



Observation of the effect of closed-loop health management based on an internet platform in patients with peritoneal dialysis: a randomized trial

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Background: Peritoneal dialysis (PD) uses the peritoneum as the dialysis membrane. PD is a simple operation for self-treatment at home, and has become the preferred option for most patients with chronic renal failure (CRF). This study aimed to explore the effect of a closed-loop health management (CLHM) system based on an Internet platform in patients with PD.

Methods: A total of 102 patients with PD who were admitted to Xuzhou Central Hospital from May 2019 to May 2020 were selected and randomly divided into two groups ($n=51$). The control group received routine care, and in the observation group a CLHM based on an Internet platform was introduced. The incidence of complications and changes in disease knowledge, nutritional status, quality of life (QOL) before and after the intervention were compared between groups.

Results: The incidences of peritonitis, tunnel entrance infection, poor drainage, and hypokalemia in the observation group were lower than in the control group ($P<0.05$). The disease-related knowledge mastery scores of the observation group were higher than those in the control group after 3 months of intervention ($P<0.05$). Malnutrition-inflammation score (MIS) and serum creatinine (SCr) in the observation group were lower than in the control group after 3 months of intervention ($P<0.05$), and the body mass index (BMI), albumin (ALB), and hemoglobin (Hb) of the observation group were higher than those of the control group ($P<0.05$). The QOL scores of the observation group were higher than those of the control group after 3 months of intervention ($P<0.05$).

Conclusions: The application of a CLHM system based on an Internet platform to patients with PD could effectively reduce complications, and improve patients' knowledge of disease, nutritional status and QOL.

Trial Registration: ClinicalTrials.gov Identifier: ChiCTR2100046122.

Keywords: Internet platform; closed-loop health management (CLHM); peritoneal dialysis (PD); complications; quality of life (QOL)

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Introduction

Chronic renal failure (CRF) is chronic progressive renal parenchymal damage with a varying etiology. It clinically mainly manifests as water-electrolyte, acid-base balance disorders, and metabolic disorders of fat, carbohydrates,

amino acids, proteins (1). Most patients have CRF accompanied by other organ dysfunction (1). Peritoneal dialysis (PD) uses the peritoneum as the dialysis membrane. The basic principle is to use the difference in concentration gradient between the dialysate and blood to continuously

update the PD fluid through osmosis and diffusion to achieve the purpose of removing metabolites and correcting water and electrolyte disorders (2). PD is simple operation for self-treatment at home, and has become the preferred option for most patients with CRF (3). During their home treatment, patients' mastery of the PD procedure and related knowledge directly affects the treatment effect and the risk of related complications, so health management is particularly important (4). Compared with traditional communication methods, Internet platforms have unique convenience and efficiency (5). In this study, patients with PD were introduced to a closed-loop health management (CLHM) system based on an Internet platform, and the effect on the incidence of complications, disease knowledge, nutritional status and quality of life (QOL) was examined. We present the following article in accordance with the CONSORT reporting checklist (available at <https://dx.doi.org/10.21037/apm-21-1402>).

Methods

Patient selection

This paper was a comparative study of Two Parallel intervention measures of patients with PD, and allocation ratio is 1:1. A total of 102 patients with PD who were admitted to Xuzhou Central Hospital from May 2019 to May 2020 were selected and randomly divided into two groups of 51 cases. Patients met the following criteria to be eligible to participate in this study: (I) met the CRF diagnostic criteria of "Clinical Diagnosis and Treatment Guidelines-Nephrology Section" (6), and glomerular filtration rate $<15 \text{ mL}/(\text{min}\cdot 1.73 \text{ m}^2)$; (II) stable condition and no contraindications for PD; (III) duration of PD ≥ 3 months; (IV) aged ≥ 18 years; and (V) patient or family members voluntarily signed informed consent. Conversely, patients were excluded from the study if they met any of the exclusion criteria: (I) mental disorder; (II) communication difficulties and unable to use WeChat, QQ and other software; (III) severe heart or lung infection; and (IV) treatment interrupted or transferred to using the other kidney instead of treatment. The study was approved by the Ethics Committee of Xuzhou Central Hospital (No. KYLC2019005), and conducted in accordance with the Declaration of Helsinki (as revised in 2013). All patients provided informed consent.

