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# **Design and Prototype Evaluation of a Mini Program for Diet Management Focusing on Patients with Chronic Kidney Disease**

Department of Nursing Science

Master's thesis

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## Abstract

**Background** Chronic kidney disease (CKD) is a global public health problem and has become a common chronic non-communicable disease threatening human well-being. There is no effective cure for CKD, and once it progresses to end-stage renal disease, only renal replacement therapy can be performed, which brings a heavy medical burden to families and the country. Dietetic-nutritional management is closely related to delaying the progression of CKD and improving health outcomes and is essential in the treatment of CKD. However, dietary compliance of patients is currently a major challenge in clinical work. With the integration of mobile Internet and healthcare, mobile health, represented by smartphones, has become an important tool for healthcare services. Previous studies have shown that information tools can motivate users to make positive eating behaviour changes and improve their confidence in achieving their dietary goals. In recent years, diet management tools for CKD patients have gradually increased in China, but most patients still face difficulties in self-managing their diet at home.

**Aims** Given that the advantages of WeChat Mini Program in China and the cost limitation of the study, the purpose of this study is to follow the concept of human-centred design to design an open accessible WeChat Mini Program for home diet management, and with CKD patients and caregivers as the target users, to ultimately improve the patient's experience of diet management and improve their dietary compliance to obtain the optimal benefits of medical nutrition therapy. To understand the usability and design flaws of this Mini Program through the prototype development and evaluation, to further improve the design and provide a reference for future development.

**Methods** This study was divided into three stages. The first stage was the requirements analysis of diet management Mini Program: stakeholders, i.e., CKD patients and caregivers, renal dietitians, nephrologists, and specialist nurses, were interviewed through a qualitative study to explore their functional needs and suggestions for the Mini Program. The second stage was the design and expert evaluation of the Mini Program for CKD patients: based on literature review and stakeholders' requirements analysis and drawing on the features of the existing applications on the market, the first draft of the written design of this Mini Program was completed and then the written design and technical feasibility of the Mini Program were evaluated by multidisciplinary experts, including renal dietitians, nephrologists and specialist nurses, as well as WeChat Mini Program development technicians, to further revise and finalize the written design of this Mini Program. The third stage was prototype development and evaluation of the Mini Program: using Mocking Bot to develop the prototype and then was a mixed study, 15 testers were recruited to evaluate the prototype by convenience sampling. mHealth App Usability Questionnaire (MAUQ) (patient version) was used to collect quantitative usability scores, and qualitative interviews were conducted to explore their experience and suggestions for improvement of the Mini Program.

**Results** 1. Requirements analysis of diet management Mini Program: 22 stakeholders were interviewed, including 9 CKD patients, 4 caregivers, and 9 clinical professionals. Three

themes are extracted, which are attitudes towards the Mini Program (overall, highly expected the Mini Program for diet management), functional requirements of the Mini Program (including provide comprehensive diet management information, diet decision support, professional diet self-management skills, and emotional support channels), and performance requirements of the Mini Program (easy to use and learn, with simple interface). There are 12 specific functional requirements, which is expected to provide reliable dietary knowledge, food nutrient query, individualized dietary advice, dietary nutrition monitoring, customize individual recipes, recommend disease-specific foods, diet record and analysis, nutrition consultation, promote family participation, communication among patients, user feedback, and intelligent reminder.

2. Design and expert evaluation of the Mini Program: After two rounds of evaluation and feedback from multidisciplinary experts, the final version of the written design of the Mini Program was formed, including 4 modules, namely, Home Page, Interactive Community, Health Record, Personal Centre; and 19 functions, including Site Search, Diet Management, Popular Science Articles, and News (Home Page), Circle of Patients, My Doctors, Doctor's Lectures, My Family (Interactive Community), BP Record, BG Record, Wt. Record, Exercise Record (Health Record), and Basic Information Setting, Health Report, My equipment, My favourites, My Posts, Product Introduction, Feedback and Help (Personal Centre).

3. Prototype development and evaluation of the Mini Program: the prototype developed in this study was high-fidelity and interactive. Quantitative result: the mean value of the overall scoring of MAUQ was 1.39, with a standard deviation of 0.29, indicating that patients and caregivers recognize the Mini Program as usable. Qualitative result: clinical professionals, CKD patients, and caregivers who participated in the testing have a high acceptance of the Mini Program. Clinical professionals consider the Mini Program to be comprehensive, helpful for patients' diet management, and to reduce the burden of clinical diet education; patients and caregivers consider the Mini Program to be a comprehensive, easy-to-use, and practical tool that facilitates access to professional knowledge, improves their confidence in diet management and social support, and they have a positive attitude towards using it and express their great expectations. The main shortcomings of the Mini Program are the need to adjust the colour scheme and optimize the layout of the user interface and to highlight the main functions of diet management, and to realize the function of voice use if the development technology is feasible.

**Conclusion** The Mini Program designed in this study meet the needs and demands of home diet management for CKD patients and may positively affect their diet self-management. In the future, we consider further collaboration with information technology companies and clinical usability assessment and effectiveness evaluation would be necessary, to determine the clinical effect and economic cost-effectiveness of interventions for CKD patients based on such a WeChat Mini Program, and to promote the close integration of mHealth and clinical practice.

**Key words:** chronic kidney disease, diet management, mini program, prototype.



## Abstrakti

**Tausta** Krooninen munuaistauti (*eng. Chronic kidney disease CKD*) on maailmanlaajuinen kansanterveysongelma ja siitä on tullut yleinen krooninen sairaus, joka uhkaa ihmisten hyvinvointia. Krooniseen munuaistautiin ei ole olemassa tehokasta parannuskeinoa, ja sairauden edetessä ainut hoitokeino voi olla munuaissiirto. Kroonisen munuaistaudin etenemistä voidaan hidastaa ravitsemushoidolla ja terveellisillä elämäntavoilla. Siitä huolimatta, potilailla on haasteita noudattaa terveellistä ruokavaliota. Älypuhelinien yleistymisen myötä terveysalan mobiilisovelluksista (*engl. mobile health*) on tullut tärkeä työkalu terveydenhuollolle. Aiemmat tutkimukset ovat osoittaneet, että teknologian avulla voidaan motivoida käyttäjiä syömään terveellisemmin ja parantaa heidän itseluottamustaan ruokavaliotavoitteidensa saavuttamiseksi. Viime vuosina, kroonista munuaistautia sairastavien potilaiden ruokavalion hallintaan liittyvät työkalut ovat vähitellen lisääntyneet Kiinassa, mutta silti useimmilla potilailla on edelleen vaikeuksia noudattaa terveellistä ruokavaliota kotona.

**Tavoitteet** Tämän tutkimuksen tarkoituksena on kehittää avoimesti saatavilla oleva WeChat Mini -ohjelma ruokavalion hallinnan tueksi kroonista munuaistautia sairastaville potilaille. Ohjelman kehittämisessä hyödynnetään ihmiskeskeisen suunnittelun periaatteita (*engl. human-centered design*). Tutkimuksen tavoitteena on parantaa potilaan kokemusta ruokavalionsa hallintaan liittyen ja parantaa potilaan sitoutuneisuutta terveellisen ruokavalion noudattamiseksi, jotta potilas hyötyisi ravitsemushoidosta parhaalla mahdollisella tavalla. Ohjelman prototyypin kehittämisen ja käytettävyyden arvioinnin avulla, ohjelmaa voidaan kehittää edelleen ja tutkimuksen tuottaman tiedon avulla voidaan tarjota kehitysehdotuksia tulevaisuudelle.

**Menetelmät** Tämä tutkimus sisälsi kolme vaihetta. Ensimmäisessä vaiheessa tehtiin ohjelman vaatimusanalyysi. Sidosryhmän jäseniä kuten kroonista munuaistautia sairastavat potilaat ja heidän hoitajansa, ravitsemusterapeutit, nefrologit ja erikoissairaanhoitajat, haastateltiin ja laadullisen tutkimuksen tarkoituksena oli kuvata tarpeita ja ehdotuksia ohjelman kehittämiseksi. Toisessa vaiheessa ohjelma suunniteltiin ja se arvioitiin asiantuntijoiden toimesta. Ohjelman suunnittelussa hyödynnettiin kirjallisuuskatsausta, sidosryhmien haastattelujen tuloksia ja arvioimalla markkinoilla jo olevien nykyisten sovellusten ominaisuuksia. Ohjelman ensimmäisen luonnoksen valmistuttua, monialainen asiantuntijajoukko, joka sisälsi ravitsemusterapeutteja, nefrologeja, erikoissairaanhoitajia ja teknisen alan asiantuntijoita, arvioivat ohjelman sisällön sekä teknisen toteutettavuuden ja käytettävyyden. Ohjelmaa muokattiin arviointien perusteella. Kolmannessa vaiheessa ohjelman prototyyppi kehitettiin ja pilotoitiin (n=15). Aineisto kerättiin *mHealth App Usability Questionnaire (MAUQ)* -kyselyn ja haastattelujen avulla.

**Tulokset** 1) Ohjelman vaatimusanalyysi: Haastattelut tehtiin sidosryhmän jäsenille (N=22): munuaistautia sairastavilla potilaille (n=9), hoitajille (n=4) ja kliinisille asiantuntijoille (n=9). Haastatteluiden perusteella tunnistettiin kolme teemaa: asenteet ohjelmaa kohtaan (yleisesti ottaen ohjelmaan suhtauduttiin odottavasti), ohjelman toiminnalliset vaatimukset

(ymmärrettävä tieto ruokavalioon liittyen, tuki, ruokavalion noudattamiseen liittyvät hallintataidot ja emotionaalisen tuen mahdollisuus) ja käytettävyyteen liittyvät vaatimukset (helppokäyttöisyys ja selkeys). Haastattelujen perusteella tunnistettiin 12 erityistä vaatimusta ohjelmalle: tarjotaan luotettavaa tietoa ruokavalioon liittyen, elintarvikkeiden ravintoainekyselyt, yksilöity ravitsemusneuvonta, ruokavalion noudattamisen seuranta, yksilölliset reseptit, suositukset ruokavalioon liittyen, ruokavalion kirjaus ja analysointi, ravitsemukseen liittyvä neuvonta, perheen osallisuuden edistäminen, kommunikointi potilaiden kesken, käyttäjäpalautte ja muistutukset. 2) Ohjelman suunnittelu ja arviointi: Kahden arviointikierroksen jälkeen, muodostettiin ohjelman lopullinen suunnitelma. Ohjelma koostuu neljästä erilaisesta moduulista: kotisivu, interaktiivinen yhteisö, terveystiedot ja henkilökohtainen keskus, jotka sisältävät yhteensä 19 erilaista toimintaa. 3) Ohjelman prototyypin kehittäminen ja testaaminen: MAUQ -kyselyn keskiarvopisteet olivat 1.39 (SD 0.29), joka osoitti, että osallistujat ja hoitajat kokivat ohjelman käytävyyden hyväksi. Haastatteluiden perusteella ohjelma todettiin hyväksyttäväksi testaajien osalta. Kliiniset asiantuntijat kokivat ohjelman olevan ymmärrettävä, tukevan potilaita ruokavalion hallinnassa ja vähentävän ravitsemusohjauksen tarvetta. Potilaat ja hoitajat kokivat ohjelman olevan ymmärrettävä, helppokäyttöinen ja käytännönläheinen työkalu, joka tukee tiedon saavutettavuutta ja ruokavalion hallintaan liittyvää itsetuntoa sekä tarjoaa sosiaalista tukea. Potilailla oli myös positiivinen asenne ohjelman käyttöön. Suurimmat puutteet liittyivät visuaalisuuteen: värimaailmaa tulee vielä kehittää, samoin sivujen asetteluja. Käyttäjät toivoivat, että sivustoa voisi käyttää myös ääniohjauksen avulla.

**Johtopäätökset** Tässä tutkimuksessa suunniteltu ohjelma vastaa munaistautia sairastavien potilaiden tarpeita ja vaatimuksia ruokavalion hallintaan liittyen ja ohjelma voi vaikuttaa positiivisesti potilaiden ruokavalion hallintaan. Tulevaisuudessa tulisi arvioida ohjelman kliinistä käytettävyyttä ja vaikuttavuutta yhteistyössä tietotekniikan asiantuntijoiden kanssa, jotta voidaan määrittellä, onko ohjelma kliinisesti ja taloudellisesti vaikuttava. Tulevaisuudessa tulee myös yhä edistää terveysalan mobiilisovellusten integraatiota terveydenhuoltoon.

