STUDY PROTOCOL

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Management of volume load for patients undergoing hemodialysis via WeChat and home monitoring in China: a protocol for a cluster-randomized trial

Xiaocui Wang^{1,2†}, Bonan Yan^{1,2†}, Shipeng Zhang^{1,2†}, Yuanke Zhou¹, Qinxiu Zhang^{1,2*} and Xueying Li^{1,2*}

Abstract

Background Volume overload is a major mortality risk in hemodialysis (HD) patients. Drug therapy and conventional dialysis limitations underscore the importance of managing volume load through effective lifestyle interventions. In this regard, WeChat, along with its built-in self-monitoring function, has demonstrated considerable potential for application. WeChat, a versatile social media platform in China, integrating Facebook, WhatsApp, Twitter, and PayPal functionalities, shows potential in managing volume load, especially when paired with home monitoring. This method may also reduce adverse events and improve patient outcomes.

Method The study will be conducted at the Hemodialysis Center of the Hospital of Chengdu University of Traditional Chinese Medicine, recruiting 135 participants. All patients will be cluster randomly assigned to three group according to their HD schedules. The control group will receive standard care. The WeChat group will receive volume load management via WeChat message in addition to standard care. The home monitoring-feedback group will be required to monitor their blood pressure and weight at home, and upload the number to WeChat subscription account "Health Dialysis" in addition to standard care and volume load management via WeChat message. Data will be collected during the baseline period, one, two, and three months after the intervention starts, and three months after the intervention ends to evaluate the effectiveness of this intervention measure.

Discussion This study aims to effectively manage the volume load of HD patients and enhance their quality of life through a combination of intervention methods utilizing the WeChat platform and home monitoring. If this intervention measure proves effective, it will not only provide empirical evidence for managing HD patients through the WeChat platform but also serve as a reference model for other HD centers in addressing patient volume load issues. What's more, if significant differences are observed between the results of the WeChat groups and the home

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monitoring-feedback group, this will further substantiate the importance and impact of home monitoring in volume load management.

Trial registration Clinical Trials.gov (NCT06333574). Registered 13 March 2024.

Keywords Hemodialysis, WeChat, Interdialytic weight gain, Home monitoring, Volume overload, Protocol

Background

In recent years, the prevalence of chronic kidney disease (CKD) has been steadily increasing. Since 1990, the prevalence of CKD has increased by 29.3% [1]. It is estimated that approximately 434.3 million people in the eastern, southern and south-eastern regions of Asia are affected by CKD [2]. Among these patients, approximately 10% will progress to end-stage kidney disease (ESKD), in which case patients rely on dialysis or kidney transplantation to sustain their lives, and about half of them choose to receive hemodialysis (HD) treatment. Chronic volume overload is a long-term and challenging problem for patients undergoing chronic HD treatment [3], with an estimated prevalence rate between 40 and 60%. This condition is also an important risk factor for all-cause mortality and cardiovascular death in HD patients [4].

Interdialytic weight gain (IDWG), as an important index to evaluate fluid retention and volume overload, objectively reflects the control of diet and fluid intake of patients during the HD interval [5]. Previous studies have demonstrated that IDWG is closely associated with adverse clinical outcomes, and is an independent predictor of all-cause and cardiovascular mortality in long-term HD patients. It is also an important predictor of mortality and hospitalization rates in patients who frequently receive HD treatment [6-8]. It is generally believed that %IDWG (calculated by dividing IDWG by dry weight) should be limited within the range of 3–4.5% [9]. Exceeding this range of %IDWG means additional dialysis is required, which not only reduces the patient's quality of life but also increases the burden on medical resources [10]. However, due to poor patient compliance and a lack of efficient self-management strategies, many patients find it difficult to achieve reasonable limits on the %IDWG. The limitations of medication and dialysis therapy further underscore the importance of lifestyle interventions such as dietary control and fluid intake restriction to effectively manage the volume load of HD patients. But proposed methods of dietary control, such as home-delivered meals, suffer from higher costs. Moreover, some studies have shown that dietary education and behavioral counseling are ineffective in reducing sodium intake and IDWG [11]. Therefore, it is of great significance to propose a low-cost and highly feasible lifestyle intervention for volume management.

Currently, the rapid advancement of communication network technology, particularly the high penetration

rate of the Internet, mobile phones, and other portable electronic devices, has significantly promoted the development of lifestyle interventions. There is emerging evidence that Internet-based lifestyle intervention can have a positive impact on people with chronic diseases at a lower cost [12]. And Sufficient evidence indicates that the application of lifestyle intervention strategies based on the Internet and mobile electronic devices in HD patients is both feasible and effective [13]. In China, WeChat, as one of the most popular social platforms, is highly valued for its practicality and widespread use [14]. WeChat has become an effective technological method of managing chronic diseases, widely used in the management of chronic diseases such as hypertension, diabetes and coronary heart disease [15]. And We believe that WeChat can also provide a new communication channel for medical professionals to share knowledge about HD and manage volume load in HD patients.

Home blood pressure (BP) monitoring is widely recommended as an economically effective and straightforward intervention for self-management of hypertension. Evidence indicates that home BP monitoring, particularly when supplemented with additional interventions such as remote monitoring, can result in reductions in BP levels [16]. For HD patients, home monitoring measures are particularly crucial [17]. Self-monitoring BP and weight at home can provide powerful data on fluid retention, help patients adjust the %IDWG to alleviate volume overload, and mitigate the risk of cardiovascular complications.

