledge levels and adherence to therapeutic regimens among patients with various chronic conditions, such as atrial fibrillation,[33] hypertension, type-2 diabetes mellitus,[34] and acne vulgaris.[35] Also, it improves self-care behaviors and quality of life and prevents illness-related complications.[36]

Regarding the importance of HD adequacy, IDWG, and the role of patient education in patients undergoing HD, the present study was conducted to assess the effect of individualized education on HD adequacy and IDWG of patients undergoing HD.

## Materials and Methods

### *Study Design and Setting*

This study is a single-blind, two-arm, and parallel-group randomized controlled clinical trial. It was a large project in the field of HD. The study was conducted in the largest dialysis center in Iran (Emam Reza HD Center) affiliated with Tabriz University of Medical Sciences, Tabriz, Iran.

### *Participant Recruitment*

The aim of the study was explained to all participants, and their willingness to participate was assessed. An informed consent form was obtained from all participants. Inclusion criteria for participants were, patients with ESKD aged 18 years or older, patients who were going HD at least three times a week for at least three months, absence of mental disorders (severe depression and dementia) based on the patient's medical records, absence of cognitive disorders based on the Mini-Mental State Examination (MMSE).[37] Exclusion criteria were, participant's unwillingness to continue the study, patients who changed kidney replacement therapies from HD to other treatments (kidney transplantation or peritoneal dialysis) during the study period, patients who changed their HD center during the study, decreased consciousness of the participant during the study for any reason, and patient participation in another similar study during the study.

The results of a previous study[38] were used for the estimation of sample size. By considering the alpha at 0.05 and power (1-β) at 0.99, $M_1 = 3.20$, $M_2 = 1.89$, $SD_1 = 1.06$, and $SD_2 = 1.7$, a sample size of 43 is required for each two groups. Considering about 20% attrition rate, the final sample size was considered 51 participants in each group.

### *Randomization and Blinding*

102 patients were randomly assigned to one of the intervention (individualized education) or control (educational brochures) groups. The study flow chart is shown in Figure 1. Randomization was conducted using block sizes of 4 and 6, with the allocation ratio (1:1) for individualized education and control groups. For allocation concealment the Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) method was applied. An independent staff prepared the envelopes and another person enrolled participants. Participants in the intervention and control groups were not aware of their allocation. However, due to its nature, the trial intervention could not be blind for educator. The allocation sequence was blinded for examiners/assessors, too. Furthermore, the statistician conducting the data analysis was blinded for the group allocation.

### *Intervention Group*

Patients in the intervention group participated in individualized education. Individualized education included specific educational sessions for each patient. The education was provided by a student in nursing (MSc student), with a specialized certificate in nursing care of HD patients. At the first session, an individualized assessment session was conducted for each patient. This session lasted approximately 60 minutes and the baseline data such as the demographics and clinical data of each patient were assessed and recorded ($T_1$). Each patient