**Avainsanat:** krooninen munaistauti, ruokavalion hallinta, ohjelma, prototyyppi

## Abbreviations

BG	Blood glucose
BMI	Body mass index
CKD	Chronic kidney disease
CV	Coefficient of variation
CKD-EPI	Chronic Kidney Disease Epidemiology Collaboration
CKD-MBD	Chronic kidney disease-mineral and bone disorder
CK-NET	China Kidney Disease Network
CVD	Cardiovascular disease
DNT	Dietetic-nutritional therapy
DKD	Diabetic kidney disease
DN	Diabetic nephropathy
ESRD	End-stage renal disease
eGFR	Estimated glomerular filtration rate
HCD	Human-centred design
HD	Haemodialysis
LPD	Low-protein diet
LSD	Low-salt diet
MAUQ	mHealth App Usability Questionnaire
MP	Mini program
MDRD	Modification of Diet in Renal Disease
MNT	Medical nutrition therapy
MV	Mean value
NT	Nutritional therapy
NCD	Non-communicable disease
NKF	National Kidney Foundation
PD	Peritoneal dialysis
PEW	Protein-energy wasting

QoL	Quality of life
RRT	Renal replacement therapy
RMB	Renminbi
SHPT	Secondary hyperparathyroidism
SGA	Subjective global assessment
SD	Standard deviation
UE	User experience
UV	User viscosity
Wt.	Weight
WMP	WeChat Mini

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# 1 Introduction

## 1.1 Background

Chronic kidney disease (CKD) is a global public health issue that seriously endangers human health<sup>[1, 2]</sup>, and is characterized by high prevalence, low awareness and poor prognosis<sup>[1, 3]</sup>. Patients' quality of life (QoL) is seriously compromised, and they need to rely on expensive renal replacement therapy (RRT) to maintain their lives<sup>[4, 5]</sup>. It is estimated that 9.1%-14.3% of adults suffer from CKD worldwide<sup>[6, 7]</sup>. With the rapid development and changes of people's lifestyle, China has been to the rank of countries with high prevalence of CKD<sup>[8]</sup>, the morbidity rate is 10.8%-13.2% in adults<sup>[9, 10]</sup>, with more than 130 million CKD patients<sup>[7]</sup>. Furthermore, CKD shows a growth and rejuvenation trend<sup>[10-15]</sup>, which has become a heavy economic and medical burden for families and the country<sup>[3, 16, 17]</sup>. Therefore, prevent and slow down the progression of CKD is urgent<sup>[18]</sup>.

Diet and nutrition are important modifiable determinants of chronic disease<sup>[19]</sup>. Currently, nutritional therapy (NT) is considered indispensable in the treatment of CKD, and diet management is the key to NT<sup>[18, 20, 21]</sup>, which is directly related to tertiary prevention of CKD and is a cost-effective intervention<sup>[15, 18, 21, 22]</sup>. It has been confirmed that diet adjustment adopted by CKD patients can not only delay disease progression and postpone receiving RRT; but also alleviate body symptoms and reduce or mitigate complications, thus improving their health outcomes<sup>[8, 21]</sup>. Therefore, diet management for CKD patients is important and necessary, and is an effective strategy to reduce the economic burden on families and save national medical resources<sup>[18, 23]</sup>.

However, the biggest challenge in clinical practice is the low dietary compliance, which means patients have trouble in long-term adherence, and accurately implement CKD diet<sup>[17, 24]</sup>. Although patients also recognise the significance of NT, their attitudes and behaviours are inconsistent<sup>[25]</sup>. The previous survey found that patients' compliance of low protein diet (LPD) was only 28.30%<sup>[26]</sup>, 34.9% of patients had good compliance with salt restriction<sup>[27]</sup>, protein intake generally exceeded the recommended intake, and most patients had insufficient energy intake<sup>[18, 28, 29]</sup>. Many factors affecting patients' diet management, including the complexity of CKD diet itself<sup>[30]</sup>, confusing and conflicting dietary information received and not actionable<sup>[31, 32]</sup>, whether family support<sup>[33, 34]</sup> and supervised by clinical professionals<sup>[15, 34]</sup>, thus weakening patients' self-efficacy in diet management.



With the integration of mobile Internet technology and medical care, that provides a solution to standardize diet management for CKD patients at home. To promote CKD patients to participation in disease management, access to health information, and adopt health behaviours to improve clinical outcomes and reduce medical expenditures, CKD-related information tools are increasingly common internationally, which enhance patients' self-efficacy in diet management by providing them with dietary guidance, diet self-monitoring, individual recipes, and nutrition counselling, thus positively influencing their eating behaviours<sup>[35, 36]</sup>. In recent years, China began to value diet management in CKD patients, and relevant tools are in rapid development. Usually, some hospitals develop their own information systems, mobile applications or use WeChat groups and WeChat official accounts to serve their clinical work, which have not yet really reached most CKD patients nationwide for home diet self-management. Therefore, it is essential to explore an accessible and open tool for diet management to assist CKD patients at home.

Considering the current high penetration rate of Internet and mobile phones<sup>[37]</sup>, and WeChat has covered more than 94% of smartphone users in China<sup>[38]</sup>. Since the launch of WeChat Mini Program (WMP), it have been widely used in daily life and also serve as carriers for mobile health (mHealth) due to they are portable, real-time, accessible and interactive, suggesting that WMP may become a mainstream application in the era of 5G. Currently, a few studies<sup>[39, 40]</sup> have reported that Mini Program (MP) is effective tool to promote CKD patients' healthy eating behaviours and diet compliance. However, with the main functions are recipe recommendation or food composition query, these MPs are not insufficient to satisfy demands of CKD patients for diet self-management at home<sup>[35, 41]</sup>. In addition, a certain number of diet management MPs for CKD patients are available on the market, but some issues cannot be ignored, for example, almost all of them are not developed by medical institutions and lack descriptions on the development process, reference sources, clinical usability, effectiveness, and safety, and most of them have a single function and high homogeneity, which may have potential hazard and undesirable user experience (UE), resulting in poor user viscosity (UV) and unpromising utilization. Therefore, it is necessary to continue to explore home diet management tools for CKD patients using WMP, adopting the design philosophy of human-centred design (HCD) to ensure that the expectations and needs of end users (including CKD patients and caregivers) are maximally met and that the entire development process is rigorous and scientific.

It is interesting to note that prototyping is an essential and most cost-effective step in the development of user-centred applications, through intuitively grasp the product interface, functionality, and interaction, to expose the design and functional defects as early as possible, and to ensure that the final product is based on the requirements of end-users to ultimately reduce recall and revision. Prototype evaluation is decisive factor in design iteration, so it is critical to recruit target users for prototype testing in real usage environments<sup>[42, 43]</sup>. To the author's knowledge, many foreign studies<sup>[44-49]</sup> have reported the prototype development and evaluation of medical devices, but the similar information available in literature is very rare in the domestic medical research.

In summary, we attempted to design a practical diet management tool to assist patients in accurately performing CKD diet, to further obtain the best benefits from dietetic-nutritional therapy (DNT), delay time to receive RRT and improve their QoL. In this study, we invited relevant stakeholders (multidisciplinary clinical professionals, CKD patients and caregivers, and development technicians) to participate in the design of a CKD patient-centred, open accessible WeChat Mini Program for home diet management, and usability testing of the prototype of the designed Mini Program was conducted, which is expected to provide a reference for the future development.

## **1.2 Literature review**

### **1.2.1 Overview of CKD**

#### *1.2.1.1 Epidemiology*

In the past decade or so, CKD has become a common chronic non-communicable disease (NCD)<sup>[50]</sup> and is deemed to be the 5th leading cause of death worldwide by 2040<sup>[51]</sup>. The prevalence of CKD in adults worldwide is estimated to be 9.1-14.3%<sup>[6, 7]</sup>, which among patients with CKD stages 3-5 is about 10.6% (9.2-12.2%)<sup>[52]</sup>. Some developed countries such as the United States, Norway and Japan have presented with high prevalence of CKD, which is 15%<sup>[53]</sup>, 11.1%<sup>[54]</sup>, and 12.9%<sup>[55]</sup> respectively. In 2012, the first cross-sectional survey results of CKD epidemiology in China were released, which surveyed 47,204 adults from 13 provinces and cities, and the results showed that the prevalence of CKD among adults in mainland China was 10.8%<sup>[9]</sup>. In recent years, the prevalence of CKD (13.2%) in China has been on the rise<sup>[10]</sup>, and the data on young and middle-aged groups in various regions indicate a younger population with CKD<sup>[11-13]</sup>. The number of people with CKD in China was about

132 million in 2017, accounting for about 18% of the globe (697 million)<sup>[7]</sup>. Moreover, the average age of patients on dialysis in China (55 years) is relatively young (59.1 years in the United States and 66.6 years in Japan)<sup>[16, 56, 57]</sup>.

### 1.2.1.2 Clinical characteristics

In clinical practice, estimated glomerular filtration rate (eGFR) is generally used as the basis for the diagnosis and staging of CKD<sup>[58]</sup>, as shown in **Table 1**. eGFR is mainly calculated using MDRD (Modification of Diet in Renal Disease) equation and CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) equation<sup>[59-61]</sup>, and CKD-EPI equation is more suitable for Chinese<sup>[62]</sup>.

Table 1 Staging of CKD

Note: eGFR= Estimated glomerular filtration rate

Staging	eGFR[mL/(min·1.73m <sup>2</sup> )]	Description
G1	≥90	normal or elevated
G2	60-89	mild decline
G3a	45-59	mild to moderate decline
G3b	30-44	moderate to severe decline
G4	15-29	severe decline
G5	<15	renal failure

As a chronic disease, the causes and progression of CKD are complicated. In western developed countries, diabetic kidney disease (DKD) and hypertensive nephropathy (HTN) are the two main causes of ESRD<sup>[63]</sup>. In recent years, diabetes (26.70%) has replaced chronic glomerulonephritis and become the first cause of CKD in China<sup>[3, 64]</sup>. It is estimated that about 1/3 of diabetic patients will develop kidney disease 15 years after the diagnosis of diabetes, and if without intervention, China is probably reach the peak of ESRD caused by DKD in the next 10-20 years<sup>[63, 65, 66]</sup>. HTN (21.39%) is the second most common cause<sup>[3]</sup>, and the association with CKD is complex, which is the cause and consequences of CKD<sup>[66, 67]</sup>. Other causes include polycystic kidney disease, obstructive urinary tract disease, glomerular nephrotic syndrome or nephritis syndrome such as focal segmental glomerulosclerosis, membranous nephropathy, lupus nephritis<sup>[68]</sup>. In addition to the uncontrollable factors (e.g., age, gender, race), common factors that deteriorate renal function are: high blood pressure, high blood sugar, continuous proteinuria, metabolic acidosis, cardiovascular disease (CVD), obesity, hyperlipidaemia, high uric acid, high protein diet, nephrotoxic drugs, urinary tract obstruction, infection, fatigue, smoking etc.<sup>[69-72]</sup>. It can be

seen that most of these factors can be prevented or improved through a healthy lifestyle, especially a reasonable diet, and can also prevent nutritional problems in CKD patients<sup>[18]</sup>.

CKD is generally irreversible with an insidious onset, and may last for many years without obvious clinical symptoms, or with symptoms such as fatigue and increased nocturia, so it is also considered as a "silent" disease<sup>[73]</sup>. Regardless of the cause of CKD (i.e., diabetes, hypertension, or glomerular disease), as kidney function declines and disease progresses, a series of systemic complications will happen. After entering CKD stage 3, patients will suffer from a significantly higher risk of other complications and progression to ESRD, and begin to experience loss of appetite, metabolic acidosis, hypertension, renal anaemia, chronic kidney disease-mineral and bone disorder (CKD-MBD), secondary hyperparathyroidism (SHPT), protein-energy wasting (PEW), etc.; once entering uraemia, functional disorders throughout multiple body systems will occur, and severe cases may die of heart failure, hyperkalaemia, gastrointestinal bleeding, central nervous system disorders<sup>[70, 74]</sup>.

#### 1.2.1.3 Burden of CKD

Since a lack of effective means to eradicate CKD, and once it progresses to ESRD only RRT can be performed. Unfortunately, 1.2 million people died from CKD worldwide in 2017, which resulting in 35.8 million disability-adjusted life years (DALYs)<sup>[7]</sup>, and 2.3-7.1 million adults die prematurely each year worldwide due to RRT is unavailable<sup>[75]</sup>. In addition to being a serious threat to people's lives, CKD also places a heavy economic burden on countries and societies. The burden of CKD varies widely around the world and is even more severe for developing countries than for developed countries<sup>[52, 76]</sup>.

Data from China Kidney Disease Network (CK-NET) showed that the total medical expenditure of all CKD inpatients (including dialysis patients) in 2016 was 27.646 billion renminbi (RMB), which was 6.50% of the total medical expenditure of inpatients, but the number was only 4.86% of all inpatients<sup>[3]</sup>. Although only about 2% of CKD patients will go into ESRD<sup>[77]</sup>, the cost of dialysis is a major medical burden. In 2016, the per capita cost of peritoneal dialysis (PD) and haemodialysis (HD) in China was 87,125 RMB and 89,257 RMB, respectively, which was higher than in 2015<sup>[3, 16]</sup>. Besides, the estimated national dialysis population was 419.12/1000,000 compared to 2015 (311.29/1000 000) was a significant increase<sup>[3]</sup>. The number of people receiving RRT is expected to reach 5.4 million globally by 2030<sup>[75]</sup>, and the situation is even more critical in China, where the number of HD patients will exceed 2 million in 2023<sup>[8]</sup>. Furthermore, the national residents' disposable

annual income in 2020 was 30,732.8 RMB, of which urban residents and rural residents have disposable annual income was 42,358.8 RMB and 16,020.7 RMB respectively<sup>[78]</sup>. In 2012, China included HD into the major medical insurance compensation, and the current reimbursement ratio of urban basic medical insurance is 75.6%, but the insurance ratio of dialysis population is only 0.21%<sup>[3]</sup>. Therefore, dialytic treatments could be unaffordable financial burden for a family without medical insurance coverage.