However, due to insufficient health literacy and low patient adherence, it is often challenging to ensure timely home monitoring of BP and weight. By integrating WeChat with home monitoring technology, healthcare professionals can effectively encourage patients to follow monitoring plans and improve their adherence. Meanwhile, utilizing the WeChat platform to widely disseminate knowledge related to HD is expected to enhance the self-efficacy and self-management abilities of HD patients. Multiple studies have confirmed the tremendous potential of WeChat and self-monitoring in lifestyle interventions [18]^{*} [19].

Nonetheless, the feasibility and effectiveness of combining WeChat with home monitoring for interventions to manage volume load in HD patients still lack systematic research. Therefore, this study aims to evaluate the

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feasibility and effectiveness of this combined intervention measure.

Methods and analyses

Hypothesis

Our research hypothesis posits that HD patients who manage volume load via the integration of WeChat and home monitoring are more likely to exhibit the following characteristics:

H1: Compared with HD patients receiving standard care, they will experience a reduction in the %IDWG and pre-dialysis systolic BP, along with improve compliance. This is our primary and key hypothesis.

H2: Compared with HD patients receiving standard care, they will exhibit improved HD adequacy.

H3: Compared with HD patients receiving standard care, they will demonstrate enhancements in dialysis-related quality of life, anxiety, depression, and nutritional status, and relief from dialysis-related symptoms.

H4: Compared with HD patients receiving standard care, they will have a reduced likelihood of experiencing adverse events during HD.

Trial design

This study is a cluster randomized controlled trial designed to include 135 patients and will be sequentially conducted as follows: enrolment according to inclusion and exclusion criteria, randomization, follow-up visit, and assessment. (Fig. 1 Study protocol flowchart of managing volume load for patients undergoing hemodialysis via WeChat and home monitoring)

Study population

Sample size

The determination of the sample size was calculated using G*Power 3.1 software. The effect size of 0.27 was based on a randomized controlled trial on psychosocial interventions thirst and interdialytic weight gain in patients on chronic hemodialysis [20]. To ensure that the experiment has 80% statistical power $(1-\beta)$ and maintains an effect size of 0.27 at a significance level (α) of 0.1, the calculation results indicate that at least 111 participants are needed. However, we decided to recruit 135 participants (at least 45 patients in each group), considering a 20% withdrawal rate.

Recruitment

The target participants of this study are maintenance HD patients at the Hemodialysis Center of Hospital of Chengdu University of Traditional Chinese Medicine. During the recruitment phase, a combination of online advertising and offline printed promotional materials will be utilized to attract potential research subjects. We will extensively promote the management skills of volume

load through WeChat platform, WeChat subscription accounts, and posters within the hospital. Interested potential participants can register and sign up at the HD center via WeChat messages, text messages, phone calls, or in person. It is important to note that all participants who successfully complete the follow-up will receive a free color Doppler ultrasound examination service.

Inclusion and exclusion criteria for patients

Inclusion criteria: (1)age \geq 18 years old; (2) undergoing HD for \geq 3 months; (3) life expectancy.

more than 12 months; (4) the patient can use WeChat, or has a close-knit family member who can use WeChat (for patients unable to use WeChat but interested in this study); (5) the patient is equipped for home blood pressure and weight monitoring; (6) the patient is willing and able to provide informed consent.

Exclusion criteria: (1) the patient has cognitive and intellectual impairments and can't read and understand WeChat; (2) suffering from mental illness; (3) the occurrence of other serious complications (other serious complications include serious infection, alimentary tract hemorrhage, uremia encephalopathy, acute coronary syndrome, acute exacerbation of chronic heart failure, acute heart failure, malignant arrhythmia, cerebral apoplexy and so on).

Inclusion and exclusion criteria for family members

WeChat, as a widely used communication tool, is suitable for people of all ages to use. However, for some elderly people who are not familiar with the operation, there may be certain difficulties in using it. For this reason, the study specifically allows elderly patients who are willing but not yet proficient in using WeChat to participate in the study with the assistance of their family members. Family members will be nominated by the patients themselves and designated as supporters of these special patients during the intervention process, especially for those patients who cannot operate WeChat themselves.

Inclusion criteria: (1) Participants must be at least 18 years old; (2) They must live with patients undergoing HD treatment and provide daily support; (3) Family members must have the ability to read and understand the information forwarded to patients on WeChat.

Exclusion criteria: (1) Long-term non-living with patients; (2) Family members do not have the ability to use WeChat.

Withdrawal criteria for patients

(1) Researchers can't contact patients through WeChat (In this case, we will require patients to respond after receiving WeChat messages. If the patient does not reply once during the week, we will use WeChat's voice call function to contact them, ensuring that the message has

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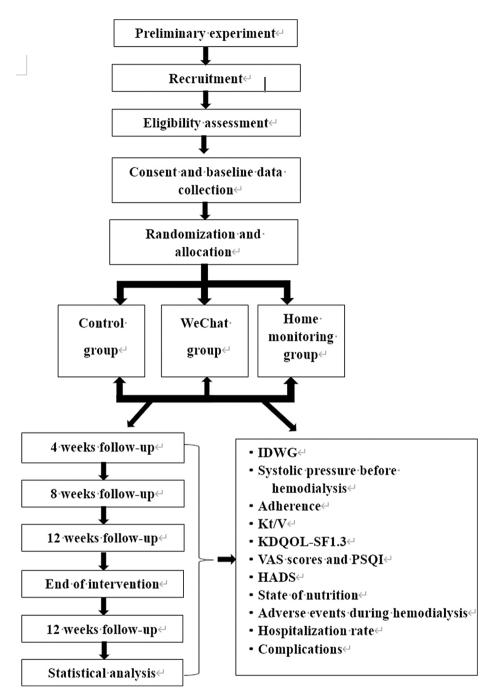