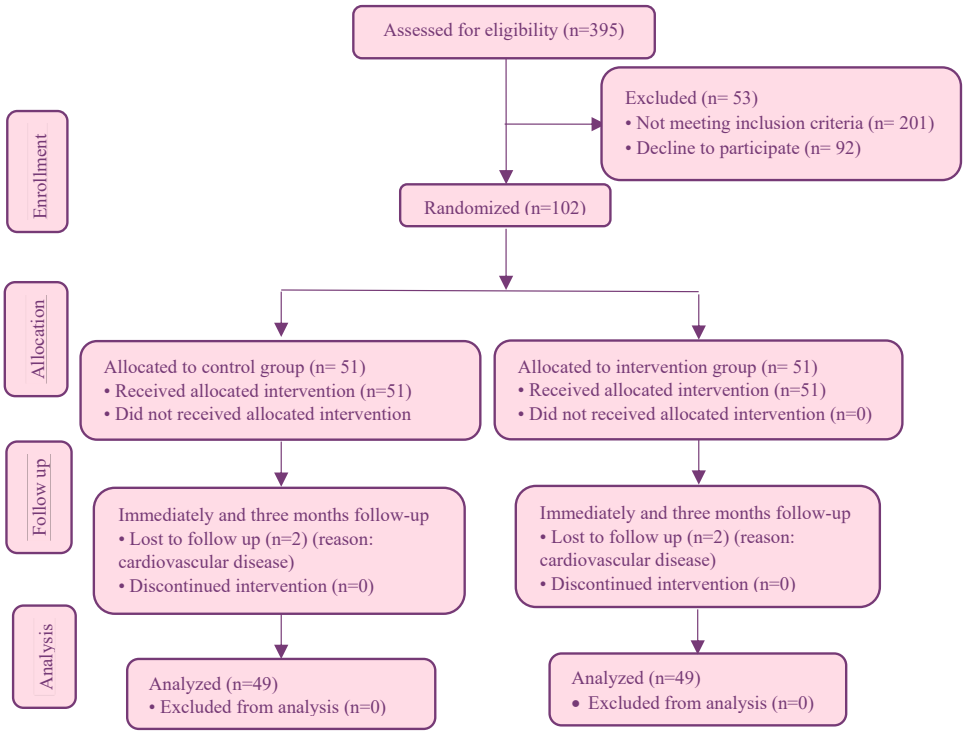


**Figure 1.** CONSORT flow chart

was asked to determine his/her individualized goals on diet, proper weight gain, medication adherence, and managing complications related to the disease based on their preferences and willingness. Each participant was motivated and supported to set individualized goals.

In the next sessions, each patient received individualized education according to the information obtained in the first session and based on each patient's needs, education level, age, and cognitive status. The individualized patient education approach is based on the proposed method of previous studies in individualized education,[33,39-47] considering that the nature of ESKD is different from other diseases. So, the educational content of each session was prepared according to the latest updates of the international guidelines of dialysis (Kidney Disease Outcomes Quality Initiative (KDOQI)).[48-51] The content of individualized education sessions consisted of 4 main components:

1) The explanation of the CKD, symptoms, complications, warning signs, follow-up (time to visit a doctor), prognosis, and kidney replacement therapies.
2) Recommendations on diet, fluid, salt, protein, vitamins, physical activity, and dry weight.
3) The medications that each patient takes (Indication, possible side effects, warning signs)
4) The complications management (skin and vascular access care, edema and itching, constipation, anemia, etc.)

At the end of each session, the patient was encouraged to ask his/her questions. If specialized questions were raised, a nephrologist was asked to provide appropriate answers to the patient's questions. Moreover, at the beginning of each session, the materials presented in the previous sessions were reviewed, and some questions were asked from the patient. If the patient could not remember the materials presented in the previous sessions, those materials were repeated. To ensure the patient's understanding of the educational materials, feedback was obtained at the end of each session. If the participant did not understand the content, the educator presented the content until they understood the content.

If the participant was successful in achieving the goals, strategies such as positive support, effective feedback, and encouragement were implemented to maintain positive behavior. If the participant was not successful in using the educational materials, the obstacles were assessed and the appropriate solutions were provided in collaboration with each patient. Moreover, patients could ask their questions at home by calling or by sending an SMS to the educator. Education provided for each participant was documented in their medical records. The education was primarily delivered at the beginning of the HD sessions when the patient was connected to the HD machine. Individualized education varied from 3 to 6 sessions for each patient. The duration of each session varied from 10 to 45 minutes. The sessions continued until the patient could correctly express the content and properly answer. To maintain continuity and prevent forgetting of educational materials, at least one educational session was held for each participant every week. To improve the patient's adherence to intervention protocols, each session continued until the patient felt neither tired nor experienced complications such as hypotension. Education was provided in the preferred language of each patient (Persian or Turkish). Simple and understandable sentences were used for each

patient. Moreover, we tried not to use specialized medical terminology or incomprehensible terms. To prevent contamination, the participants were requested not to share the individualized education with other patients until the end of the study.

The content validity of the individualized education program was evaluated by a specialized healthcare professional team including a nephrologist, an associated professor in nephrology nursing, an HD supervisor, and an experienced HD nurse. A supervisor of the study who is an expert in the dialysis field and clinical trial checked the study protocol to ensure intervention adherence.