Interventions

The control group received routine care, consisting of routine treatment and care during hospitalization, including medications, health education, psychological care etc., guidance in the PD method 1 day before discharge, and advised patients to follow up on time.

The observation group was introduced to a CLHM system based on an Internet platform on the basis of the control group, as follows.

- (I) Establish the Internet platform. The platform included patient intelligent terminals and hospital server terminals, providing access to electronic medical records, online medical consultation, health management and so on. The patient or his family members accessed the health management system through a mobile phone.
- (II) Set up a health management team, consisting of 1 chief physician, 1 deputy chief physician, 2 attending physicians, 4 deputy chief nurses, and 4 specialist nurses. Team members discussed and formulated the health management plans, organized relevant knowledge training for intervention personnel regularly, and were committed to providing patients with high-quality and efficient medical services.
- (III) CLHM: (i) in-hospital health management. (a) Establish an electronic medical record file comprising basic information such as patient age, sex, education level, and recorded blood glucose, blood pressure, blood routine and other inspection index data. (b) Health assessment: patients were assessed before and after catheter placement, and PD specialist nurses formulated personalized nursing plans to help strengthen confidence and courage to manage the disease. (c) Health education: the specialist nurses were responsible for educational activities, including personal guidance, distribution of health brochures, group lectures, etc. The education content included dialysis principles, operating procedures, disinfection and cleaning, abnormal handling, etc. (d) Registered members: the health management team members assisted patients or their family members in logging in with their mobile phones, registering server ports, uploading electronic case files, and telling patients

or their family members how to use them. (ii) Out-of-hospital health management. Out-of-hospital health management adopted the self-management model of “active-passive-active”. Intervention staff regularly followed up the patients to understand their dialysis status, vital signs, 24-hour urine output, psychological status, laboratory test results, etc. Based on the above information, the intervention staff assessed the patient’s health and nutrition status, provided health guidance via phone calls, text messages or WeChat, and asked the patients or their family members to watch instructional videos on the health management system, and regularly track, monitor, and feed back the results of the intervention. In addition, the intervention personnel responded to patients’ related health consultations in a timely fashion.

Evaluation indexes

Incidence of complications

The number of patients with peritonitis, tunnel entrance infection, poor drainage, and hypokalemia in the two groups during the intervention period were counted, and the incidence of each was calculated.

Disease knowledge

An in-hospital-designed PD questionnaire was used to evaluate the relevant knowledge mastery of the two groups before and after the intervention. The questionnaire included three dimensions: medication knowledge and disease monitoring, operation technology and complication management, diet and water and salt management, each with a score of 0–100. A higher the score indicated better knowledge.

Nutritional status

The malnutrition-inflammation score (MIS) was used to evaluate the nutritional status of the two groups before and after the intervention, the body mass index (BMI) was measured and calculated, and the serum creatinine (SCr), albumin (ALB) and hemoglobin (Hb) levels were recorded.

QOL

A short-form health survey (SF-36) (7) was used to assess the QOL of the two groups before and 3 months after the intervention. SF-36 includes 8 dimensions of physiological function, physiological duty, emotional function, social

function, physical pain, mental health, vitality, and general health. Each dimension scores 0–100 points, and a higher score indicates a higher quality of the corresponding dimension.

Incidence of complications and QOL scores were the primary outcomes we analyzed in this study, while Disease knowledge and Nutritional status were the secondary outcomes.

Statistical analysis

The statistical analysis in this study was performed using SPSS 20.0 (SPSS Inc., Chicago, IL, USA). Disease knowledge, nutritional status and QOL were expressed as mean \pm standard deviation ($\bar{x}\pm s$), and compared using 2-tailed *t*-tests. The incidence of complications was expressed by rates and percentages, and compared using the chi-squared (χ^2) test or rank-sum test. A P value <0.05 was considered statistically significant.