As mentioned above, the large patient base, the high cost of dialysis, and is subject to a considerable variety of complications in progression of disease, undoubtedly, CKD has become a huge burden for patients and families, and health care system<sup>[77, 79]</sup>. Therefore, if the CKD population that has not yet come to ESRD can be effectively managed to slow down the disease progression, reduce or avoid dialysis, and improve health outcomes, it will play a pivotal role in reducing the economic and mental burden that CKD brings to families and saving national health resources<sup>[3, 80]</sup>. Currently, diet and nutrition management of CKD patients is recognized and valued. Effective diet and nutrition management is one of the most important interventions to slow down the progression of CKD, prevent ESRD, and delay time to dialysis, which cannot be replaced in the treatment of CKD<sup>[8, 18, 81-83]</sup>. Thus, the cost-effective and patient self-controlling intervention (diet and nutrition management) should be vigorously promoted.

## 1.2.2 Overview of diet management of CKD patients

Medical nutrition therapy (MNT) not only plays an important role in helping CKD patients maintain nutritional balance, prevent and improve PEW, CKD-MBD, CVD, and metabolic imbalance, but is also directly related to disease progression and health outcomes, and is suitable for all CKD patients<sup>[82, 84, 85]</sup>, which has been confirmed as a effective and safe approach in clinical practice<sup>[8, 20]</sup>.

### 1.2.2.1 Importance of diet management in CKD patients

Diet and nutrition are important modifiable determinants of chronic diseases, and the association between diet and chronic NCD deserves attention<sup>[19, 86]</sup>. For chronic diseases, physicians should write two prescriptions, one for the disease condition and the other for dietary nutrition<sup>[20]</sup>. Poor dietary habits have long been recognized as a key modifiable risk factor for the progression of CKD, and their correlation is the development of insulin resistance and metabolic syndrome, diabetes, and hypertension in patients<sup>[87-89]</sup>. During the

long-term course of CKD, malnutrition becomes a common complication in CKD patients<sup>[90]</sup>, so CKD is also known as a nutrition-related health problem<sup>[82]</sup>.

For patients with CKD who have not yet go into ESRD, diet management is an effective and economical intervention, and therefore, it should be the first-line intervention in clinical practice<sup>[15, 18, 21, 82]</sup>. The purpose of dietetic-nutritional therapy (DNT) for pre-dialysis CKD patients is to: (1) delay disease progression: 1) LPD can reduce the burden of nitrogenous metabolic waste excretion in the kidneys<sup>[72]</sup>, reduce glomerular hyper perfusion, hyperfiltration and hyper pressure<sup>[91]</sup>, reduce proteinuria, protect residual renal function, thereby delaying the deterioration of renal function, reducing the risk of patients ESRD by 4-13%<sup>[17, 92]</sup>, and avoiding or delaying dialysis treatment<sup>[92]</sup>, and studies have shown that 1 in 18 patients who adhere to a LPD are spared death or dialysis<sup>[18, 93]</sup>. 2) restricting salt intake in the diet can significantly improve the disease prognosis and delay disease progression in terms of affecting blood pressure, urinary protein, and GFR<sup>[94]</sup>. (2) reduce and mitigate complications: 1) restriction on dietary sodium, potassium, phosphorus and fluid intake can correct calcium and phosphorus metabolic disorders, reduce water and sodium retention, and prevent complications such as CVD, CKD-MBD, hypertension, hyperkalaemia, and SHPT<sup>[17]</sup>; 2) reduce dietary protein intake, improve metabolic acidosis<sup>[17, 22]</sup>, and improve insulin resistance to reduce the risk of DKD<sup>[22, 95]</sup>. 3) ensure adequate caloric and moderate protein intake can maintain good nutritional status to improve body immunity and renal anaemia, which is also the preferred treatment for PEW<sup>[96]</sup>. (3) reduce the risk of death and improve their QoL: under reasonable diet, by delaying the progression of CKD, delaying the time to entry into dialysis, reducing or minimizing complications and ensuring good nutritional status, the mortality rate of patients can be cut and their QoL can be improved<sup>[21, 97-99]</sup>. (4) save economic resources: protein-restricted diet can delay to dialysis and has better cost-economic benefits<sup>[100]</sup>. Wu et al.<sup>[99]</sup> conducted an economic evaluation of protein-restricted diet in CKD patients and indicated that the very low-protein diet combined with keto acid resulted in a cumulative treatment cost saving of 180037.2 RMB and 163,517.9 RMB over 5 years compared with full-protein and low-protein diet. In addition, the fast pace of contemporary life and the pressure of work can easily lead to irregular and unhealthy diet, making the population of obesity, hypertension and diabetes more and more large, and it is urgent to strengthen the diet management of these people if the occurrence of CKD<sup>[18]</sup>.

### 1.2.2.2 Requirements and contents of diet management for CKD patients

CKD patients are the primary participants in diet management, requiring close collaboration between multidisciplinary professionals (e.g., renal dietitians, physicians, nurses, psychologist), while also encouraging the active participation of caregivers<sup>[101, 102]</sup>. For CKD patients, regardless of the stage, individualized DNT plan should be customized according to the patient's personal needs, nutritional status, medication, co-morbidities, renal function. The basic dietary principles are to eat in accordance with the recommended, reduce protein intake, ensure adequate caloric intake, reduce the intake of sodium, phosphorus and potassium, and consume adequate dietary fibre, and adequate intake of vitamins and other minerals<sup>[101-103]</sup>.

#### (1) Nutrition screening, assessment, monitoring, and evaluation

Nutrition screening is the first step in MNT. Screening patients at risk for malnutrition followed by further detailed nutrition assessment and targeted interventions to guarantee the safety of DNT<sup>[102, 104]</sup>. Nutrition screening and assessment should preferably be performed by renal dietitians or equivalent personnel<sup>[103]</sup>. Nutrition assessment should focus on the timing and content of the assessment. CKD patients should have their nutritional status assessed regularly during outpatient follow-up, and patients with stable CKD stages 1-3 should have routine nutrition screening at least every six months, and patients with CKD stages 4-5 should have nutrition screening at least every three months; if clinical changes, screening for malnutrition should be performed as early as possible<sup>[103, 104]</sup>. The nutrition assessment usually includes anthropometric measurements (e.g., body mass and body mass index/BMI, skinfold thickness, grip strength), appetite and history dietary intake survey (e.g., 3-day diet records, 24-hour food review, food frequency questionnaires), body composition, and subjective global assessment (SGA) in combination with biochemical indicators (e.g., normalized protein catabolic rate, serum protein and/or serum pre-serum protein)<sup>[103, 105]</sup>. Some factors other than nutrition-related ones, such as substance use, dietary knowledge, eating behaviours, beliefs and attitudes, and cognition, which enable nutrition interventions more effective<sup>[103]</sup>. For patients at home, simple nutritional self-measurement such as anthropometry can be performed but note that BMI alone is not convincing to diagnose malnutrition unless BMI is very low ( $<18.0 \text{ kg/m}^2$ ), but low BMI is an important predictor of mortality<sup>[103]</sup>. Regular dietary nutrition monitoring is also needed to evaluate the compliance and effectiveness of DNT, especially to monitor dietary protein and energy intake in order to adjust their DNT<sup>[103, 105]</sup>.

## (2) Protein

Appropriate protein-restricted diet is safe in the short or long term, provided that the energy intake is adequate, and the requirements of essential amino acid are met<sup>[101, 103]</sup>. Regardless of the stage of CKD, a high-protein diet ( $>1.3\text{g}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$ ) is contraindicated, and 50%-70% of dietary protein should be derived from high-quality protein. Although evidence is insufficient that CKD patients should routinely be on a LPD or consume a specific protein (plant-based or animal-based), but red meats (e.g., beef, pork, lamb) and processed meats (defined as those that have been cured, smoked, or dried) are strongly associated with the development and progression of CKD, and the risk for ESRD is not relating to protein from poultry, fish, eggs or dairy products, and is commonly believed that low-fat dairy products reduce the risk and slow down the progression of CKD<sup>[106-110]</sup>. However, protein restriction is indicated from CKD stage 3 onwards, especially in patients with hypertension, oedema, high levels of serum potassium, nitrogen and phosphorus, and patients with diabetic nephropathy, the restriction of protein intake may need to be stricter<sup>[102, 103]</sup>. National guidelines<sup>[105]</sup> recommend that protein intake for patients with CKD stage 1-2 is  $0.7\text{-}0.8\text{ g}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$ , and if patients with massive proteinuria, keto acid can be added at the same time, and protein intake  $\leq 0.6\text{ g}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$  is not recommended; for patients with CKD stage 3-5, LPD ( $0.6\text{ g}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$ ) or very low protein diet ( $0.3\text{ g}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$ ) is recommended, combined with their conditions to give keto acid preparations. Since CKD patients need to restrict protein intake, the conventional rice and noodle diet is not good enough to help patients control protein intake. In recent years, free (low) protein products have been available on the market, which provide sufficient calories but contain almost no protein, phosphorus, sodium, and potassium, and become substitutes for the staple food of CKD patients<sup>[101, 102]</sup>.

## (3) Carbohydrates and lipids

In CKD patients, while adopting a LPD, the proportion of carbohydrates and fats should be increased accordingly to give the body sufficient energy<sup>[111]</sup>, which increases the utilization of protein and reduces the accumulation of nitrogenous metabolites in the kidneys and protects residual kidney function<sup>[112]</sup>. It is recommended that carbohydrate energy supply ratio for CKD patients is 55% to 65%, and those with abnormal sugar metabolism should limit refined sugar intake and consume high-fibre foods, such as mixed grain cereals, oatmeal, whole wheat bread, mixed fruits, and vegetables to provide calories, which can regulate intestinal flora and have laxative effect. And fat energy supply ratio is 25% to 35%, of which saturated



fatty acids do not exceed 10%, and no more than 1% trans fatty acids, n-3 fatty acids and monounsaturated fatty acids intake can be increased appropriately and replace butter (animal fats) with vegetable oils such as flaxseed oil, tea seed oil or olive oil, as animal fats aggravate atherosclerosis and inhibit haematopoiesis. But no evidence show that low-fat diet can improve patients' prognosis, and those with disorders of lipid metabolic should have a low-fat diet with cholesterol intake <300 mg/d, and the maximum daily vegetable oil dosage is about 60 g [70, 100, 105, 111, 113]. The individualized recommended energy intake for CKD patients should be based on the patient's age, gender, physical activity, target weight, defatted weight, body composition, inflammatory reaction, CKD stage, and co-morbidities to maintain a normal nutritional status<sup>[103, 105]</sup>. National guidelines<sup>[105]</sup> recommend that for non-diabetic patients with CKD stage 1-2, adequate caloric intake to maintain a stable healthy weight; for diabetic patients with CKD stage 1-2, the recommended energy intake is 30-35 kcal·kg<sup>-1</sup>·d<sup>-1</sup>, with a reduced intake (1,500 kcal/d) for obese patients, and 30 kcal·kg<sup>-1</sup>·d<sup>-1</sup> may be considered for elderly patients with diabetic nephropathy; for patients with CKD stage 3-5, the recommended energy intake is 30-35 kcal·kg<sup>-1</sup>·d<sup>-1</sup>.

#### (4) Minerals and vitamins

*Sodium* Excessive salt intake is detrimental to blood pressure control, cardiovascular and renal health<sup>[106, 114]</sup>. For patients with CKD, dietary restriction of sodium intake is strongly recommended to reduce fluid retention, control blood pressure, and reduce the risk of CVD, and reduce proteinuria in conjunction with drug therapy to improve the prognosis<sup>[94, 106, 115, 116]</sup>. It is estimated that potassium salt substitution would provide considerable benefits if used nationwide, reducing deaths in CKD patients, so potassium salt can be used instead of sodium salt to reduce sodium intake, but is not recommended for CKD patients at risk of hyperkalaemia<sup>[112]</sup>. National guidelines<sup>[105]</sup> recommend that dietary sodium intake in patients with CKD stages 1-5 not exceed 2.3 g/d (equivalent to 6 g/d of table salt). However, it is important to note that increased and/or decreased serum sodium are independently associated with mortality in non-dialysis CKD patients, regardless of the presence of congestive heart failure, and therefore sodium intake below 1.5 g/d is not recommended<sup>[106, 117]</sup>. Usually, the sodium content of food consumed throughout the day is around 1000 mg, which can increase about 3.3g of salt intake to reach the sodium intake of 2.3 g/d<sup>[112]</sup>.