### *Control Group*

Participants in the control group received the educational brochures, which are routinely provided by the dialysis center. The contents of the brochures were about the patients' self-care on diet, vascular access, fluid restrictions, medications, etc. These brochures were in the Persian language and they may not be understood by illiterate patients or patients with other languages who are not familiar with the Persian language.

### *Data Collection*

This study was conducted from October 2023 to April 2024. Data collection was done by a trained researcher who was not aware of the participants' allocation into intervention or control groups.

The baseline data, including socio-demographic and clinical characteristics of each patient, were collected using demographics and clinical information questionnaires through a face-to-face interview and using medical records. This questionnaire included participants' demographic and clinical characteristics, including etiology and the duration of HD. These characteristics were extracted from the patient's medical records.

Two main primary outcomes of HD adequacy (Kt/V) and IDWG were assessed for each patient before the intervention ($T_1$), immediately after the intervention ($T_2$), and three months after the intervention ($T_3$).

The value of Kt/V was collected from patients' medical records using the Daugirdas formula of Kt/V.[48] IDWG, as an easily measurable parameter in the dialysis unit, was calculated as the difference between the pre-dialysis weight and the weight at the end of the previous dialysis session. Patients' weight in both the intervention and control groups was assessed by a standard scale, using a regularly calibrated digital auto platform scale (Gambro Korea Co. Ltd, Seoul, Korea) in the dialysis unit, that were zeroed before each use. The participants were instructed to measure their weight using the same scale. It was computed as the average of the recordings over a 4-week period.

### *Data Analysis*

The collected data were analyzed using SPSS version 26 software. To ensure the accuracy of the data, the collected data were checked by two independent researchers after being entered into the software and the range of scores was also checked by the researchers. Descriptive statistics, comprising frequencies (percentage) and mean (SD), were utilized to portray baseline characteristics. The Kolmogorov-Smirnov test was used to assess the normality of the data. Dependent-samples t-test, independent-samples t-test, chi-square test, and repeated measures ANOVA were used for within-group and between-group analyses. A $P$ value < 0.05 was considered statistically significant.

## Results

### *Participants' Characteristics*

A total of 98 patients completed the protocol (completion rate, 96.07%). Four participants died of cardiovascular causes during the study (two from the intervention group and two from the control group). The intervention had no adverse effects. The majority of participants in the individualized education group (n = 25 [51.02%]) attended 4 educational sessions.

The mean age of participants in the control and intervention groups was 59.72(13.24) and 58.54 (11.13) years, respectively. The demographics of the participants are shown in Table 1. The analysis showed that the two groups were comparable in terms of demographic characteristics, the etiology of the disease, and the duration of HD (Table 1).

### *Effects of Individualized Education on HD Adequacy (Kt/V)*

The results of the independent-sample t-test showed that there was no statistically significant difference in the mean score of HD adequacy between the two groups before the intervention (Mean Difference [MD]; 95% confidence interval [CI]: 0.02; -0.06 to 0.11, $P = 0.71$). However, a statistically significant difference was found immediately and three months after the intervention between the two groups (MD (95% CI): -0.06 (-0.10 to -0.01), $P = 0.01$, MD (95% CI): -0.05 (-0.09 to -0.001), $P = 0.04$, respectively) with a total effect size of 0.67. The results of repeated measures ANOVA also indicated a significant increase in the mean score of the HD adequacy at two-time points of measurement ($T_2$ and $T_3$) in the intervention group compared to the control group ($P = 0.001$) (Table 2 and Figure 2). However, according to the within-group analysis, the mean score of HD adequacy in the control group showed no significant differences between the three time points ($T_1$, $T_2$, and $T_3$) ($P = 0.65$).