Results

General information

This study included 102 patients with PD from from May 2019 to May 2020. The duration of continuous intervention for both participant groups was 3 months. The control group included 28 males and 23 females, aged from 23 to 71 years old (average 42.43 ± 9.59 years); primary diseases: 25 cases of CRF, 12 cases of diabetic nephropathy, 3 cases of chronic pyelonephritis, 7 cases of uremia, 4 others; education level: 10 cases of elementary school, 15 cases of junior high school, 26 cases of high school and above. The observation group included 26 males and 25 females, aged from 25 to 69 years old (average 41.79 ± 9.46 years); primary diseases: 24 cases of CRF, 11 cases of diabetic nephropathy, 4 cases of chronic pyelonephritis, 9 cases of uremia, 3 others; education level: 11 cases of elementary school, 16 cases of junior high school, 24 cases of high school and above. *Figure 1* for details.

There were no statistically significant differences between the two groups of patients in general data such as sex, age, education level, and primary disease ($P>0.05$). See *Table 1* for details.

Incidence of complications

The observation group had 1 case of peritonitis, 2 cases of

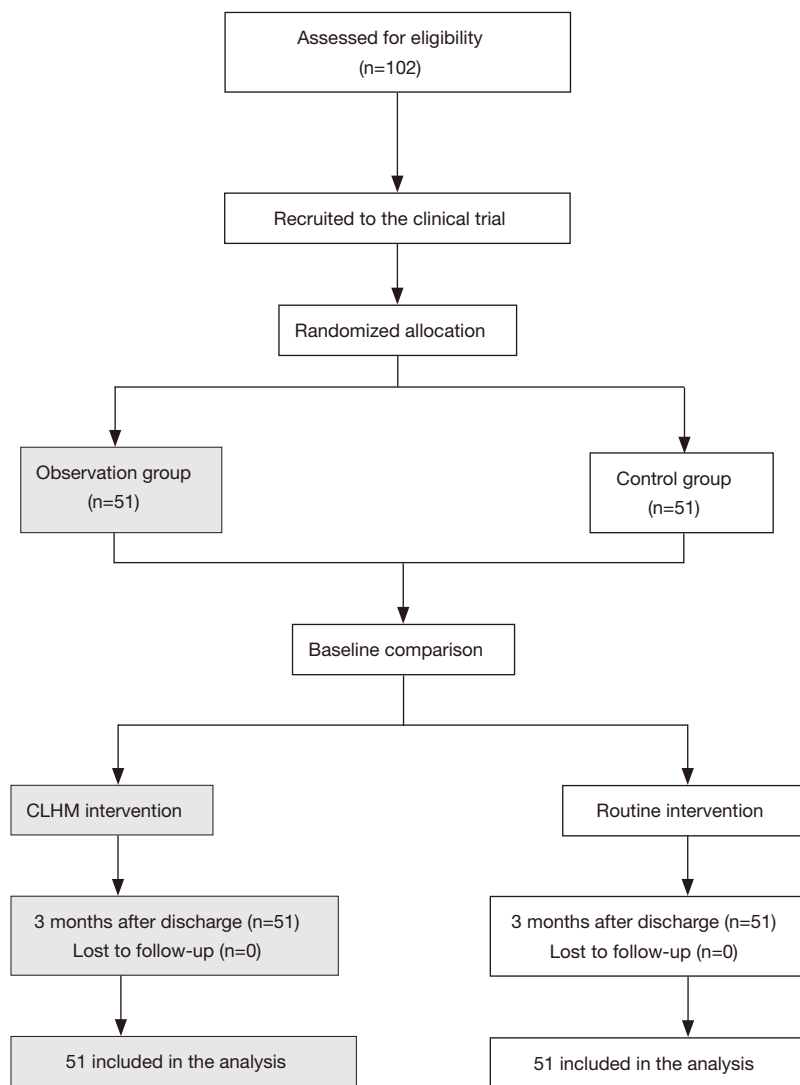


Figure 1 Study flow chart. CLHM, closed-loop health management.

tunnel entrance infection, 3 cases of poor drainage, and 7 cases of hypokalemia, while the control group had 9 cases of peritonitis, 11 cases of tunnel entrance infection, 12 cases of poor drainage, and 16 cases of hypokalemia. The incidence of peritonitis, tunnel opening infection, poor drainage, and hypokalemia in the observation group were lower than in the control group ($\chi^2=7.096, 7.141, 6.331, 4.547$; $P=0.008, 0.008, 0.012, 0.033$, respectively). See *Table 2* for details.