*Phosphorus* Phosphorus is an essential nutrient for many physiological functions, but excessive phosphorus intake has adverse effects on the skeletal, renal, and cardiovascular

systems, especially in patients with CKD who are more susceptible to high phosphorus intake<sup>[118, 119]</sup>. Although dietary phosphorus intake is not a key determinant of blood phosphorus concentrations and is not strongly associated with the occurrence of ESRD and all-cause mortality in patients with CKD<sup>[106, 120]</sup>. However, the more phosphorus in food consumed, the more the body absorbs. Normally 80% of phosphorus in the body is excreted through the kidneys, so for CKD patients there may be an increased risk of high blood phosphorus, so a phosphorus-restricted diet is still important for the prevention and treatment of hyperphosphatemia<sup>[121-123]</sup>. Since each 1g of protein contains 12-14 mg of phosphorus on average, the intake of essential protein also increases phosphorus intake, i.e. high protein intake in the diet is often closely related to high phosphorus intake<sup>[112, 124]</sup>, but low phosphorus diet is not equal to low protein diet, it is recommended to restrict phosphorus intake without restricting protein intake. Otherwise, excessive phosphorus restriction may lead to insufficient protein intake and affect the nutritional status of patients bringing adverse prognosis and increase the risk of death<sup>[121, 124, 125]</sup>. Patients with CKD are advised to limit processed foods containing phosphorus additives and preservatives, choose fresh, additive-free foods, foods with low phosphorus/protein ratio (<12mg/g) and low absorption of organic phosphorus, and not to consume fast food/cooked food products for convenience<sup>[8, 118, 125, 126]</sup>. National guidelines<sup>[105, 126]</sup> recommend that patients with CKD stages 3-5 should limit dietary phosphorus intake to maintain serum phosphorus in the normal range, while those with malnutrition and hypophosphatemia can increase phosphorus intake appropriately.

*Potassium* The main route of potassium excretion in normal adults is urine (80%-90%), and the intake of potassium-rich foods (from plant foods such as vegetables and fruits) usually does not cause hyperkalemia, but patients with CKD are prone to hyperkalemia due to decreased kidney function, with an incidence of 22.89%, commonly in patients with advanced CKD<sup>[127-129]</sup>. Current medical evidence is insufficient to demonstrate that dietary potassium intake is associated with CKD progression<sup>[116, 130]</sup>, and lack of recommended optimal dietary potassium intake for delaying and influencing CKD progression<sup>[131]</sup>. Therefore, for CKD patients with serum potassium >5.0 mmol/L, education on low-potassium diet is necessary, prohibition of special table salt such as low sodium salt and balanced salt, less use of condiments such as soy sauce, and vegetables with high potassium content should be soaked and blanched before cooking<sup>[128, 132]</sup>. However, a potassium-rich plant-based diet is alkaline and can lower blood pressure, reduce the risk of stroke and kidney stones, improve metabolic acidosis, protect bone health, and have a role in cardiovascular protection<sup>[8, 130, 133, 134]</sup>.

Hypokalaemia is associated with muscle weakness and hypertension in CKD patients, and dietary over-restriction of potassium intake also predisposes to constipation, potentially exacerbating the risk of cardiovascular events and all-cause mortality, as well as uremic toxin accumulation in CKD patients<sup>[106, 128, 135]</sup>. National guidelines<sup>[105]</sup> recommend that individualized adjustment of dietary potassium intake in CKD patients to ensure serum potassium is maintained within normal range, and that patients with hyperkalaemia should reduce and limit dietary potassium intake and take oral potassium-lowering medications if necessary. However, patients with CKD should not blindly restrict dietary potassium intake to avoid hyperkalaemia<sup>[130]</sup>.

*Calcium* The kidneys play an important role in calcium reabsorption, so as CKD progresses, blood calcium levels decrease<sup>[106, 136]</sup>, leading to SHPT and disorders of bone metabolism, while hypercalcemia increases the risk of CVD and death in patients<sup>[8, 105]</sup>. Calcium-rich foods (especially dairy products) often also contain phosphorus, protein, and fat, which are more slowly absorbed than inorganic calcium supplements and may reduce the risk of hypercalcemia and CVD<sup>[137, 138]</sup>. In patients with CKD, maintaining of blood calcium balance requires consideration of several factors, including renal function, bone metabolism, vitamin D analogues, and calcium use<sup>[106]</sup>. Although the recommended intake of dietary calcium is unclear, CKD patients should consume appropriate dietary calcium to maintain calcium homeostasis<sup>[106]</sup>. National guidelines<sup>[105]</sup> recommend a total elemental calcium (including calcium from food, calcium tablets and calcium-phosphorus binding agents) intake of 800-1000 mg/d for patients (not taking active vitamin D) with CKD stages 3-4.

*Nutritional vitamin D* Although active vitamin D has been widely used in clinical CKD treatment, nutritional vitamin D supplementation is equally valuable, it is beneficial to improve the concentration of 1,25 (OH) 2D (calcitriol, active vitamin D), which protects the kidneys in multiple ways, i.e., correcting abnormalities in calcium and phosphorus metabolism, preventing SHPT, improving renal anaemia and insulin resistance, controlling blood pressure, reducing urinary protein, decreasing infection. And it also reduces the risk of fractures and falls, lowers the risk of CVD, and improves patients' prognosis<sup>[139-142]</sup>. Ninety percent of the body's vitamin D is synthesized through ultra-violet light exposure to the skin, with only a small portion coming from the diet, mainly referring to vitamin D2 and vitamin D3, the former from plant foods (e.g. olive oil, flaxseed oil) and the latter from animal foods (e.g. deep-sea fish, cod liver oil, egg yolk)<sup>[143-145]</sup>. Therefore, although there are no guidelines for safe doses of vitamin D supplementation, CKD patients may be appropriately

supplemented with dietary nutritional vitamin D and have serum calcium, phosphorus, and 25(OH)D measured regularly, especially in patients taking calcium-phosphate-containing conjugates and/or active vitamin D analogues<sup>[105, 106, 111]</sup>.

Other vitamins, such as B vitamins, vitamin C, and folic acid, can be supplemented appropriately if clinical signs and symptoms confirm a deficiency or risk of deficiency, but are not recommended for routine supplementation<sup>[105]</sup>. Similarly, other minerals /micronutrients, such as selenium and zinc, are not clinically recommended for routine supplementation and should only be provided to patients with CKD who have symptoms or biochemical abnormalities associated with micronutrient deficiencies<sup>[103, 105]</sup>.

#### (5) Water

Increased fluid intake in CKD population is a potentially important treatment, and increasing daily urine output (i.e., urine volume  $\geq$  3000 ml/d) may be beneficial in slowing the decline of renal function, especially in patients with early stage of CKD (G1-G2)<sup>[112]</sup>. For pre-dialysis CKD patients, fluid restriction may be unrestricted in the absence of oedema, hypertension, and normal urine output; if mild oedema is present, appropriate restriction of water intake is sufficient. If CKD patients have severe oedema, oliguria (urine volume <400ml/d) or combined with severe CVD, fluid intake should be strictly limited, with the principle of quantity out as quantity in, generally limiting fluid intake to less than 1000ml per day<sup>[111]</sup>. However, care should be taken to avoid hyponatremia caused by combined diuretics and acute exacerbation of CKD<sup>[112]</sup>. National guidelines<sup>[105]</sup> suggest that patients with CKD stage 3-5 should limit and adjust fluid intake appropriately according to urine output to maintain fluid balance in the body.

#### (6) Dietary fibre

It has been shown that there is a negative correlation between dietary fibre intake and the risk of CKD, with an increase of 5 g of fibre (from legumes and vegetables) in the diet per day reducing the risk of CKD by 11%, suggesting that a high intake of dietary fibre may reduce the occurrence of CKD<sup>[146]</sup>. For CKD patients, high dietary fibre intake is also beneficial, including regulating body weight and blood lipids, and reducing hunger in obese patients; promoting intestinal motility and defecation, regulating intestinal flora composition and metabolism, repairing gastrointestinal dysfunction, and promoting urinary toxin and potassium excretion<sup>[8, 88, 115, 147]</sup>; slowing the decline in GFR, reducing the risk of CVD, and

even avoiding or delaying entry into dialysis<sup>[88, 148, 149]</sup>; to treat DN or reduce the risk of developing type 2 diabetes<sup>[149]</sup>; it can also reduce mortality in CKD patients<sup>[88, 150]</sup>. National guidelines<sup>[111]</sup> recommend that CKD patients should increase the intake of fruits and vegetables to reduce net acid, and that a daily dietary fibre intake of 14g/4180 kJ (1000 kcal), with attention to monitoring serum potassium and phosphate, and ultimately a high fibre diet is safe and beneficial<sup>[150]</sup>.

It can be seen that to ensure the safety and effectiveness of CKD diet, in terms of interventions, patients should be regularly screened and assessed for nutrition, dietary nutrient monitoring and evaluation; the key to dietary intervention is a low-protein diet, but adequate caloric intake should be ensured; other dietary supplements related to complications and/or comorbidities in patients with CKD that have an important impact on the body's metabolism and maintenance of internal environmental homeostasis, such as minerals (sodium, phosphorus, potassium, etc.), should be appropriately reduced; vitamins (vitamin B, vitamin C, vitamin D, folic acid, etc.) should be supplemented in appropriate amounts to meet clinical indications; and appropriate adjustment of fluid intake and moderate consumption of vegetables and fruits are beneficial to patients with CKD. It is worth noting that exercise should be included in DNT<sup>[101]</sup>. Therefore, the functions of diet management MP for CKD patients designed in this study should be comprehensive including but not limited to the above aspects to ensure that the diet self-management of CKD patients meets the clinical requirements, i.e., scientific, effective, and safe.

### *1.2.2.3 Status of diet management in CKD patients*

After CKD patients are diagnosed, they are often very nervous. They know that diet has influences on the development and prognosis of the disease. Currently, they possibly take the initiative to seek diet-related knowledge from different channels. However, CKD diet management is a complex issue, not just a question of what they should or should not eat. Therefore, most patients say that they should have a high-quality low-protein and low-salt diet (LSD), and believe that DNT is very important, their attitudes toward CKD diet are positive<sup>[151, 152]</sup>. However, their attitudes and behaviours are inconsistent, which means the difficulties in long-term adherence and accurately perform CKD diet<sup>[17, 24]</sup>. A study investigated the current status of nutritional knowledge, belief and behaviour of 170 patients with CKD stage 3-4, and the results showed that the score of knowledge was (9.98±4.49) (total score was 20), the score of attitude was (40.96±2.15) (total score was 50), and the score

of behaviour was  $(17.93 \pm 2.37)$  (total score was 25), suggesting to strengthen diet management in CKD patients<sup>[151, 153, 154]</sup>.

A LPD is a dietary treatment prescribed and administered by nephrologists and dietitians that limits protein supply, with or without keto acid/amino acid supplementation, while ensuring adequate energy intake<sup>[155]</sup>. One study surveyed 150 inpatients with CKD stages 3-5 and their awareness of LPD was low at 41.34%-70.67%<sup>[156]</sup>. The survey by Huang<sup>[157]</sup> showed that 71.9% of CKD inpatients were unaware of the contents of LPD, and another study surveyed 180 patients with CKD stages 3-5 and found that only 28.30% had good compliance with LPD<sup>[26]</sup>. As CKD progresses from stage 3 to stage 5, there is a decreasing trend in protein intake and an increasing trend in low protein diet adherence in patients<sup>[158]</sup>. It can be seen that due to the vague concept of LPD in CKD patients, only a few patients can achieve reasonable protein intake, some patients excessively restrict protein intake, most patients eat too much protein, and/or accompanied by a low proportion of high-quality protein, and consume less high-quality protein from poultry, legumes and aquatic products, meanwhile, the intake of the three major energy supplying nutrients is unreasonable and caloric intake is insufficient, and especially from CKD stage 3, we should pay attention to the nutritional problems<sup>[26, 28, 159-161]</sup>.

A low-salt diet (LSD) (<6g/d) is the most basic requirement for CKD patients, while the fact is most patients have excessive salt intake. A study investigated salt intake of 605 patients CKD for salt restriction and found that 81.1% of them were willing to reduce salt intake, but only 34.9% had good compliance<sup>[27]</sup>. One study used 24-hour urine sodium measurement to investigate the salt intake of 178 CKD patients, and the 24-hour urine sodium was  $(135 \pm 58.4)$  mmol/d (ideally, 100 mmol/d). The study concluded that patients had active behaviour, but did not understand and pay enough attention to the need for LSD, lacked of knowledge and skills on salt restriction, and was also associated with previous lifestyle and family members' interference<sup>[162]</sup>, which is consistent with the findings of other scholars<sup>[163]</sup>.

As CKD progresses, renal excretory function decreases, and in order to prevent and control metabolic disorders, CKD patients should adopt a diet of low sodium, potassium and phosphorus, and high calcium<sup>[28]</sup>. The results of the dietary knowledge survey of 100 hospitalized CKD patients revealed that patients knew 68% and 65% about potassium restriction and invisible salt, respectively, but only 40% about phosphorus restriction<sup>[164]</sup>. A study investigated 96 non-dialysis patients with CKD stages 3-5 showed that the dietary intakes of sodium, potassium and phosphorus were higher than the recommended intake of

Chinese residents, while calcium intake was insufficient<sup>[28]</sup>, but another small sample survey indicated that the intake of phosphorus in patients with CKD stages 3-5 was within the recommended<sup>[158]</sup>.

Nutritional vitamin D can correct vitamin D insufficiency or deficiency, lower parathyroid hormone, reduce proteinuria, prevent falls, improve cardiac function, and help improve disease prognosis<sup>[165]</sup>. However, CKD patients are commonly with nutritional vitamin D deficiency, which is a prominent feature of CKD patients, with vitamin D insufficiency and deficiency up to 96.7% in pre-dialysis CKD stage 3-5 patients<sup>[166]</sup>.