### *Effects of Individualized Education on IDWG*

The results showed that the mean scores of IDWG were not significantly different between the two groups before the intervention (MD (95% CI): 0.09 (-0.25 to 0.44), $P = 0.68$). Within-group analysis showed that the mean scores of IDWG in the intervention group showed a

**Table 1.** Homogeneity of baseline characteristics between the groups

| Variables | Control group (n=51) | Intervention group (n=51) | t or $\chi^2$ | *P* value |
|---|---|---|---|---|
| Gender, No. (%) | | | | |
| Male | 39 (76.47%) | 33 (64.71%) | | |
| Female | 12 (23.53%) | 18 (35.29%) | 1.70 | 0.19 |
| Education level, No. (%) | | | | |
| Illiterate | 8 (15.69%) | 11 (21.57%) | | |
| ≤High school diploma | 36 (70.59%) | 31 (60.78%) | 1.09 | 0.57 |
| College | 7 (13.72%) | 9 (17.65%) | | |
| Marital status, No. (%) | | | | |
| Married | 42 (82.35%) | 41 (80.39%) | | |
| Single | 4 (7.8%) | 3 (5.9%) | 0.11 | 0.76 |
| Divorced | 1 (2.0%) | 3 (5.9%) | | |
| Widowed | 4 (7.8%) | 4 (7.8%) | | |
| Living place, No. (%) | | | | |
| City | 46 (90.20%) | 45 (88.24%) | 0.10 | 0.75 |
| Village | 5 (9.80%) | 6 (11.76%) | | |
| Occupation, No. (%) | | | | |
| Public employee | 1 (2%) | 3 (5.9%) | | |
| Worker | 0 (0%) | 2 (3.9%) | | |
| Homemaker | 12 (23.5%) | 16 (31.4%) | 9.48 | 0.09 |
| Freelancer | 9 (17.6%) | 5 (9.8%) | | |
| Retired | 21 (41.2%) | 11 (21.6%) | | |
| Jobless | 8 (15.7%) | 14 (27.5%) | | |
| Income, No. (%) | | | | |
| Low | 8 (15.69%) | 8 (15.69%) | | |
| Moderate | 34 (66.66%) | 36 (70.59%) | 0.30 | 0.85 |
| High | 9 (7.65%) | 7 (13.72%) | | |
| Etiology, No. (%) | | | | |
| Diabetes | 3 (5.88%) | 7 (13.72%) | | |
| Hypertension | 20 (39.22%) | 13 (25.49%) | 5.35 | 0.25 |
| Diabetes & Hypertension | 18 (35.29%) | 15 (29.41%) | | |
| Others | 10 (19.61%) | 15 (29.41%) | | |
| Age (y), Mean (SD) | 59.72 (13.24) | 58.54 (11.13) | 0.48 | 0.14 |
| Duration of hemodialysis (y) | 3.84 (3.88) | 3.51 (2.76) | 0.50 | 0.65 |

significant decrease at two time points of measurement ($T_2$ and $T_3$) compared to the $T_1$ point (MD (95% CI): 0.38 (0.05 to 0.72), $P=0.02$, MD (95% CI): 0.35 (0.02 to 0.68), $P=0.03$, respectively) with a total effect size of 0.66. However, there were no significant differences between the three time points ($T_1$, $T_2$, $T_3$) within the control group ($P=0.03$). The results of repeated measures ANOVA indicated a significant difference in the mean score of IDWG at two time points of measurement ($T_2$ and $T_3$) in the intervention group compared to the control group ($P=0.001$) (Table 2 and Figure 2).

## Discussion

This study investigated the effect of individualized education on HD adequacy and IDWG among HD patients. Our results showed that individualized education helps patients to increase HD adequacy and decrease IDWG, which is important to improve quality of life.