Fig. 1 Study protocol flowchart of managing volume load for patients undergoing hemodialysis via WeChat and home monitoring

been delivered, and remind the patient to respond to the message the next time they receive it. If the patient does not reply to any WeChat messages for three consecutive weeks or if we are unable to contact the patient through voice call, it will be deemed as an inability to contact through WeChat and considered as one of the conditions for withdrawal.; (2) absent from hemodialysis more than 6 times in a month or transfer to another hemodialysis center; (3) stopped hemodialysis due to transplantation of kidney; (4) serious complications (including serious

infection, alimentary tract hemorrhage, uremia encephalopathy, acute coronary syndrome, acute exacerbation of chronic heart failure, acute heart failure, malignant arrhythmia, cerebral apoplexy and so on) or even death during the research process; (5) clearly expresses their unwillingness to continue participating in the study; (6) For safety reasons, patients have the right to voluntarily withdraw from the study at any time.

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Signing of the informed consent

When patients express interest in joining the study and meet both the inclusion and exclusion criteria, they must sign a detailed informed consent form. This consent form will fully disclose the specific purpose, potential benefits and risks of participating in the study, and clearly list the obligations and responsibilities that patients should undertake throughout the entire research process. Additionally, the consent form will emphasize that patients' personal privacy information will be strictly protected

< **Health Dialysis** Warm tips for dialysis patients 给透析友友们的温馨提示 给透析友友们的温馨提示亲爱的透析的友友们: 您们 Warm tips for hemodialysis patients. Hello, dear hemodialysis patients 3月19日 上午10:55 Process of home weight monitoring for hemodialysis patients 血液透析患者家庭体重管理流程 请各位患者朋友认真阅读,清楚个人操作流程,谢 Please read it carefully and be clear about the process, thank you! 3月20日上午08:43 Warm tips for dialysis patients 给透析友友们的温馨提示 给透析友友们的温馨提示亲爱的透析友友们: 您们好 Warm tips for hemodialysis patients. Hello, dear hemodialysis patients = 生命体征 ≡患者问卷 ≡营养状态 Patient Questionnaires Nutritional status Vital signs

Fig. 2 The interface of WeChat subscription account "Health dialysis"

to ensure it is not obtained or abused by unauthorized personnel.

Baseline data collection

Prior to randomization, baseline data will be collected for all included patients. Baseline data contains demographic characteristics, underlying disease and duration of undergoing HD. Demographic characteristics include sex, age, height, weight, marital status, income, smoking and drinking status, and degree of education (elementary, middle school, high school, college degree or above).

Blinding and randomization

The study will employ a cluster randomized design. All patients will be clustered by hemodialysis shift schedule (including morning, afternoon, and evening shifts on Mondays, Wednesdays, and Fridays; as well as morning, afternoon, and evening shifts on Tuesdays, Thursdays, and Saturdays.). And all hemodialysis shift schedule will randomly be assigned to the control group, WeChat group, and home monitoring-feedback group on a 1:1:1 basis by simple randomization with the help of Microsoft Excel software.

The prerequisites for implementing cluster randomization are as follows: Firstly, ensure that the number of patients in each HD shift schedule is basically balanced. Secondly, conduct a pre-analysis to ensure that there are no significant differences in key measurement indicators under different HD shift schedules (including sex, age, complication, time of undergoing hemodialysis and so on). Thirdly, allocate based on a fixed shift schedule for HD to ensure the convenience and feasibility of the study. Finally, strive to minimize social contact between each shift to reduce potential contamination risks.

Given the unique nature of intervention measures, it is impossible to maintain the blindness of researchers responsible for implementing interventions. However, to ensure the fairness of the data, researchers responsible for data analysis will remain blinded until all data analysis work is successfully completed.

Intervention

Development of WeChat subscription account "Health dialysis"

The establishment of the WeChat subscription account "Health dialysis" (whose pinyin name is Jian Kang Tou Xi) originated from a literature review and practical experience summary on the management of volume load (Fig. 2 The interface of WeChat subscription account "Health dialysis"). In the initial development stage, we will invite technical experts from the Information Center to provide technical guidance on the development and operation of WeChat subscription accounts, and form a professional team composed of doctors from nutrition, cardiovascular

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surgery, vascular surgery, and rehabilitation departments to jointly explore and determine the content settings of WeChat subscription accounts. Additionally, during the development process, we will first send pre-push notifications to five patients who are willing to cooperate with the research to verify the practicality of the content and functionality. All content of WeChat subscription accounts will be specifically designed in Chinese for patients to understand and operate.