Disease knowledge

Before the intervention, there were no significant differences in the scores of the observation group for medication knowledge and disease monitoring, operation

techniques and complication management, diet and water and salt management compared with the control group ($t=1.450, 1.067, 0.987$; $P=0.150, 0.289, 0.326$, respectively). After the intervention, the scores of the observation group were higher for each of the three dimensions than those of the control group ($t=9.416, 8.199, 7.997$; $P=0.000, 0.000, 0.000$, respectively). See *Table 3* for details.

Nutritional status

Before the intervention, there were no significant differences in MIS score, BMI, SCr, ALB, and Hb between the observation and control groups ($t=0.658, 0.907, 0.280, 0.510, 0.501$; $P=0.512, 0.367, 0.780, 0.611,$

Table 1 Comparison of baseline information between the two groups (n, %)

| Variable | Control group (n=51) | Observation group (n=51) | Statistic value | P value |
|-------------------------------|----------------------|--------------------------|-----------------|---------|
| Age ($\bar{x}\pm s$, years) | 42.43 \pm 9.59 | 41.79 \pm 9.46 | $t=0.349$ | 0.727 |
| Sex | | | $\chi^2=0.157$ | 0.692 |
| Male | 28 (54.90) | 26 (50.98) | | |
| Female | 23 (45.09) | 25 (49.01) | | |
| Education level | | | $\chi^2=0.160$ | 0.923 |
| Elementary school | 10 (19.60) | 11 (21.57) | | |
| Junior high school | 15 (29.41) | 16 (31.37) | | |
| High school and above | 26 (50.98) | 24 (47.06) | | |
| Primary disease | | | $\chi^2=0.446$ | 0.931 |
| CRF | 25 (49.02) | 24 (47.06) | | |
| Diabetic nephropathy | 12 (23.53) | 11 (21.57) | | |
| Chronic pyelonephritis | 3 (5.88) | 4 (7.84) | | |
| Uremia | 7 (13.73) | 9 (17.65) | | |
| Other | 4 (7.84) | 3 (5.88) | | |

CRF, chronic renal failure.

Table 2 Comparison of the incidence of complications between the two groups (n, %)

| Group | Peritonitis | Tunnel entrance infection | Poor drainage | Hypokalemia |
|--------------------------|-------------|---------------------------|---------------|-------------|
| Control group (n=51) | 9 (17.65) | 11 (21.57) | 12 (23.53) | 16 (31.37) |
| Observation group (n=51) | 1 (1.96) | 2 (3.92) | 3 (5.88) | 7 (13.73) |
| χ^2 value | 7.096 | 7.141 | 6.331 | 4.547 |
| P value | 0.008 | 0.008 | 0.012 | 0.033 |

Table 3 Comparison of disease knowledge mastery between the two groups ($\bar{x}\pm s$, points)

| Time | Group | Medication knowledge and disease monitoring | Operation techniques and complication management | Diet and water and salt management |
|------------------------|--------------------------|---|--|------------------------------------|
| Before intervention | Control group (n=51) | 60.87 \pm 5.73 | 57.64 \pm 6.41 | 61.48 \pm 5.97 |
| | Observation group (n=51) | 59.26 \pm 5.48 | 56.29 \pm 6.37 | 60.37 \pm 5.37 |
| | t value | 1.450 | 1.067 | 0.987 |
| | P value | 0.150 | 0.289 | 0.326 |
| After the intervention | Control group (n=51) | 70.46 \pm 5.48 | 67.82 \pm 6.87 | 70.38 \pm 7.03 |
| | Observation group (n=51) | 81.42 \pm 6.25 | 79.48 \pm 7.48 | 81.43 \pm 6.96 |
| | t value | 9.416 | 8.199 | 7.977 |
| | P value | 0.000 | 0.000 | 0.000 |