Dietary fibre and gastrointestinal symptoms interact and influence each other in CKD patients, and it is generally recommended that CKD patients should have a daily dietary fibre intake of 14 g/1,000 kcal<sup>[167]</sup>. A study investigated the dietary fibre intake of 108 hospitalized CKD patients, and the results showed that the dietary fibre intake was generally low, with an average of  $(6.31 \pm 1.86)$  g/1,000 kcal, and only 32 cases (29.6%) had a daily dietary fibre intake of  $\geq 10$  g<sup>[168]</sup>. The study also suggested to focus on CKD patients who are elderly, male, with low education, and have gastrointestinal symptoms, and combined hypertension and diabetes<sup>[167, 168]</sup>.

The above shows that the current situation of diet management in CKD patients is worrying, how to help patients to self-manage their diet should become the focus of clinical work<sup>[15, 18]</sup>.

#### *1.2.2.4 Factors affecting diet management in CKD patients*

Diet changes in CKD patients are lifelong, which is a major psychological and behavioural challenge and affects their self-management<sup>[31, 169]</sup>. For patients themselves, their socio-demographic factors (such as age, gender, education, economic status, marital status, work status), as well as disease-related factors such as CKD stage, disease duration, comorbidities, complications, number of hospitalizations, and health care payment patterns also have an impact on their eating behaviours<sup>[26, 33, 170-172]</sup>. Exemption from dialysis motivate CKD patients to change their eating behaviours<sup>[173]</sup>, but the complexity of CKD diet itself is the primary resistance<sup>[30, 174]</sup>, and patients regard LPD as cumbersome, recipes are too narrow, and with poor taste<sup>[160, 175]</sup>. Moreover, CKD patients have lower self-efficacy, which is an independent factor affecting their diet compliance<sup>[26, 176]</sup>. In the absence of obvious physical symptoms, patients do not have a strong sense of changing their eating behaviours, and being in a specific dietary culture also contributes to the difficulty of adhering to CKD diet in the

long term<sup>[173]</sup>. Besides, patients often receive dietary information from multiple sources, which can also reduce the effectiveness of their diet management when contradictory and conflicting dietary advice is presented<sup>[31, 173]</sup>. In addition, concerns about malnutrition caused by LPD is also an important reason why patients do not want to adhere<sup>[156]</sup>.

Family members are the most important part of social support. Effective family support has a multiplier effect on improving patients' self-management, and the involvement of caregivers is influential, especially in the early stages of CKD<sup>[177]</sup>. Family members support and assist patients in implementing the CKD diet, which can improve diet implementation and prolong implementation time<sup>[30]</sup>. For dialysis patients, only family companionship during dialysis can also improve their diet compliance<sup>[178]</sup>, which shows the importance of family support and family participation in CKD diet management should be encouraged. However, it was also found that most families do not understand CKD diet, and making CKD diet can be challenging for families, especially in families with children<sup>[30, 179]</sup>. Therefore, this may require family-based dietary education to increase caregivers' awareness of CKD diet.

Diet management of CKD patients is a long-term, complex task, and multidisciplinary clinical professionals (e.g., doctors, nurses, dietitians, rehabilitators, psychologists) have a profound impact on dietary changes in CKD patients, including their communication skills, early nutrition intervention and individualized diet prescription, providing long-term ongoing nutritional guidance, assessment, adjustment and support<sup>[32, 173, 180, 181]</sup>. However, with over 130 million CKD patients in China, there is a serious shortage of registered dietitians, and doctors and nurses have limited knowledge of CKD diet, which, coupled with busy clinical work, prevents them from providing simultaneous DNT for patients<sup>[21, 182-184]</sup>. Clinical dietary education is often very general and lacks quantitative, qualitative, individualized guidance as well as practical operability, and lacks dietary education tools to meet the needs of patients' diet self-management<sup>[30, 31, 157, 185]</sup>. Therefore, the majority of CKD patients have discontinuous diet management. 72.5% of patients reported that they had received dietary guidance from dietitians, but only about 21% received dietary guidance in the past year<sup>[159]</sup>, indicating that patients rely on self-management most of the time. Especially non-dialysis CKD patients, nearly 1/10 of them did not receive individualized dietary education and counselling from dietitians<sup>[82, 186]</sup>. Therefore, patients with CKD in China tend to check the Internet on their own, most often through "Baidu", and there are more than 70 million results for "chronic kidney disease diet". Most patients have difficulty in screening such a wide range



of information on the Internet, which may cause potential harm to their health, and reduce their motivation to adopt CKD diet.

Now, we can know that the implementation of CKD diet is not satisfactory. Most patients have heard of high-quality low protein, low-salt and low-fat diets, but many patients have also suggested that in the actual implementation of CKD diet, they will encounter a variety of problems that cannot be solved and feel confused, such as the fear that wrong food choices will aggravate the disease, the misconception that they can only eat a specific food, not knowing whether the dietary nutritional intake is up to standard, worrying that LPD will cause malnutrition. The lack of continuous dietary counselling and follow up has weakened their motivation to manage their diet and eventually led them to choose to give up<sup>[156, 161]</sup>.

#### *1.2.2.5 Diet management intervention for CKD patients*

Diet management is the key to nutrition intervention in CKD patients<sup>[21, 105]</sup>, the most restrictive diet of all chronic diseases<sup>[85, 187]</sup>, and moreover, the core of CKD management<sup>[188, 189]</sup>, thus diet management has become an important part in clinical work. By providing individualized and systematic dietary education and counselling services, enhancing their awareness of diet management, which is the best motivation for patients to actively participate in diet self-management. Hegazy et al.<sup>[190]</sup> concluded that providing one-on-one dietary education and consultation is beneficial to improve dietary knowledge and health status of CKD patients. Currently, some hospitals have set up CKD-nutrition joint clinic, which usually involve multidisciplinary teamwork among dietitians, physicians, and nurses, to help patients recognize the importance of DNT, disseminate dietary knowledge, correct dietary misconceptions, provide individualized dietary guidance by assessing their renal function, nutritional status, dietary preferences, health literacy, and economic status, etc. In addition, it helps patients to form good dietary behaviours, which has a significant impact on improving their ability of self-management and diet compliance, and their QoL<sup>[191, 192]</sup>.

While traditional model of in-hospital face-to-face dietary intervention is effective, CKD populations often have no access to continuous. And individualized dietary support due to many factors such as the lack of renal dietitians, limited time in outpatient or inpatient, geographical position, time, and economics, as well as COVID-19 pandemic. Furthermore, the mismatch between patients' needs and current clinical service delivery highlights the urgent need to consider alternative strategies to support patients. With the application of Internet in healthcare, providing timely, convenient, cost-effective, and individualized support

via mobile devices such as cell phones offers a new idea for the standardized management of the diet of CKD patients. In recent years, the evidence suggests that information technology (IT) has advantages in promoting patients to adhere to CKD diet. It can provide different formats (e.g., image-text, videos), dynamic dietary information, to better meet the needs of patients and the growing demand for services to assist patients' diet self-management and thus enhancing their willingness to manage their diet<sup>[15, 36, 91, 193, 194]</sup>. An Australian study conducted focus group interview with non-dialysis patients with CKD and caregivers on their diet management experiences and recommended the use of telemedicine technology to support diet management<sup>[89]</sup>. In addition, an American study that interviewed 30 HD patients to explore factors contributing to their dietary compliance barriers, and it also suggested that IT interventions are needed to address these barriers to allow patients to choose food and make real-time decisions, customize their diets according to their preferences<sup>[195]</sup>. Therefore, we believed that CKD patients' needs a scientific and accessible diet management tool<sup>[196]</sup>.

### 1.2.3 Application of Internet for diet management in CKD patients

#### 1.2.3.1 Prospects of mobile Internet in healthcare

According to the National Bureau of Statistics bulletin<sup>[37]</sup>: the number of people online in 2020 was nearly 1 billion, the Internet penetration rate was 70.4%, and the mobile phone penetration rate exceed 1 per person. It was expected that China's mobile medical users would reach 700 million in 2021<sup>[197]</sup>, and health management accounts for 70% of the user services<sup>[198]</sup>. One scholar<sup>[199]</sup> once mentioned that 65% of patients in China have installed at least one health App, 79% of doctors considered mobile devices can improve medical efficiency, and 68% of doctors said they were willing to recommend patients to use mobile Apps for chronic disease management. In 2017, a study<sup>[200]</sup> reported 134 cases of CKD patients' demand for Internet health management services, in which the demand for individualized e-health plans and remote diet monitoring and guidance were 88.81% and 86.57%, respectively, suggesting that CKD patients have great demand for Internet-based health management. West et al.<sup>[201]</sup> indicated that dietary/nutritional Apps can motivate users to make positive dietary behaviour changes, which are beneficial for improving users' self-efficacy, dietary knowledge and attitudes, as well as increasing their confidence in achieving their dietary goals.

Internet is highly popular in today's China, smart phones are the most used mobile devices, and people attach more importance to health management, so the market of mobile medical will continue to expand, and the use of mobile phone to achieve health management will become an important supplement to medical services in China.

### *1.2.3.2 Internet-based tools for diet management in CKD patients*

With the integration of internet and medicine, internet-based diet management tools are sustainable to influence patients' dietary behaviours, support out-of-hospital patients' self-management, and improve health outcomes<sup>[33, 74, 202]</sup>. The application of diet management tools for CKD patients in clinical practice can provide with dietary knowledge, diet monitoring, individualized recipes, nutrition counselling and other services to enable scientific and reasonable control of their diets. It can not only improve patients' ability in diet self-management, promote their formation of good eating behaviours, thus improving their diet compliance and nutritional status, but also increase clinical efficiency, and facilitate communication between doctors and patients, which play an important role in the standardized management of CKD diet<sup>[15, 24, 74, 203-207]</sup>.

Currently, a variety of diet management tools are available for CKD patients abroad, such as mobile health applications<sup>[174]</sup>, personal digital assistants<sup>[208, 209]</sup>, websites<sup>[210]</sup>, and telehealth systems<sup>[211]</sup>. Different from foreign users' habits, diet management tools for CKD patients in China are mainly hospital information systems, Apps, WeChat. Manual nutrition analysis is often tedious, time-consuming and inefficient<sup>[206]</sup>. In order to optimize clinical work, Deng et al.<sup>[206]</sup> solicited the needs of clinical professionals, especially dietitians, to design and develop Nutrition Management System for Patients with CKD, which can connected with hospital information system to improve work efficiency, and also improve patients' dietary compliance and accuracy. Since the care model of hospital-community-home has been widely used in chronic disease management and has achieved good results. Therefore, Chen et al.<sup>[207]</sup> developed a hospital-community-home platform (CKD Cloud Care), which includes three ports, namely hospital side, community side and patient mobile App side (recipes, dietary knowledge and online consultation can be accessed). Wang et al.<sup>[15]</sup> developed Home Diet Monitoring and Follow-up System for CKD patients, which consists of a nurse side (computer side), a patient side (App side) and a server, with the nurse side dynamically monitoring dietary intake, helping patients manage protein and salt intake. WeChat is the most popular application in China, which is an important medium for transmitting information because the

characteristics of easy use and good interaction. In recent years, WeChat has been introduced into clinical practice, which has demonstrated a positive effect on diet management. For example, the results of studies by Xu et al.<sup>[24]</sup> and Wei et al.<sup>[203]</sup> indicated that dietary education and individualized diet guidance based on WeChat groups can improve patients' dietary compliance and facilitate online communication between doctors and patients. Wang et al.<sup>[204]</sup> also suggested that using WeChat official accounts to push dietary knowledge and videos for patients to learn can effectively improve their dietary compliance and also reduce the workload of medical staff.

To the author's knowledge, report on information-based diet management tools for CKD patients in China began to appear in the last 5 years, indicating that information-based tools have been used to manage the diet of CKD patients in China. However, the current diet management tools for CKD patients are operated by some hospitals with the purpose of serving clinical work, and such Apps reported in literatures can hardly be searched in App Store, thus it can be concluded that the information-based diet management tools only benefit a small number of CKD patients. Therefore, a suitable and open accessible diet management tool for CKD patients to self-manage their diet at home is needed.

### *1.2.3.3 WeChat Mini Program for diet management in CKD patients*

#### (1) Advantages of WeChat Mini Program

WeChat is a free App launched by Tencent in 2011 and has covered more than 94% of smartphones in China in 2016<sup>[38]</sup>. WeChat Mini Program (WMP) is an application that can be used in WeChat environment without downloading and installing<sup>[212]</sup>. The user volume of WMP in China was about 750 million in June 2019<sup>[213]</sup>, and daily number of active user of WMP reached 400 million by 2020, which shows that WMP is increasingly popular among users<sup>[214]</sup>. Since WMP is developed on the basis of the development guidelines and development tools provided by WeChat official, the development of WMP is less technically difficult and has a shorter development cycle, and also lower system maintenance costs compared with App, and not have to download, install, register, users can open and logged in WMP directly through their WeChat account, which is convenient and with good UE<sup>[215]</sup>. While comparing with WeChat official accounts, there are more than 100 entrances to WMP, which can be accessed directly through search, QR code, WeChat official accounts, etc. The WMP will be hidden automatically after use, so pay attention to it or take it off repeatedly is unnecessary<sup>[214, 215]</sup>. Because WMP is close to a original App, users can get information more

efficiently, and WMP is more suitable for providing products and services than WeChat official accounts, which is more powerful and interactive<sup>[215]</sup>. Obviously, WMP is a suitable and open accessible tool to assist most CKD patients to self-manage their diets at home.