Kt/V and IDWG are used as measures of dialysis quality and patients adherence on fluid restriction.[15,16] Individualized education can enhance patients' adaptability and self-regulation skills, encouraging them to follow medical staff guidance and improve compliance.[52,53]

According to the results, providing individualized education significantly increased Kt/V in HD patients. BUN, which is used for calculation of dialysis adequacy, is influenced by the protein intake and patients' dietary. According to the KDOQI guidelines, the dialysis adequacy value should be maintained at least 1.2 or higher. This value is an important indicator of HD adequacy.[48] According the previous studies, higher HD adequacy is associated with better health quality and reduced mortality of patients on HD.[54,55] Similar to our study, Suk et al showed that video education increased the mean score of Kt/V.[56] Baraz et al[57] conducted a study to assess the effect of self-care education based on Orem theory on physical problems in HD patients. The study revealed that educational program successfully decreased blood urea, creatinine, and IDWG. Likewise, Dsouza et al showed that a significant enhancement in knowledge of fluid and nutritional adherence by providing an educational/ cognitive intervention.[58]

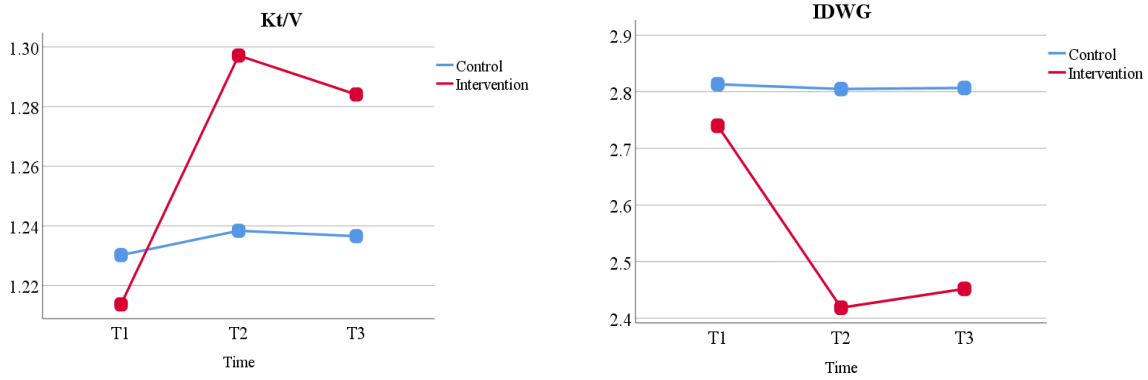


**Figure 2.** Changes in hemodialysis adequacy (Kt/V) and IDWG between the two groups across time. IDWG, Interdialytic weight gain; $T_1$, pre-test; $T_2$, immediately after the intervention; $T_3$, three months after the intervention

**Table 2.** Comparison of the mean score of the hemodialysis adequacy and IDWG between the study groups

| Variables | Time of measurement | Mean (SD) | | Mean difference (95% CI) | *P* value |
|---|---|---|---|---|---|
| | | Control group (n=49) | Intervention group (n=49) | | |
| Kt/V | $T_1$ | 1.23 (0.03) | 1.21 (0.03) | 0.02 (-0.06 to 0.11) | 0.71* |
| | $T_2$ | 1.24 (0.02) | 1.30 (0.02) | -0.06 (-0.10 to -0.01) | 0.01** |
| | $T_3$ | 1.23 (0.02) | 1.28 (0.02) | -0.05 (-0.09 to -0.001) | 0.04** |
| *P* value | | 0.65*** | 0.001*** | | |
| IDWG | $T_1$ | 2.83 (0.80) | 2.74 (0.96) | 0.09 (-0.25 to 0.44) | 0.68* |
| | $T_2$ | 2.80 (0.82) | 2.42 (0.85) | 0.38 (0.05 to 0.72) | 0.02** |
| | $T_3$ | 2.80 (0.81) | 2.45 (0.82) | 0.35 (0.02 to 0.68) | 0.03** |
| *P* value | | 0.32*** | 0.001*** | | |

SD, Standard deviation; CI, Confidence interval; IDWG, Interdialytic weight gain; $T_1$, pre-test; $T_2$, immediately after the intervention; $T_3$, three months after the intervention.
*Independent sample t-test; ** ANOVA test; *** Repeated measures ANOVA.