Table 4 Comparison of nutritional status between the two groups before and after intervention ($\bar{x}\pm s$)

| Time | Group | MIS (points) | BMI (kg/m ²) | SCr (μ mol/L) | ALB (g/L) | Hb (g/L) |
|------------------------|--------------------------|------------------|--------------------------|---------------------|------------------|-------------------|
| Before intervention | Control group (n=51) | 15.63 \pm 2.62 | 20.48 \pm 2.64 | 916.47 \pm 105.63 | 35.75 \pm 4.46 | 96.46 \pm 8.69 |
| | Observation group (n=51) | 15.28 \pm 2.75 | 20.94 \pm 2.48 | 910.53 \pm 108.26 | 35.29 \pm 4.65 | 95.58 \pm 9.04 |
| | t value | 0.658 | 0.907 | 0.280 | 0.510 | 0.501 |
| | P value | 0.512 | 0.367 | 0.780 | 0.611 | 0.617 |
| After the intervention | Control group (n=51) | 12.87 \pm 2.17 | 21.04 \pm 1.98 | 843.68 \pm 94.63 | 36.86 \pm 2.38 | 91.39 \pm 10.04 |
| | Observation group (n=51) | 8.58 \pm 1.21 | 22.98 \pm 1.76 | 601.46 \pm 87.36 | 41.37 \pm 2.47 | 101.46 \pm 9.36 |
| | t value | 12.331 | 5.230 | 13.431 | 9.390 | 5.239 |
| | P value | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |

MIS, malnutrition-inflammation score; BMI, body mass index; SCr, serum creatinine; ALB, albumin; Hb, hemoglobin.

0.617, respectively). After the intervention, the MIS score and SCr of the observation group were lower than those of the control group ($t=12.331$, 13.431 ; $P=0.000$, 0.000 , respectively), and the BMI, ALB, and Hb of the observation group were higher than those of the control group ($t=5.230$, 9.390 , 5.239 ; $P=0.000$, 0.000 , 0.000 , respectively). See *Table 4* for details.

QOL

Before the intervention, there were no significant differences in the scores of the observation group for physiological function, physiological duty, emotional function, social function, physical pain, mental health, vitality, and general health compared with the control group ($t=0.679$, 0.870 , 0.411 , 0.517 , 0.485 , 0.458 , 0.512 , 0.485 ; $P=0.499$, 0.386 , 0.682 , 0.606 , 0.629 , 0.648 , 0.609 , 0.629 , respectively). After the intervention, the scores of the observation group were higher than those of the control group ($t=6.586$, 5.204 , 5.471 , 4.940 , 5.946 , 7.741 , 6.586 , 5.565 ; $P=0.000$, 0.000 , 0.000 , 0.000 , 0.000 , 0.000 , 0.000 , 0.000 , respectively). See *Table 5* for details.

Discussion

Efficacy of CLHM based on an Internet platform for the provision of good medical services for patients with PD

Today's society is a networked age; information technology promotes revolutionary changes in the medical field, and the traditional medical service model is shifting to an

information model (8). Health management comprises establishing personal files and recording relevant test results, and professionals conduct health assessments and give health guidance (9). A CLHM system emphasizes a virtuous circle, controlling goals throughout the process, and carrying out effective tracking, feedback, analysis and continuous improvement (10). Patients with PD require skills in long-term home treatment and self-management. The patient's mastery of dialysis and related knowledge is directly related to the treatment effect. Because it is difficult to ensure comprehensive education in the short-term hospitalization period, establishing a communication bridge between the patient and the hospital is very important (11). Currently, the Internet is gradually replacing traditional follow-up methods and becoming the main platform for management of chronic diseases and home treatment guidance (12).