## (2) WeChat Mini Program and diet management in CKD patients

WMP was just launched in 2017, so only a few clinical studies have been reported on WMP and diet management in CKD patients. For example, a WMP called Personalized Diet for Kidney Disease allows patients to choose foods according to their preferences within a certain range to customize individual recipes, and help patients estimate the recommended food weight accurately by providing a graphical representation of the amount of each food assessed with bare hands. The results of the study indicated this WMP simplifies CKD diet and promotes healthy eating behaviours, improves dietary compliance and nutritional status in CKD patients<sup>[39]</sup>. In addition, to identify high phosphorus content foods when eating at home and improve compliance with low phosphorus diet, patients can use High Phosphorus Food Bank (WMP) to check the phosphorus content of foods<sup>[216]</sup>. Similarly, On Line Kidney is another WMP used for diet intervention among out-of-hospital patients<sup>[217]</sup>, with which patients can search for phosphate content of food to control phosphorus intake, and meanwhile patients and their families are encouraged to use WeChat official account to obtain dietary knowledge, WeChat group and paper dietary diary.

As mentioned above, the current diet management WMP for CKD patients has the shortcomings of not having diversified functions, and they mainly serve to query food nutrient and recommend recipes, which unable to meet the needs of CKD patients to manage their diet at home. Furthermore, literatures about clinical usability assessment of mobile medical Apps are available in recent years<sup>[218-220]</sup>, but domestic diet management tools for CKD patients go straight to clinical effectiveness interventions, which needs attention to ensure reliable diet management tools for CKD patients.

### *1.2.3.4 Market survey on diet management applications for CKD patients*

The number of mobile medical Apps is increasing year by year, and some Mini Programs (MPs) or Apps for CKD diet management are available in WeChat and App Store, but little is known about their development process, clinical usability, effectiveness, and safety. However, to learn and compare the characteristics of these MPs and Apps on the market and to provide references for this study, we searched them use both Chinese and English search terms,

"CKD", " kidney", "renal", and "nephro" in WeChat and App Store (Android and iOS) and acted as their target users to operate them to get comprehensive information. Based on the contents and requirements of diet management in CKD patients described above, as well as the results of the qualitative study of dietary needs of patients with CKD stages 3-5 by Jiang et al.<sup>[41]</sup> and the qualitative study on experiences of diet management in CKD patients by Wang et al.<sup>[180]</sup>. Then the following 11 functions, namely dietary knowledge, nutrition screening, dietary nutrition monitoring, individual dietary advice, diet record, individual recipes, food composition query, online consultation, family support, patient communication, and online shopping, were used to classify and score the included MPs and Apps, and each of the above functions was scored 1 point, with a maximum possible score of 11.

Excluding duplication, unusable ones, and those requiring payment, a total of 26 MPs or Apps were included. They were Huibang Kidney, Wisdom Kidney Health, Kidney Aibao, Chinese Kidney Cloud Doctor, Online Nephrology, Kidney Friends Help i, Shentai.com Health Terminal, Aishen.com, Yiben Kidney Internet Hospital, Personalized Diet for Kidney Diseases, Weigao Kidney Friends Mall, Xieyun Kidney UCKH, Kang Ai Kidney Disease Dietary Survey Assistant, Kidney Disease Diet Maintenance, High Potassium Diet, High Uric Acid Diet, High Phosphorus Diet, Kidney Disease Centre, Kidney Online, CKDcloud, Beirong Kidney Baojian, Handheld Kidney Doctor, Low Phosphorous Foods, Renal Care Compass, DecideDiet, Nefrodiet, Kidney Friendly Recipes. The analysis suggested that: (1) In terms of developers: the majority (16/26) of developers are medical technology companies, very few are developed by healthcare organizations (2/26), and even some (6/26) are developed by information technology companies, and their detailed development process are unknown (e.g., whether they are developed in collaboration with clinical professionals, other stakeholders, i.e., patient and caregiver whether they are involved). However, mobile medical devices should be developed in collaboration with patients, clinical professionals, IT companies and other possible stakeholders such as caregivers<sup>[221]</sup>. (2) In terms of publishing platforms, App Store (iOS) (8/26) and WeChat (18/26) are more popular compared to App Store (Android), in addition to the advantages of iOS itself, the large WeChat users suggests that MP may become the future trend and development hotspot for mobile medical applications in China. (3) In terms of the number of downloads: MPs are not required to be downloaded and installed, but the current number of downloads for most (6/11) Apps is unknown, probably due to the small number of users. (4) In terms of references: most (22/26) does not state whether they refer to medical evidence. Ying et al.<sup>[222]</sup>, scholars in Taiwan,

have pointed out that the current medical Apps developed in China lack the description of the source of reference, and suggested that the relevant guidelines or requirements for medical device development should be followed and state the reference sources. (5) In terms of functions: most of them provide the following functions: dietary knowledge (13/26), dietary nutrition monitoring (12/26), diet record (15/25), food composition query (12/26), online consultation (12/26), and online shopping (8/26); when it comes to individual functions, such as individual dietary advice (4/26) and individual recipes (4/26), and patient communication (5/26) are not common, especially nutrition screening (1/26) and family support (0). Besides, the scores show that most of them have incomplete functions (e.g., 2/26 with a score of 2 and 8/26 with a score of 3), and even some of them have single function and high homogeneity (7/26 with a score of 1), suggesting that most current MPs and Apps may be unable to meet the needs of CKD patients. This is similar to the results of content analysis of 177 CKD-related Apps, where 23.64% of Apps used by CKD patients were with single function, and also suggested that free to use and that do not require registration may increase users' willingness to use them, and that users' privacy and security should be guaranteed<sup>[222]</sup>.

It can be known that although a certain number of diet management MPs and Apps for CKD patients exist in WeChat and App Store, the usage is not optimistic, which makes the high cost developed applications lose their vitality and fail to achieve the expected clinical value. There are two reasons that might explain. First, their design lacks theoretical guidance, and not fully considering the needs and preferences of stakeholders, resulting in a poor UE and users' expectations are not met, thus failing to attract target users. Second, the developers are mainly medical technology companies and IT companies, but they do not provide transparent information about development processes, such as whether they collaborate with clinical professionals, whether they refer to authoritative sources or evidence-based medical materials, and whether they conduct clinical usability assessment and effectiveness evaluation to ensure the safety and reliability of the applications. Therefore, patient-centeredness is crucial in the development of medical applications, and involve stakeholders in the development process, collect their actual needs and conduct testing and evaluation is a key to keep mobile medical applications valuable.

Through this market survey, we believe that when designing a patient-centred diet management MP, the functions should be diverse, not only to meet the basic requirements of diet management, such as dietary knowledge, nutrition monitoring, diet records, food composition query, but also focus on the individuality of CKD patients and provide

individualized dietary advice and recipes. Nutrition screening and assessment is conducive to early detect and correct malnutrition, which usually assessed by renal dietitians, but simple home nutrition assessment should be considered. Diet management for CKD patients is long-term or even lifelong, which affects patients' social activities, so support from family and friends is beneficial for mental health, suggesting that the Mini Program could be served as a communication bridge between patients and their family and friends. In open and mobile Internet information, reliable information is a guarantee to improve user viscosity (UV). To strength user confidence, it is suggested that evidence-based references should be described in the product introduction.

In this survey, we learn about the design features of these included MPs and Apps, and also experienced and operated them as users. We found that those provide the function for diet record or individual recipe, although presenting with quantitative units, such as grams or taels/liang. However, most CKD patients reported that they seldom use kitchen scales to measure food but estimate by themselves, thus reducing the effectiveness of DNT, which suggested that we should optimize this function, for example, use different sizes of dishes and bowls as the measurement tools, and combined with ruler, palm, fist, spoon, etc. Besides, visual, and quantitative actual food diagram is also necessary. Moreover, in today's information technology, it is possible to apply 3D or virtual reality (VR) technology to provide intuitively visual and sensory quantitative food illustrations. Another poor UE is that some Apps require troublesome registration and detailed personal information, which reminded that this really needed to be simplified to protect user privacy, in addition to the information for individual diet plan. Fortunately, this designed diet management tool for CKD patients in this study is based on WeChat, which complies with the information security certification standards and has prescribed "user personal information protection" and "user privacy specification" for Mini Program development. Users only need to authorize their WeChat accounts to log in, avoiding unnecessary and complicated registration procedures.

#### 1.2.4 Summary

The incidence of CKD is increasing year by year and has become one of the major public health problems in China. Once CKD patients progress to ESRD, they need to rely on RRT to sustain their lives, which is expensive. Today, mobile Internet-based smart hospitals are common in most hospitals in China and are having a positive impact on health care<sup>[223, 224]</sup>. The development and application of mobile medical applications in clinical practice are



rapidly increasing. If mobile IT can be appropriately applied, it will significantly help to improve the quality of CKD management and ultimately reduce disease burden<sup>[225]</sup>. When it comes to the CKD population, it is necessary to integrate the characteristics of CKD and the current medical model in China. Since CKD patients in China rely on self-management most of the time and the importance of DNT in CKD treatment, which requires scientific and intelligent diet management tools to help CKD patients to manage their diets at home. However, the current diet management tools for CKD patients only benefit a narrow group of patients, to further promote intelligent disease management, such tools need to be accessible for patients to divert and maximize the utilization of medical resources.

In recent years, WeChat has been widely used to manage chronic disease, and its usability and effectiveness have been affirmed. Therefore, it is feasible to apply WMP to provide support for home diet management in CKD patients. It is worth noting that, prototype development is a regular in the product development process. It is necessary to recruit users to participate in testing during the product design and development process, and prototype evaluation can identify and optimize product design, to improve product quality and thus improving the usability and user experience. However, in domestic medical field, a growing number of scholars are conducting studies on clinical intervention about mobile medical applications, little attention has been devoted to prototype development and evaluation, ignoring the participation of relevant stakeholders in the development process, resulting in low user viscosity. Therefore, to provide patients with effective and efficient mobile medical tools and to achieve the goal of improving patients' QoL and reducing healthcare costs, prototype evaluation of medical applications is essential.

Above all, this study aims to design a patient-centred and open accessible WMP for home diet management for CKD patients, which is suitable for use by patients themselves and their caregivers, to assist patients in managing home diet, improving their experience in diet changes to enhance dietary compliance, and thus delaying disease progression and improving QoL. Based on the cost consideration, this study conducted a prototype design and evaluation of this designed WMP to provide a reference for the future development.

## 1.3 Research purpose

### 1.3.1 Overall aim

Design a patient-centred and open accessible Mini Program for diet management, where CKD patients and caregivers are the target users, and conduct prototype development and evaluation of this Mini Program to further revise the design, and provide references for future development, aiming to assist CKD patients in home diet management, so that patients can truly benefit from dietetic-nutritional therapy to slow down disease progression and improve their quality of survival.

### 1.3.2 Specific goals

- (1) Interviews with relevant stakeholders, including CKD patients and caregivers, clinical professionals (e.g., renal dietitians, nephrologists, and specialist nurses) to explore their functional needs and suggestions on this diet management MP for CKD patients.
- (2) Invite experts from multiple disciplines, including clinical nephrologists and specialist nurses, renal dietitians, and MP development technicians to evaluate and give feedback on the design and its technical feasibility, and revise the written design of the MP.
- (3) Use Mocking Bot to develop a high-fidelity, interactive prototype based on the written design, and recruit clinical professionals, CKD patients, and caregivers to test the prototype to gain a preliminary understanding of the usability and design shortcomings, providing a reference for future design iterations.