The functional composition of the "Health Dialysis" WeChat subscription account is as follows: (1) Regularly publish health education knowledge about HD, allowing patients to easily obtain these health information by following this subscription account (Fig. 3 Example tweet about health knowledge on WeChat subscription account "Health dialysis"); (2) Send a series of questionnaires through the WeChat subscription account to collect and evaluate multidimensional information such as patients' quality of life, nutritional status, anxiety level, depression

through the Wenjuanxing application (a professional survey platform) and then uploaded to the WeChat subscription account, enabling patients to easily and conveniently fill out the questionnaire through the WeChat subscription account after following the account, ensuring the efficiency and accuracy of the data collection process.

level, and sleep quality. (3) Utilize the WeChat subscrip-

tion account function to allow patients to record daily

The design of the questionnaire will be completed

Methods of intervention

family weight and BP data.

(1) Control Group: Standard Care Only. The specific content encompasses two main aspects: Firstly, a series of promotional posters, including but not limited to "dry weight" and "common food moisture content", are posted at the HD center to enhance patients' awareness of HD-related knowledge through visual promotion methods.

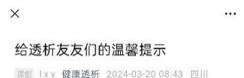
Warm tips for hemodialysis patients

Dear hemodialysis patients, In order to ensure the adequacy and effectiveness of your hemodialysis, and for the sake of your health, our hemodialysis centre would like to remind you to pay attention to the following points:

1.Before and after each hemodialysis, you'd better remember to weigh yourself, measure blood pressure and inform the doctor to record.

2.Before hemodialysis, please check yourself for oedema, heart fatigue and tightness of breath, relief of black stools, bleeding, trauma as well as diarrhoea, etc. If you have, please be sure to tell your doctor, and we will adjust the dialysis programme according to your actual situation.

3.Dry weight isn't permanent. Now it is the



の听全文

给透析友友们的温馨提示 亲爱的透析友友们: 您们好呀!为了您们的透析充分 性、有效性得到有力的保证,为了 您们身体更加健康,我们透析中心 贴心提醒大家注意以下几点:

 每次透析之前、透析结束后 大家一定记得称体重、测量血 压,并告知医生记录。

2、透析前查看自己有无水肿、 有无心累气紧,近期有无解黑大 便、有无出血、有无外伤,有无 腹泻,如果有,请一定要告诉医 生,我们会根据您的实际情况调 整透析方案。

3、 透析干体重°不是永恒不变



Fig. 3 Example tweet about health knowledge on WeChat subscription account "Health dialysis"

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Secondly, this group of patients will be required to subscribe to the WeChat official account called "Health dialysis", through which they will regularly receive the latest HD information and health education content.

(2) WeChat Group: WeChat group: On the basis of integrating routine care, implement volume load management strategies through the WeChat platform. This group of patients will first receive the same routine care as the control group to ensure basic medical security. Secondly, an experienced HD doctor will lead the creation and operation of a dedicated WeChat account, establishing a convenient and intimate communication bridge between doctors and patients by adding patients as WeChat friends. With the support of this WeChat platform, researchers responsible for managing WeChat accounts will dynamically calculate IDWG and %IDWG based on patients' dry weight assessment. They will then push personalized messages to patients on non-HD days via WeChat according to the assessment results, reminding them to control their fluid intake reasonably. For example, for patients undergoing HD on Monday, Wednesday, and Friday, researchers will send WeChat messages on specific days such as Tuesday, Thursday, Saturday, and Sunday. The specific contents of these messages are detailed in Table 1. Thirdly, during the first weekly HD session, researchers will provide patients with detailed feedback on the %IDWG from the previous week. Patients with %IDWG < 4.5% will be commended, while those with %IDWG≥4.5% will receive additional health education. Additionally, during the same dialysis shift, we will organize peer education activities for similar patients to build a support network for mutual assistance and learning for patients with %IDWG < 4.5% and %IDWG≥4.5%.

The goal of this peer education program is to form a self-structured support team that promotes communication, exchange, and experience sharing among team members. Patients who successfully meet the %IDWG standard will take responsibility for guiding those who

do not meet the standard, assisting them in gradually improving their lifestyle and effectively controlling the %IDWG.

To enhance the impact of this educational process, we will select three outstanding patients who meet the % IDWG criteria each month as forum speakers. These speakers need to have a solid foundation of knowledge related to HD, at least a junior high school education level, and demonstrate excellent communication skills. In the forum speech, they will share their feelings and practical experience in fluid intake management, daily diet, and activity level, and carefully analyze the personal challenges and emotional fluctuations they face in diet control and fluid control. Throughout the entire process, researchers will continue to be involved, ensuring precise guidance is provided, timely correction of potential cognitive biases, and actively encouraging all patients to learn valuable lessons from the speaker's experience.

(3) Home monitoring-feedback group: In addition to the standard routine care and volume load management traditionally provided on the WeChat platform, we have introduced a special home monitoring mode.

The specific content covers the following two aspects: Firstly, volume load management through WeChat, which includes providing usual care and guidance within WeChat group. Secondly, guiding patients to complete home BP and weight monitoring tasks, and utilizing the WeChat subscription account "Health dialysis" platform to promptly upload home monitoring data by completing questionnaires (Fig. 4 The interface of questionnaire for home monitoring on WeChat subscription account "Health dialysis").