Efficacy of CLHM based on an Internet platform for improving the self-management ability of patients with PD

In this study, the incidences of peritonitis, tunnel opening infection, poor drainage, and hypokalemia in the observation group were lower than those in the control group ($P<0.05$). This result showed that CLHM based on an Internet platform could effectively reduce the occurrence of complications in PD patients. The reason may be that the intervention staff can regularly track, monitor, and feed back the patient's status through the health management system, which has the advantage of adjusting the care plan

Table 5 Comparison of quality of life between the two groups before and after intervention ($\bar{x}\pm s$, points)

| Time | Group | Physiological function | Physiological duty | Emotional function | Social function | Physical pain | Mental health | Vitality | General health |
|------------------------|--------------------------|------------------------|--------------------|--------------------|-----------------|---------------|---------------|-------------|----------------|
| Before intervention | Control group (n=51) | 58.37±9.57 | 55.93±9.62 | 50.64±10.36 | 49.62±9.55 | 51.36±10.47 | 48.63±9.57 | 50.36±10.57 | 52.58±10.47 |
| | Observation group (n=51) | 59.73±10.63 | 54.28±9.53 | 51.49±10.53 | 50.62±9.97 | 50.38±9.94 | 49.51±9.85 | 51.39±9.71 | 53.59±10.57 |
| | t value | 0.679 | 0.870 | 0.411 | 0.517 | 0.485 | 0.458 | 0.512 | 0.485 |
| | P value | 0.499 | 0.386 | 0.682 | 0.606 | 0.629 | 0.648 | 0.609 | 0.629 |
| After the intervention | Control group (n=51) | 65.72±10.35 | 64.87±9.63 | 67.52±9.61 | 71.29±9.35 | 65.39±9.28 | 65.35±10.47 | 65.28±10.57 | 69.38±9.86 |
| | Observation group (n=51) | 78.72±9.57 | 75.29±10.57 | 78.38±10.42 | 80.52±9.52 | 76.43±9.47 | 81.47±10.56 | 78.43±9.57 | 80.53±10.37 |
| | t value | 6.586 | 5.204 | 5.471 | 4.940 | 5.946 | 7.741 | 6.586 | 5.565 |
| | P value | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |

at any time when encountering special problems (13). At the same time, patients can conduct online consultations to solve problems in real-time, avoid blind care, and reduce a series of complications caused by incorrect operations (14). In addition, patients can learn or refresh their dialysis-related knowledge anytime and anywhere through the mobile phone login system, which can promote learning enthusiasm to a certain extent (15). In the study, the scores of the observation group for medication knowledge and disease monitoring, operation techniques and complication management, diet and water and salt management were higher than those of the control group after 3 months of intervention ($P<0.05$). This was further proof that a CLHM based on an Internet platform could significantly improve the disease knowledge of PD patients.

Efficacy of CLHM based on an Internet platform for improving QOL of PD patients

In this study, the MIS and SCr of the observation group were lower than in the control group after 3 months of intervention ($P<0.05$), and the BMI, ALB, and Hb were higher than those of the control group ($P<0.05$). This finding suggested that CLHM based on an Internet platform effectively improved the nutritional status of the PD patients and promoted physical recovery (16). A good physiological status is the basis and prerequisite for all activities (17). PD patients are not only troubled by the disease itself, but also the pain, psychological pressure, and economic burden caused by the disease, reducing their QOL (18,19). Through the intervention of the health management system, patients with PD achieved significant results in terms of complications and nutritional status. In this study, the scores of physiological function, physiological duty, emotional function, social function, physical pain, mental health, vitality, and general health of the observation group after the intervention were higher than those of the control group ($P<0.05$). It could be seen that a CLHM system based on an Internet platform can effectively improve the QOL of PD patients (20).

Conclusions

The application of a CLHM system based on an Internet platform for patients with PD effectively reduced complications, and improved patients' knowledge of disease, their nutritional status and QOL.

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Footnote

Reporting Checklist: The authors have completed the CONSORT reporting checklist. Available at <https://dx.doi.org/10.21037/apm-21-1402>

Trial Protocol: Available at <https://dx.doi.org/10.21037/apm-21-1402>

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://dx.doi.org/10.21037/apm-21-1402>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work, including ensuring that questions related to the accuracy or integrity of any part of the work were appropriately investigated and resolved. The study was approved by the Ethics Committee of Xuzhou Central Hospital (No. KYLC2019005), and conducted in accordance with the Declaration of Helsinki (as revised in 2013). All patients provided informed consent.

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