Several studies have been carried out to assess the effect of educational interventions on biochemical parameters, Kt/V, and IDWG showing positive or partially positive outcomes.[9,38,58-61] Cukor et al utilized cognitive behavior therapy and education to decrease IDWG,[59] and Cho[60] implemented a health contract intervention, resulting a partially positive outcome. Howren et al used the self-regulation theory to improve IDWG.[9] Hou et al utilized rational emotive behavior therapy to improve blood pressure and IDWG.[61] Dsouza et al implemented educational intervention on HD patients and found an improvement in the patients' adherence to fluid and nutrition restrictions.[58] In a study by Başer and Mollaoğlu in Turkey, a reduction in IDWG was found following a patient education program in which educational topics were explained verbally, receiving feedback and answering each patient's questions.[38] It seems that empowering patients through personalized education appears to be more effective than standardized, routine education approaches. This may be because during routine care, patients often had limited initiative in acquiring relevant knowledge and were passive in the learning process. In contrast, the use of individualized education can more actively engage patients in the learning process. With this approach, patients are fully informed about the importance of acquiring relevant knowledge, which can motivate them to learn and actively participate in managing their self-care. Similarly, Arslan and Bekar Tunçalp reported reductions in fluid volume after the training given by the researcher-nurse regarding diet and fluid restriction.[62] Valsaraj et al in India indicated that cognitive behavior therapy by nurses leads to a significant decrease in IDWG.[63] Baraz and colleagues' study found that participants' average IDWG decreased following training sessions delivered with videotapes or verbally for each patient.[64]

Also, educational/cognitive, counseling/behavioral, and psychological/affective interventions significantly reduce IDWG in chronic HD patients.[11] Fauzi and Oktaviani indicated that repeated HD diet education programs have been effective in enhancing dietary knowledge and self-care adherence, leading to improvements in IDWG.[65] Furthermore, training sessions based on self-enrichment program have positively impacted adherence to diet and fluid restrictions, resulting in decreased IDWG and improved fluid control in HD patients, emphasizing the importance of patient education in managing the disease effectively.[66]

## Strengths and Limitations

There were several limitations in our study. Due to the nature of the intervention, the trial could not be blind for educator. Another limitation of this study was the short-term follow-up period. Moreover, this study was conducted at a single center. Therefore, conducting a multicenter trial with a long-term follow-up is recommended in future studies.

## Conclusion

The results showed that individualized education could improve HD adequacy and reduce patients' IDWG. Individualized education highlights the important role of patients in self-management and self-care. Moreover, developing an interdisciplinary team consisting of nephrology nurses and nephrologists to tailor the patients' education could lead to better outcomes. In conclusion, it is recommended to make changes in patient education strategies and utilize effective educational methods by considering each patient's needs and preferences. Furthermore, individualized education should begin at the early stages of CKD before HD.

### Acknowledgments

This study is related to the MSN thesis project of the first author. We thank all the patients who participated in this research. Also, we thank the Tabriz University of Medical Sciences.

### Authors' Contribution

**Conceptualization:** Seyyede Leila Sajjadi, Mansour Ghafourifard, Hamid Tayebi Khosroshahi.
**Data curation:** Seyyede Leila Sajjadi, Mansour Ghafourifard,

## Research Highlights

**What is the current knowledge?**

- The educational materials given to patients do not take into account the differences in patients' characteristics and preferences, as they are presented to all patients using the same format and wording.
- There is an ongoing emphasis on addressing each patient's preferences and requirements in nursing care.

**What is new here?**

- Individualized education improved HD adequacy and significantly reduced patients' IDWG compared to the control group.
- Developing an interdisciplinary team consisting of nephrology nurses and nephrologists to tailor the patients' education could lead to better patients' outcomes.

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### Competing Interests

The authors declare that they have no competing interests.

### Data Availability Statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

### Ethical Approval

Ethics approval was obtained from the Research Ethics Committee of Tabriz University of Medical Sciences (Code: IR.TBZMED.REC.1401.960). This study was registered at the Iranian Registry of Clinical Trials (identifier: IRCT20221031056352N1). Written informed consent was obtained from all participants. The patients assured that the collected information will be confidential and will only be used for research and the results of the study will be provided to them.

### Funding

Tabriz University of Medical Sciences funded this study and provided financial support (code: 1401.960).

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