To ensure that patients can continue to perform home monitoring tasks even while hospitalized, the hospital department has equipped BP monitors and weight scales to assist in completing this "home monitoring" process. Before commencing the study, patients will be reminded to ensure the accuracy of home BP and weight measurements. If any abnormal results are observed, such as

Table 1 Contents of messages

Phase/messages	Examples of message title				
Health education phase	Dear ****, I am Dr.***. To reduce associated with hemodialysis and improve your quality of life, I would like to remind you that during the interval between your last hemodialysis session and the next, also known as the inter-dialysis period, it is crucial to keep your weight gain within a safe limit. Specifically, your weight gain should not exceed 3% of your dry weight, and ideally should not surpass 4.5% of your dry weight at most. Now, your dry weight is *kg. It is advisable to limit your interdialytic weight gain to no more than *kg and at most * kg. Weight gain beyond this limit may lead to increased blood pressure, pulmonary oedema, heart failure, and significantly increase the risk associated with your next dialysis session. Please monitor your weight regularly at home and limit your fluid intake accordingly. Together, let's work towards maintaining a healthy weight and ensuring you feel healthy and happy every day!				
Maintain phase	Dear ***, it is advisable to follow a light diet and reduce your fluid intake to manage your fluid intake effectively. Please remember to monitor your weight regularly at home. It is recommended to keep your interdialytic weight gain within *kg and ideally no more than * kg. Fighting!				
Habit formation phase	Dear ***, it is advisable to adhere to a light diet and reduce fluid intake. Additionally, please ensure you complete your weight monitoring on time. It is recommended to limit your interdialytic weight gain to no more than *kg and ideally no more than * kg. You can limit your fluid intake based on your weight.				

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Weight Recording Questionnaire 透析友友们,每天定时监测体重,有利于我们时时了解体重增长情况,预防透析间期体重增长过多引起血压增高、肺水肿、心力衰竭等严重并发症。 Dear hemodialysis patients:Regular monitoring of body weight on a daily basis helps us to understand weight gain and prevent serious complications such as increased blood pressure, pulmonary oedema and heart failure caused by excessive weight gain during the dialysis period. *1. 您的姓名: Your name *2. 您今天在家称的体重是一一公斤? How much did you weigh at home today—kg?



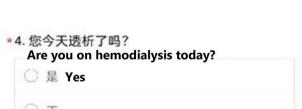


Fig. 4 The interface of questionnaire for home monitoring on WeChat subscription account "Health dialysis"

significantly higher or lower home BP readings without accompanying physical discomfort symptoms, or a difference of more than 1 kg between home weight and the weight measured by the HD center, the measuring equipment should be recalibrated immediately to prevent errors from affecting the validity of the data.

To ensure the scientific validity of the intervention, we have strict requirements for researchers who manage and maintain WeChat accounts and subscription accounts. These researchers must have at least six months of practical experience in nephrology or HD. Before the formal implementation of the intervention, these researchers need to undergo a week-long systematic training and participate in a one-month pilot study phase post-training to validate and refine the intervention plan. During the formal intervention period, all researchers are required

to hold a weekly meeting to summarize the intervention process and promptly develop and adopt effective response strategies for any new issues.

Outcomes

Primary outcomes

%IDWG and systolic blood pressure before hemodialysis %IDWG refers to the difference in weight before and after hemodialysis between two consecutive dialysis sessions divided by dry body weight. Systolic blood pressure before hemodialysis (SBPBH) refers to the BP measurements made by dialysis nurses before the patient undergoes dialysis treatment. Both %IDWG and SBPBH data will be obtained from the 'Xue-Tou-Tong' system at the Hospital of Chengdu University of Traditional Chinese Medicine ('Xue-Tou-Tong' system is a computer software for hospitals to manage hemodialysis patients, which contains all the data on the patient's demographic information, personalized treatment plans, and various laboratory examination results).

Secondary outcomes

The secondary outcomes will include patient compliance, feasibility of protocol implementation, HD adequacy, dialysis-related quality of life, dialysis-related symptoms, patient anxiety and depression, nutrition status, incidence of adverse events during HD, hospitalization rates, and the incidence of various potential complications.

Compliance and feasibility The evaluation of patient compliance will be quantified through two core indicators: the effectiveness of intervention and the actual completion rate of intervention or feedback. Effective intervention will be considered as %IDWG<4.5%

($\%IDWG = \frac{IDWG}{Dry\,Weight}\%$). The effective rate of inter-

vention = $\frac{Times\ of\ effective\ intervention}{Total\ times\ of\ hemodialysis\ in\ a\ month}\%$. Patients receiving the reminding message by WeChat will be considered as finishing intervention. The finishing rate

of intervention= $\frac{Times\ of\ finishing\ intervention}{Interdialytic\ days\ in\ a\ month}\%$. Finishing home blood pressure and weight monitoring and providing feedback about the result through questionnaire via WeChat subscription account will be considered as finishing feedback. The finishing rate of feed-

back= $\frac{Times\ of\ finishing\ feedback}{The\ total\ number\ of\ days\ a\ month}\%$. The feasibility of the study will be assessed by the percentage of messages read and engagement metrics. The percentage of

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 $\begin{array}{c} Total\ number\ of\ patients \\ in\ a\ group - with drawal\ patients\ due \\ to\ unreached\ via\ WeChat \\ \hline Total\ number\ of\ patients\ in\ a\ group \\ \end{array} \%$

 $\begin{array}{c} Number\ of\ patients\ at\ the\\ completion\ of\ the\ intervention\\ Engagement\ metrics = \frac{in\ a\ group}{Total\ number\ of\ patients\ in\ a\ group}. \end{array}$

Hemodialysis adequacy Kt/V is considered a standard for measuring HD adequacy. Kt/V = the ratio of the urea product to total body water [21].