## 1.4 Research roadmap

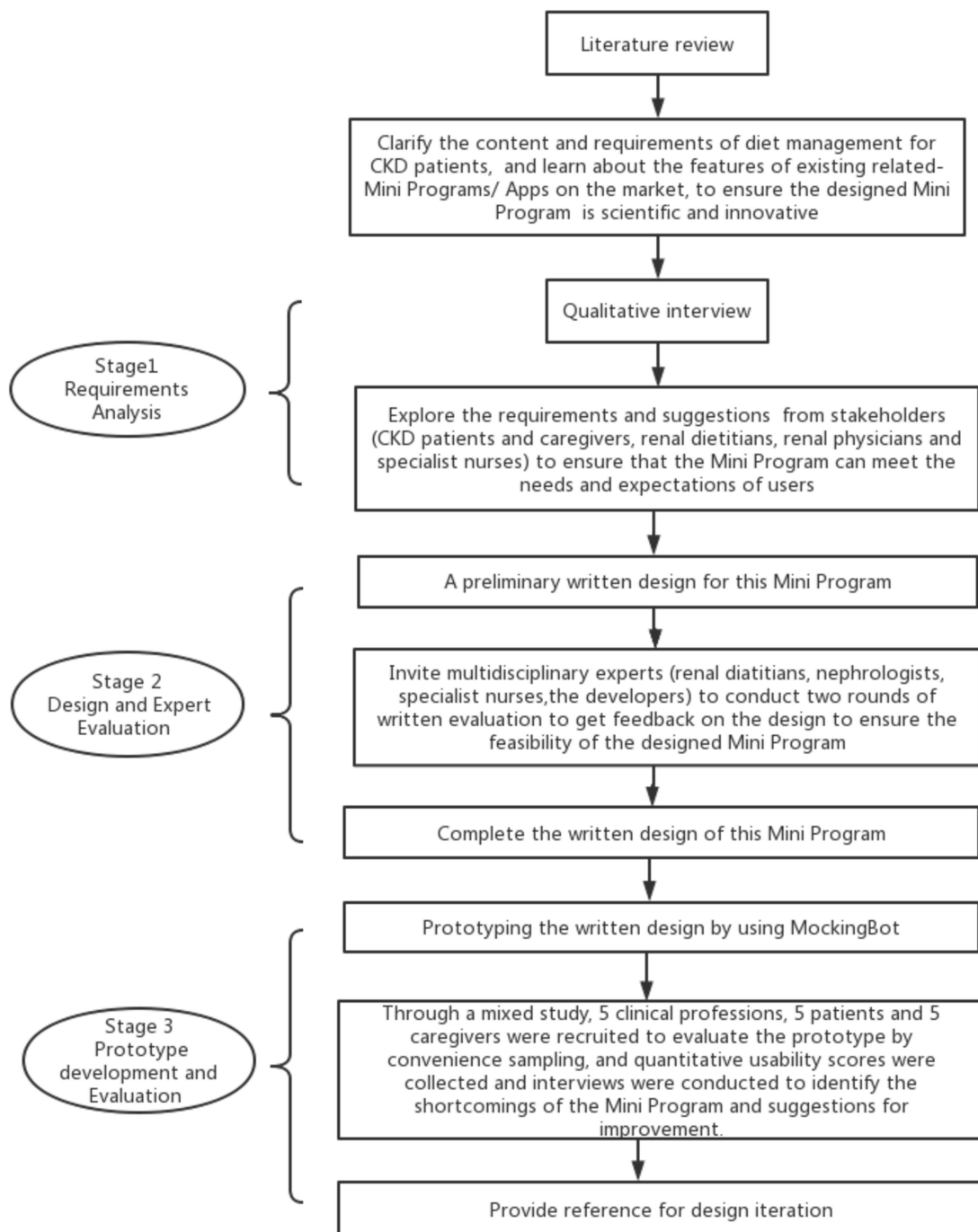


Figure 1 Research roadmap

## 1.5 Definition

### 1.5.1 Chronic kidney disease (CKD)

Also known as chronic kidney failure, it refers to structural or functional abnormality of the kidney that affects health and lasts for  $\geq 3$  months, excluding diseases such as simple renal cysts, which have structural abnormalities but do not affect kidney function<sup>[226, 227]</sup>.

### 1.5.2 Dietetic-nutritional management (DNM)

It refers to patient-centred and multidisciplinary professionals (e.g., dietitians, doctors, nurses) to extend the patient's nutritional treatment from hospital to home in order to delay disease progression, reduce complications, and avoid or reduce readmission, which highlights the patient's active participation in diet management activities, and caregivers should also be involved to jointly promote the patient to adopt healthy behaviours so that health status is maintained in a satisfactory state<sup>[228]</sup>.

### 1.5.3 WeChat Mini Program (WMP)

Its official website defines it as a kind of application that can be easily accessed and spread within WeChat without download and installation, realizing the user's dream of the application to be "within reach and ready to go"<sup>[229]</sup>.

### 1.5.4 Human-centred Design (HCD)

The concept of HCD has been used in the development of medical devices<sup>[49]</sup>. A good design must be user-centred, considering the needs and expectations of the user, which is a prerequisite to maintain user appeal<sup>[219, 230]</sup>. HCD is an interaction design approach where user-centred evaluation drives and refines the design by focusing on the needs and requirements of the user, who is involved throughout the design and development, and is a key element of prototype validation in each design iteration. This approach improves effectiveness and efficiency, user satisfaction, and offsets possible adverse effects on human health and safety<sup>[231]</sup>.

## 2 Research contents

### 2.1 Requirements Analysis of Diet Management Mini Program for Patients With CKD

National guidelines<sup>[105]</sup> suggest that patients should restrict their diets at CKD stage 1-2, but in clinical practice, patients with CKD stage 1-2 rarely consciously manage their diets, and patients may start to manage or restrict their diets at CKD stage 3 or above, so the included study subjects were patients with CKD stage 3-5; in addition, because the current CKD patients are still mainly middle-aged and elderly population, considering their ability to use smartphones and WeChat Mini Program, the target users of the MP in this study are patients with CKD stage 1-5 in clinical stability (excluding those receiving renal replacement therapy) and their family caregivers.

#### 2.1.1 Objective

Interviews with stakeholders, CKD patients and caregivers, and clinical professionals, to understand their experiences in CKD diet management and to explore their functional requirements and suggestions for this MP.

#### 2.1.2 Method

##### 2.1.2.1 *Research design*

Qualitative study

##### 2.1.2.2 *Study participants*

(1) Target population: all patients with CKD stage 3-5 and their caregivers, as well as renal physicians and specialist nurses, renal dietitians in Shanghai.

(2) Sample: patients with CKD stage 3-5 and their caregivers, renal dietitians, renal physicians and specialist nurses in Huashan Hospital, Fudan University, Shanghai.

#### 1) Patients

*Inclusion criteria:*

- i. Meet the clinical practice guideline of staging criteria of CKD stage 3-5, which was issued by National Kidney Foundation (NKF) in 2012. That is,  $GFR < 60$  ml/(min $\times$ 1.73m<sup>2</sup>).
- ii. Currently in stable condition and not yet receiving RRT (including peritoneal dialysis, haemodialysis, or kidney transplantation).
- iii. Be conscious and with normal cognition, and able to communicate in Mandarin, age  $\geq$  18 years old.
- iv. The patient himself/herself knew his/her disease conditions and volunteered to participate in this study and signed the informed consent.
- v. Proficiency in using smart phones and WeChat.

*Exclusion criteria:*

- i. Those combined with severe cardiac insufficiency, cerebrovascular diseases (e.g., cerebral haemorrhage, cerebral infarction), hematologic diseases (e.g., aplastic anaemia), liver diseases (e.g., cirrhosis, liver failure), digestive diseases (e.g., post-gastrectomy), malignant tumours, acute trauma or surgery, and diseases that seriously affect nutrition metabolism such as hyperthyroidism.
- ii. Their blood pressure exceeded 180/120mmHg, or their blood sugar was greater than 33.3mmol/L, fluctuating severely and cannot be controlled.
- iii. Prior history of mental illness.
- iv. Pregnant or lactating women.

2) Caregivers

- i. Knowing the patient's condition.
- ii. For the patient's immediate family member, such as the patient's spouse, children, parents, etc.
- iii. Be the patient's primary caregiver and weekly care time was not less than 40 hours.
- iv. Proficiency in using smart phones and WeChat.

- v. Voluntary participation in this study and signed the informed consent.

### 3) Clinical professionals

- i. Renal dietitians, renal physicians and specialist nurses, with  $\geq 5$  years of specialist work experience.
- ii. With a professional title of attending physician or nurse practitioner, or above.
- iii. Familiar with mobile medical applications.
- iv. Voluntary participation in this study and signed the informed consent.

#### *2.1.2.3 Sampling and sample size*

##### (1) Sampling

Purposive sampling method was used, with maximum differential sampling as the strategy, namely:

- i. Patients: consider their age, gender, education level, economic status, work status, residence, CKD stage, disease duration, complications, comorbidities, etc.
- ii. Caregivers: consider their relationship with patients, and their gender, age, education level, etc.
- iii. Clinical professionals: consider their specialty, professional title, education background, working years, etc.

##### (2) Sample size

The criterion of information saturation, i.e., when the maximum variability in the selection of study subjects occurs, no new information is obtained or information is duplicated, and then 1-2 additional samples are added to ensure that no new information appears, the sample size can be said to be saturated.

#### *2.1.2.4 Data collection*

A semi-structured interview method was used. After reviewing the literature related to diet management of CKD patients, the researcher combined with the purpose of this study and wrote an interview outline, which was revised after discussion by the research group. Before

the formal interview, one CKD patient, caregiver, and clinical professional who met the criteria of the study subjects were each selected for a pre-interview, and the interview outline was appropriately revised according to the results of the pre-interview to finally finish the interview outline (see **Appendix 1**)

(1) Pre-interview preparation

- 1) The researcher prepared interview materials, including the interview outline, a cell phone recorder, notebook, and black pen.
- 2) When the study subject was patient or caregiver, the researcher used the hospital information system to check basic information about the patient and medical records, and to learn about the patient from the bedside physician and nurse.
- 3) To agree on an interview time with the study subject, in the nephrology outpatient office or ward office, and to ensure that the interview room is quiet and that no other unrelated persons are present.
- 4) The researcher introduced herself, explained the purpose, process and time required for the interview, (when the subject was a patient or caregiver, the doctor in charge introduced the researcher to him/her), the study followed the principles of voluntariness and confidentiality, and signed the informed consent form (see **Appendix 2**).

(2) Interview process

- 1) The researcher tried to use descriptive, open-ended, and specific questions, and asked questions flexibly according to the interview outline.
- 2) Use recording equipment and record the study subject's tone, and nonverbal actions in notebook to organize the recorded data later.
- 3) Listen carefully to the study subject's responses, and ask appropriate questions at the right time, but do not interrupt or evaluate their responses, and avoid imposing the researcher's viewpoint on them.
- 4) Give timely responses, either verbal action, such as "hmm" and "yes?", or non-verbal action, such as nodding and smiling, to indicate the researcher's concentration.



- 5) Try to use different interview tips, such as follow-up questions, clarifications, and summaries to obtain detailed and reliable information.
- 6) End the interview when interview data are saturated, i.e., no new information can be distilled, and each interview lasts about 30 minutes, with an appointment for the next interview if necessary.

### (3) Post-interview

- 1) The researcher coded each interview data, and the interview recordings were transcribed and collated in text within 24 hours, checked by the research team members, and created electronic file separately for each study subject.
- 2) If there were any questions or doubts during the data collation process, the study subjects were contacted for confirmation.

#### *2.1.2.5 Data analysis*

Using NVivo 11.0 software, Colaizzi phenomenological method<sup>[232]</sup> was used to analyse data. Data analysis was carried out in parallel with data collection. The specific steps were as follow.

- (1) Carefully reading all interview data to generate a general understanding of the descriptions of the study subjects.
- (2) Excerpting significant statements that match the research questions.
- (3) Summarize and distil the significant statement and code it.
- (4) Aggregating the coded ideas and looking for common concepts or characteristics to form themes, theme clusters, and categories.
- (5) To relate the themes to the study subjects for an exhaustive narrative.
- (6) State the essential structures that constitute the phenomenon.
- (7) Return the results of the analysis to the study subjects to verify the authenticity of the content.

#### *2.1.2.6 Ethical consideration*

(1) Before the interview, explain in detail the purpose, process, and possible risks and benefits of this study, ensure that the study subjects are fully informed and participate voluntarily, and sign the informed consent form.

(2) When the interviewee was a patient or caregiver, the researcher learned about the patient's information from the bedside doctor and nurse, and their medical records before the interview, which was conducted not to disturb the patient's treatment.

(3) The researcher must not impose any intervention or inducements during the interview, and don't comment on their responses.

(4) The principle of confidentiality was strictly observed, the data were coded, and the real names of the study subjects did not appear throughout the study to protect their privacy.

(5) The research subject has the right to refuse to participate or request to withdraw from the study unconditionally at any time, and his or her any rights and interests would not be affected.

#### *2.1.2.7 Quality control*

(1) The researcher

- i. Receive training before the interview, including interview requirements, interview techniques, interview notes, etc., and conducting pre-interview to master the methods of qualitative interviews.
- ii. Review patient medical records before interview and communicate with health care professionals to grasp patient's information in advance.
- iii. The researcher was introduced by their doctors to gain the trust of the patient or caregiver, and then introduced herself and the research project by the researcher.
- iv. Conform any questionable description of the study subject on site.
- v. No evaluation or elicitation to the study subject's descriptions during the interview.

## (2) Study participants

- i. Ensure that the participants are fully informed of the study and participated voluntarily before the interview, to improve their compliance and obtain more reliable information.
- ii. Ensure that the interview room is quiet to avoid disturbance and eliminate concerns of the interviewee during the interview.

## (3) Interview data

- i. Purposive sampling method was used, and the selected participant were representative.
- ii. Organize the recorded data word by word into text within 24 hours after the interview and checked by research team members, and contacted the interviewees again, if necessary.
- iii. Return the collated information to the participants and check whether it matched their original intention, to improve the accuracy of the information, and integrate it into a detailed description if new information emerges during the verification process.

## 2.1.3 Results

### *2.1.3.1 Study participants Information*

When interviewing up to 9 patients, 4 caregivers, and 9 clinical professionals presenting saturated information, a total of 22 participants. Among 9 patients, 7 were male and 2 were female, their age range was 28-75 years, average age was 45.3 years, disease duration between 1 month to 15 years, average disease duration was 4.63 years, 2 were in CKD stage 3, 1 was in CKD stage 4, and 6 were in CKD stage 5, and other information is shown in **Table 2**. Of the 4 caregivers, 2 were male and 2 were female, and the relationships with the patients were mother-daughter, spouse, mother-son, and father-son, respectively, and other information is shown in **Table 3**. Of the 9 clinical professionals, 2 were renal dietitians, 3 were nephrologists, and 4 were specialist nurses, all with middle or senior titles, and the average working life was 16.7 years, and other information is shown in **Table 4**.