Dialysis-related quality of life The dialysis-related quality of life will be comprehensively evaluated using the Kidney Disease Quality of Life, Short Form, version 1.3 (KDQOL-SF1.3). The KDQOL-SF1.3 questionnaire is divided into two main parts: the SF-36 General Health Survey and 44 specialized questions related to kidney disease. The SF-36 general health survey covers multiple dimensions of health, including physical function, physical role, general health, bodily pain, social function, vitality, emotional role, and mental health. The 44 specialized questions related to kidney disease further focus on specific areas such as symptoms and discomfort, the impact of kidney disease on daily life, cognitive function, work status, the importance of kidney disease to personal life, the quality of social interactions, sleep quality, sexual function, social support networks, the support and motivation provided by the treatment team, and overall patient satisfaction [22]. These domains have a score from 0 to 100, with higher scores indicating the absence of problems.

Dialysis-related symptoms In this study, fatigue, pruritus, and sleep disorders are included in the assessment system for dialysis-related symptoms. The severity of fatigue and pruritus will be quantified using the Visual Analogue Scale (VAS), which ranges from 0 to 10, with higher scores indicating more severe symptoms. Conversely, the assessment of sleep quality is based on the Pittsburgh Sleep Quality Index (PSQI), which ranges from 0 to 21 points and is inversely related to sleep quality. A higher score indicates poorer sleep quality. Specifically, patients with PSQI scores below 7 are considered to have normal sleep quality, whereas scores above 7 indicate the presence of significant sleep disorders.

Anxiety and depression status The assessment of anxiety and depression will be comprehensively evaluated using the Hospital Anxiety and Depression Scale (HADS). HADS consists of 14 items (7 for anxiety and 7 for depression), with a total score set between 0 and 21 points for each subscale. Scores of 0 to 7 indicate the absence of anxiety or depression symptoms, scores of 8 to 10 suggests possible tendency towards anxiety or depression,

and scores of 11 to 21 clearly indicate that the patient has significant symptoms of anxiety or depression.

Nutrition status A comprehensive assessment of nutritional status will be assessed using a combination of waist circumference, biceps circumference, waist-hip ratio, handgrip strength, albumin, prealbumin, subjective global assessment (SGA), and protein-energy wasting (PEW). Among these metrics, the measurement data for waist circumference, biceps circumference, waist-hip ratio, and handgrip strength will be obtained by averaging multiple measurements taken by three different researchers at different time points within the same week to ensure the accuracy and consistency of the data. The laboratory values for albumin and prealbumin are directly derived from the patients' test results. The SGA comprehensively evaluates the nutritional status of patients through both subjective and objective aspects of their medical history, such as changes in weight, dietary intake, nutrition-related symptoms, and changes in functional capacity, as well as observations of fat loss, muscle wasting, ankle or sacral edema, and ascites during physical examination. According to the SGA assessment, patients will be categorized into three groups: well-nourished, moderate or suspected malnutrition, and severe malnutrition. Specifically, each sub-item of the SGA has three options: A, B, and C. If most items are rated as A, the patient's nutritional status is considered good; conversely, if most items are rated as C, it indicates severe malnutrition [23]. PEW is the state of decreased body stores of protein and energy fuels, diagnosed if three characteristics are present (low serum levels of albumin, transthyretin, or cholesterol), reduced body mass (low or reduced body or fat mass or weight loss with reduced intake of protein and energy), and reduced muscle mass (muscle wasting or sarcopenia, reduced mid-arm muscle circumference) [24]. In this study, patients meeting at least two of the following criteria will be diagnosed with PEW: (1) BMI < 23 kg/m2; (2) Serum albumin < 3.8 g/dL; (3) The total SGA score is either B or C [25].

Incidence of adverse events during hemodialysis The most common types of adverse events experienced during HD include hypotension, hypertension, muscle spasm, hypoglycemia, fever, cardiovascular events, and cardiac arrhythmia. The incidence of these adverse events will be accurately calculated using the "Xue-Tou-Tong" system, which has been developed by Hospital of Chengdu University of Traditional Chinese Medicine.

Hospitalization rates and complications Hospitalization rates will be calculated based on the data of "HIS" system of Hospital of Chengdu University of Traditional Chinese Medicine. Complications include renal anemia, hyperphosphatemia, secondary hyperparathyroidism,

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Table 2 Diagnostic criteria for complications

Complications	Assessment criteria				
Renal anemia	©For adults residing above sea level: male hemoglobin (Hb) < 130 g/L, unpregnant female Hb < 120 g/L, pregnant female Hb < 110 g/L; @ Based on the following hematocrit values, red blood cell count, mean corpuscular volume, mean corpuscular Hb, mean corpuscular Hb concentration, reticulocyte count, urobilinogen, urine bilirubin, serum total bilirubin, direct bilirubin, indirect bilirubin, and lactic dehydrogenase, exclude nutritional anemia, hemolytic anemia, bemorrhagic anemia, thalassemia, aplastic anemia, and hematologic malignancy; @ Previous diagnosis of renal anemia in the HIS system; @The patient is currently using erythropoietin; @The patient can be diagnosed if they meet both criteria @ and @, or any one of criteria @ and @				
Hyperphosphatemia	©The last three and the most recent examinations of serum inorganic phosphorus all show levels above 1.78 mmol; @ Previous diagnosis of hyperphosphatemia recorded in the HIS system; @ The patient can be diagnosed if they meet either criterion above				
Secondary hyperparathyroidism	©Two consecutive iPTH examinations show levels above 300 pg/L, or iPTH is continuously rising; © There is a previous diagnosis of secondary hyperparathyroidism in the HIS system; © The patient can be diagnosed if they meet either criterion above				
CKD-MBD					
Cardiovascular complications	©Persistent abnormal BP (hypertension or hypotension); ©Chronic heart failure, characterized by symptoms of systemic congestion, pulmonary congestion, or hypoperfusion, or abnormal findings on echocardiography; ③ Arrhythmia; ④ Previous diagnosis of any of the above three conditions in the HIS system; ⑤ The patient can be diagnosed if they meet any one of the four criteria above				

Table 3 Time nodes of collecting all data

Data	Baseline	4 weeks	8 weeks	12 weeks	24 weeks
Demographics	√				
%IDWG	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark	$\sqrt{}$
Systolic blood pressure before hemodialysis	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark	$\sqrt{}$
Compliance		$\sqrt{}$	\checkmark	\checkmark	$\sqrt{}$
Hemodialysis adequacy	\checkmark	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark
Dialysis-related quality of life	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark	$\sqrt{}$
Dialysis-related symptoms	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark	$\sqrt{}$
Anxiety and depression status	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark	$\sqrt{}$
Nutrition status	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark
Incidence of adverse events during hemodialysis	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark	$\sqrt{}$
Hospitalization rates and complications	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	\checkmark	$\sqrt{}$

chronic kidney disease-mineral and bone disorder (CKD-MBD) and cardiovascular complications, which will all be assessed by laboratory examination and prior diagnosis of "HIS" system (Table 2).

Data collection

In this study, the collection of baseline and scale data will be conducted via the WeChat subscription account "Health dialysis". The following data will be collected by the "Xue-Tou-Tong" system: %IDWG, dry weight, blood pressure, date of laboratory examination, and other relevant information regarding the HD treatment schedule. Additionally, measurements such as waist circumference, biceps circumference, waist-to-hip ratio, and handgrip strength will be recorded by the responsible research personnel.

Details of collecting baseline data and data scales: A WeChat subscription account is configured with an independent questionnaire web link for patients to access baseline data and scale data. Patients can open this link

through the built-in browser in WeChat. Upon completing the linked questionnaire, the data will be automatically uploaded to the back-end server of the Wenjuanxing application and stored using the name as the key index. Follow-up information will be collected using the same method. The link will be tested by three researchers prior to the study to ensure there are no technical problems. No investigators will have the ability to modify any data. A non-investigator, especially an IT worker, will release the data set to those investigators responsible for assessing the outcomes, and only unblind the groups once data analysis has been completed. The time nodes for collecting all data are shown in Table 3. Upon completion of data collection and analysis, we will store all de-identified data in Figshare (https://figshare.com/).

Statistical analysis

Given that all variables in this study are centered around individuals, we will focus on individual-level differential analysis rather than examining based on HD shift Wang et al. BMC Nephrology (2025) 26:58 Page 11 of 14

schedules. All collected data will be collaboratively summarized by two researchers using an Excel platform for preliminary processing and recoding. Subsequently, the researchers responsible for data analysis will use R version 4.3.1 software to conduct in-depth analysis of the data, maintaining the blind state of intervention allocation throughout this process. We plan to implement intention-to-treat analysis, which will comprehensively consider drop-out and missing values. We will implement estimation processing for missing data to ensure its integrity. At the same time, a linear mixed-effects model will be used to reveal the correlation between intervention measures and research outcomes. In this model, we specifically include the interaction term of "intervention x time" within the category of fixed effects.

Discussion

The aim of this study is to enhance health education for HD patients through WeChat, encouraging patients to limit fluid intake and ultimately achieve effective volume load management. This approach is convenient and efficient in China, where WeChat is widely used, allowing for optimal utilization of medical resources.

In the research framework, the intervention group was divided into two subgroups: the WeChat group and the home monitoring-feedback group. The content of WeChat messages transmitted between the two groups remains consistent, focusing on the control of fluid intake and the completion of home weight monitoring. However, participants in the home monitoring-feedback group need to upload their household monitoring data through the WeChat subscription account "Health Dialysis" to indicate that they have actually completed the home monitoring task; it is unknown whether the participants in the WeChat group have indeed undergone home monitoring. As an important tool for self-management of chronic diseases, home monitoring enables patients with chronic diseases such as hypertension or diabetes to independently adjust drug dosage and reduce the risk of adverse events. Additionally, controlling IDWG has been proven to be an effective method for HD patients [26-28]. In this study, the home monitoring-feedback group and WeChat group operated in parallel, aiming to further improve the volume load management effectiveness during the research period. If there is a significant statistical difference in %IDWG between the two groups, it will strongly support the positive impact of home monitoring on volume load management.

The outcomes of this study will be based on five questionnaires. To ensure the accuracy of the questionnaire data, professional researchers are arranged to assist patients in completing the questionnaires. Prior to the commencement of the study, all assisting personnel need to receive systematic training to accurately grasp the

meaning of questionnaire questions and option settings. During the questionnaire completion process, researchers need to consistently use clear language to explain the questions and their options to patients. When patients encounter doubts during the filling process, researchers need to provide consistent explanations to clarify them. For patients who are unable to complete the questionnaires independently, researchers will fill them out according to their specific needs.

During the pilot phase of this study, over 80% of HD patients exhibited a positive attitude towards our intervention measures, indicating good initial outcomes. However, we also identified several operational challenges. The most significant issue is that on non-dialysis days, relying solely on reminder messages sent via WeChat was insufficient for effectively managing patients' volume load, particularly among chronic capacity overload patients who have undergone HD for more than two years. There is a substantial misunderstanding regarding volume load among these patients, combined with poor adherence, making it even more challenging to correct their unhealthy lifestyle habits. Approximately 70% of patients at the Hemodialysis Center of the Hospital of Chengdu University of Traditional Chinese Medicine have been on HD for over two years, underscoring the urgent need to enhance volume load management. Given this, we plan to provide weekly feedback to patients on %IDWG during the formal intervention phase, promptly addressing any misconceptions. Additionally, we intend to organize monthly peer education forums to integrate peer education concepts into our intervention strategies. The conventional health education model, typically guided by medical personnel and focused on disease management rather than a patient-centric approaches, often results in passive patients passively receiving treatment and low compliance. In contrast, peer education fosters mutual assistance through shared life experiences, benefiting both mentors and mentees [29].

Moreover, considering that some patients are only familiar with basic chat functions of WeChat due to their age and have limited skills in operating WeChat subscription accounts, we will offer personalized usage guidance to help them become proficient with the various functions of WeChat subscription accounts. Patients can also seek assistance from family members to more conveniently access health information related to HD, complete questionnaire surveys, and upload home monitoring data. Furthermore, we have specifically designed a set of teaching charts to enhance their understanding (Fig. 5: Instructional Chart of upload home monitoring data in a week).

In summary, this study aims to significantly enhance the quality of life of HD patients and reduce their hospitalization and mortality rates through lifestyle, Wang et al. BMC Nephrology (2025) 26:58 Page 12 of 14

Flow chart of home monitoring-feedback for patients on hemodialysis on Monday, Wednesday and Friday

Monday: Finish home blood pressure and weight monitoring before hemodialysis. Finish home monitoring again after hemodialysis, and then upload the value of home monitoring

Tuesday: Finish home blood pressure and weight monitoring at a regular time, and upload the value of home monitoring

Wednesday: Finish home blood pressure and weight monitoring before hemodialysis. Finish home monitoring again after hemodialysis, and then upload the value of home monitoring

Thursday: Finish home blood pressure and weight monitoring at a regular time, and upload the value of home monitoring

Friday: Finish home blood pressure and weight monitoring before hemodialysis. Finish home monitoring again after hemodialysis, and then upload the value of home monitoring

Saturday: Finish home blood pressure and weight monitoring at a regular time, and upload the value of home monitoring

Sunday: Finish home blood pressure and weight monitoring at a regular time, and upload the value of home monitoring

Fig. 5 Instructional Chart of upload home monitoring data in a week

non-pharmacological interventions. If the intervention measures prove effective, it is anticipated to provide practical guidance for other HD centers in managing the volume load of HD patients. What's more, if the intervention is viability, efficacy, and security, we will further update and improve the intervention by integrating it with foreign social software such as Facebook, What-sApp, Twitter, and PayPal, to promote the application of the intervention and provide cost-effective volume management method for HD patients worldwide.

Abbreviations

HD Hemodialysis
CKD Chronic kidney disease
ESKD End-stage kidney disease
IDWG Interdialytic weight gain
BP Blood pressure

SBPBH Systolic blood pressure before hemodialysis
KDQOL-SF1.3 Kidney Disease Quality of Life, Short Form, version 1.3

VAS Visual analogue scale
PSQI Pittsburgh Sleep Quality Index
HADS Hospital Anxiety and Depression Scale

SGA Subjective global assessment

CKD-MBD Chronic kidney disease-mineral and bone disorder

Flow chart of home monitoring-feedback for patients on hemodialysis on Tuesdays, Thursdays and Saturdays

Monday: Finish home blood pressure and weight monitoring at a regular time, and upload the value of home monitoring



Tuesday: Finish home blood pressure and weight monitoring before hemodialysis. Finish home monitoring again after hemodialysis, and then upload the value of home monitoring



Wednesday: Finish home blood pressure and weight monitoring at a regular time, and upload the value of home monitoring

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Thursday: Finish home blood pressure and weight monitoring before hemodialysis. Finish home monitoring again after hemodialysis, and then upload the value of home monitoring

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Friday: Finish home blood pressure and weight monitoring at a regular time, and upload the value of home monitoring



Saturday: Finish home blood pressure and weight monitoring before hemodialysis. Finish home monitoring again after hemodialysis, and then upload the value of home monitoring



Sunday: Finish home blood pressure and weight monitoring at a regular time, and upload the value of home monitoring

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12882-024-03932-0.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Supplementary Material 4

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Not applicable.

Author contributions

XC W, BN Y, SP Z, QX Z and XY L designed the study together. YK Z led the application for ethics approval and consent. All authors participated in critically appraising and revising the intellectual content of the manuscript. All authors read and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The trial was ethically approved by Ethics Committee at the Hospital of Chengdu University of Traditional Chinese Medicine (2024KL-075) in accordance with the Declaration of Helsinki and International Ethical Guidelines for Biomedical Research Involving Human Subjects.

Consent for publication

Written informed consent will be obtained from each participant before randomization.

Competing interests

The authors declare no competing interests.

Trial status

The trial commenced recruitment in mid-June 2024 and 130 participants have been recruited so far. We will complete recruitment at the end of November.

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