Table 2 Patient Information

Note: P=patient

No.	Gender	Age (Years old)	Education	Occupation	Marital status	Residence	Staging /course of CKD	Main complications	Financial burden
P1	male	39	master	business-man	married	Shanghai	CKD 5/ 2 years	hypertension, hyperphosphatemia, renal anemia	mild
P2	female	51	junior middle school	retiree	married	Shanghai	CKD 4/ 15 years	hypertension, renal anemia	moderate
P3	male	75	junior college	retiree	widowed	Shanghai	CKD 3/ 7 years	hypertension, diabetes, CKD-MBD, hyperlipemia	mild
P4	female	31	junior college	unemployed	unmarried	Jiangxi	CKD 5/ 1.5 years	hypertension	severe
P5	male	49	junior middle school	freelancer	married	Shanghai	CKD 5/ 3 years	hypertension	severe
P6	male	46	bachelor	engineer	married	Jiangsu	CKD 5/ 7 years	hypertension, hyperpotassemia	mild
P7	male	43	bachelor	teacher	married	Jiangsu	CKD 3/ 6 years	none	mild
P8	male	28	master	researcher	unmarried	Jiangsu	CKD 5/ 1 month	hypertension, renal anemia, hyperphosphatemia	moderate
P9	male	46	junior middle school	driver	married	Shanghai	CKD 5/ 1.5month	hypertension	moderate

Table 3 Caregivers Information

Note: C=caregiver

No.	Gender	Age (Years old)	Relationship	Residence	Education	Occupation	Financial burden
C1	female	29	mother-daughter	Guangdong	doctor	researcher	moderate
C2	female	53	spouse	Jiangsu	junior high school	unemployed	severe
C3	male	57	mother-son	Zhejiang	junior college	manager	mild
C4	male	50	father-son	Shanghai	polytechnic school	office worker	mild

Table 4 Information of clinical professionals

Note: N=nurse, RD= renal dietitian, D=doctor

No.	Education	Professional title	Working life (years)	Professional field
N1	bachelor	nurse-in-charge	14	clinical nursing
RD2	master	physician-in-charge	14	renal nutrition
N3	master	nurse-in-charge	13	outpatient nursing
RD4	master	physician-in-charge	5	renal nutrition
D5	doctor	associate chief physician	20	chronic kidney disease
N6	bachelor	nurse-in-charge	16	clinical nursing
N7	bachelor	nurse-in-charge	28	clinical nursing management
D8	doctor	chief physician	24	chronic kidney disease
D9	doctor	associate chief physician	16	chronic kidney disease

### 2.1.3.2 Interview data

#### Theme 1 Attitudes towards the use of diet management MP for CKD patients

##### Category 1 Expressed expectation

Due to patients spend limited time in the hospital, the complexity of CKD diet itself, the wide variety of foods in daily life, and the shortage of human resources in the hospital, traditional diet education tends to be mechanistic and ignoring patients' individuality, resulting in patients only know the basic diet requirements but not actionable. Together with the fact that most patients do not receive continuous diet guidance, to reduce the accuracy of dietary nutrition intake and weaken their dietary compliance. Therefore, most of the participants were looking forward to the MP, and one patient even wanted to invest in the development of this MP.

##### (1) Recognize the importance of diet management

With the national health literacy is increasing, most patients are aware of the importance of dietary changes. For example, Patient 1: *"I used to eat out a lot, now we must change to eating at home, this was playing with life ah, who dared not pay attention, we certainly had medical means for this disease, we also needed to cooperate with diet"*. Nurse 4: *"I thought 70-80% of patients were aware of this, but if I thought only half of them would manage their diets"*. Doctor 5: *"Many patients asked us during the ward rounds or the first visit, doctor,*

*what should we eat and what should not eat, meaning that they knew that they may need control diet, but they were not sure exactly how to do it".*

## (2) Insufficient information on diet management

Most CKD patients and caregivers lack knowledge of CKD diet, so reliable and practical knowledge is needed. They may learn about CKD diet from multiple ways (e.g., clinical professionals, Baidu, patients), but the information often is scattered and not actionable, and the quality is not guaranteed, which may confuse and mislead them. Therefore, they want to a special platform to get CKD diet information. For example, Patient 1: *"I got some information from my doctor, some from other patients, and sometimes I looked it up on Baidu, but the information was scattered, and not clear and specific enough, such as less salt, how to control it, how many grams of lean meat to eat today, just not to quantify it "*. Caregiver 1: *"The doctor gave me a piece of paper to refer to, but the paper did not explain in detail, I looked up different answers on Baidu, some said yes but some said no, the answers were different, sometimes quite confused"*. Caregiver 3: *"What knowledge should patients have that you can bring together and just stop looking it up on other platforms"*.

## (3) Strengthen diet education

Most patients currently access Internet through their smart phones, and the combination of the MP with the traditional oral pattern make diet education more effective and helps to assist patients in their home diet management. Therefore, especially the medical staff also expressed interest in this MP and said they were willing to recommend it to patients. For example, Nurse 6: *"When CKD patients in our ward were to be discharged, we only roughly told them about CKD diet, on the one hand, we didn't have time, on the other hand, because the nurses in our ward, if we have worked a little bit longer, we were able to talk a little bit, but the junior ones have no experience in this, they may not be able to do a very in-depth dietary education, it would better to have this media to intervene"*. Doctor 9: *"It was an extension of the traditional dietary education, because we may not have so much time verbally to educate patients, there are many foods and different dietary habits, some advocated or not recommended, these can be made into science articles, traditional dietary education plus this modern new mode, can be combined with each other "*.

## (4) Easy and convenient to use

Nowadays, China has high cell phone penetration rate, and WMP has advantage of being available anytime, anywhere, and everywhere, making it easier for patients to manage their diets. For example, patient 6: *"A lot of things no need to remember, just opened it/MP when I needed"*. Doctor 5: *"I recommended it, especially for patients with this need, he may feel that the traditional consultation, first of all, he did not have time and also cannot be used at any time, so I thought this was better"*. Nurse 7: *"In general, now is the information society, if you can make the food composition table into it, the patient, for example, what she wanted to eat, or she wanted to know the ingredients, she directly input to check, the paper was dense and need to look to find, this MP can be directly consulted, now cell phones were portable, I thought this may be more convenient."* Doctor 8: *"Because now smart phones were very common, even some older and even in remote areas, most of them now used cell phones, so if they can, for example, what they wanted to eat today, did not want to eat what, they looked at the MP to know these amounts should eat, of course, it was good and more convenient."*

#### Category 2 Considered unnecessary

Although most of the study participants expressed the need to use an information tool such as an MP during the interview, the current main patient population is still the elderly, despite CKD patients are getting younger.

##### (1) Limited ability to use

Considering the age factor, the patient group may lack ability to use smartphones and express hesitation to use the MP. For example, doctor 5: *"But we can't deny that a part of the patient, after all, who can't use a smartphone"*. Nurse 6: *"Nowadays, some MPs were used by everyone, but I thought some older patients, and because a lot of CKD patients were older ones, they may have problems when they used them"*.

##### (2) Personal preference

Some patients also indicated that they came to hospitals for regular follow-up and preferred the traditional way where they directly communicated with clinical professionals. For example, patient 4: *"It depends, I visited hospital every month, I could call (phone) that nurse (office) if I had questions, if I was not follow-up, maybe I would use it"*. Besides, an elderly patient who was more accustomed to using the cell phone Baidu search engine. Patient 3: *"I didn't want to use the MP, because I liked to use cell phone Baidu"*.

## Theme 2 Functional requirements for this MP

### Category 1 Comprehensive diet management information

#### (1) Reliable dietary knowledge

Dietary knowledge is the first step for CKD patients to do a good job in diet management. The most important and frequently asked question is what should eat and what should not eat. During this interview, the needs of dietary knowledge mentioned by the study participants included, low salt diet and salt restriction techniques, doctor 5: *"What was a low salt diet, what kind of salt to eat, how many grams can be eaten a day, and used pictures to intuitively tell them how many grams was this amount, how to eat with this amount, and other condiments also had salt in them, such as sauces, soy melon and these foods should avoid eating"*. Patient 6: *"Specific implementation, such as 3 grams of salt, how to use these 3 grams from morning to night and provided some videos to teach us cook to reduce its intake"*. High-quality, low-protein diet, patient 7: *"Even now, I still didn't know what was quality protein"*. Nurse 6: *"high quality low protein diet was definitely the most needed, which were high-quality proteins and how many should be the daily intake"*. Phosphorus and potassium restricted diet, dietitian 2: *"Some patients with high blood potassium, they were more concerned about which foods were high in potassium and whether it can be eaten or not, although not many CKD patients with high blood phosphorus, phosphorus intake was also need to be restricted, so also provide some high phosphorus foods that should avoid eating"*. Caregiver 4: *"In fact, many people did not know which foods were low phosphorus and which were low potassium, you should do this part in detail"*. Vegetables, fruits and dietary fibre intake, Patient 5: *"Fruits, which ones were good for kidneys and which ones were not, this was very much needed, as well as how to choose vegetables"*. Nurse 7: *"Of course, if possible, this dietary fibre was also needed"*. Tea and water restriction tips, Patient 5: *"How much to drink water a day, this was very critical, for urine protein, it was said that you should not drink water, for high creatinine needed to drink more water, this was very contradictory; and tea, I liked to drink tea, but I did not know if I should drink"*. Caregiver 1: *"If I needed to restrict water, and tried not to drink water, but if I felt thirsty how should I do"*. Diet for common comorbidities (gout diet, hypertension diet, diabetes diet, renal anaemia diet), Doctor 5: *"Some patients may have gout and foods with low purine content should be eaten only"*. Nurse 6: *"Some with comorbidities, diabetes, gout, you can set up links, and those who needed them can click in to take a look"*. Nurse 7: *"Patients may combine with diabetes,*



*hypertension, these relevant dietary requirements were also necessary". Nurse 7: "About renal anaemia, how should patients adjust their diet". Dietary misconceptions (soy products, seafood, condiments), Nurse 6: "They may have some misconceptions, there were a lot of updates, for example, soy protein was a high-quality protein, they still regarded soy products as should not eat". Doctor 5: " Make some introductions, e.g., seafood, what was seafood, how much can be eaten". Doctor 8: "Chinese people liked to eat all kinds of seasonings, such as soy sauce and vinegar, which was a characteristic of our country, you can teach them whether they can eat these seasonings, and if they can, how much they can put in". Dietary practices, Nurse 1: "I also told them how to cook at home, that is, what kind of cooking method was advisable". Nurse 3: "And also told him how to handle those foods that he ate at home, that is, how to cook the dishes"*

Patients with CKD should engage in regular physical activity as an integral part of their DNT to achieve improved cardiorespiratory endurance<sup>[101]</sup>. In addition to those directly related to diet, the study participants also mentioned other aspects, such as exercise recommendations, Dietitian 4:" *Exercise recommendations could be added.*" Caregiver 3: "*A combination of both diet and exercise, I always told them no time to exercise, but had time to be sick*".

## (2) Food composition query

CKD patients need to strictly restrict their diet, and patients have their own dietary preferences, traditional diet education cannot cover everything, so they often feel confused in food selection. Most of the study participants said that a convenient and quick food composition inquiry function should be provided. For example, Patient 6: "*For each food, the content of the nutrients, it had better make the content of each food*". Caregiver 1: "*A search function was good, like some Apps had a search box, for example, what ingredients I wanted to eat, and then once I enter, it immediately listed its nutrients content*". Nurse 7: "*If you can make this food composition list inside this, the patient, what she wanted to eat, or she wanted to know the ingredients, she could directly access to*".

## Category 2 Provide support for dietary decision making

### (1) Individualized dietary advice

Ideally, dietary advice should be individually targeted. The need for individualized dietary advice was required by some patients during this interview, and clinical professionals also emphasized that individual uniqueness. For example, patient 1: "*According to each patient's*

*biochemical data, how to adjust diet correspondingly, targeted advice to choose foods to balance body mechanism". Doctor 9: "In terms of dietary guidance, combined with her individualization, for example, input their height, weight, kidney function, then generated a relatively rough recommendation for protein or calorie intake, and to provide dietary advice".*

## (2) Monitor dietary nutrition intake

Dietary nutrition monitoring provides CKD patients a basis to make reasonable dietary decisions. During this interview, some patients mentioned that they were worried about malnutrition, for example, patient 1: *"We had to control what we ate and drank, so we were afraid of not having enough nutrition, but if we eat too much, we were afraid of the effect on our body."* Patient 8: *"In fact, I ate many meals a day because I was hungry very fast, if I didn't eat many times, I worried about malnutrition"*. Therefore, real-time dietary nutrition monitoring provides a basis to adjust dietary intake and may prevent malnutrition. Both patients and nurses mentioned the function to count dietary nutrition and, ideally, also give corresponding dietary advice. For example, Patient 6: *"I thought the main one should be, let's say what dish I ate today, after I input it in that showed these nutrients (contents), and to count the amount of various nutrients that I ate this day"*. Nurse 6: *"Based on the patient's diet records to calculate protein intake and other nutrients, whether he met the requirements of high-quality protein diet that he should, that is, a comparison, and gave him some advice to adjust diet, this may be more helpful to patients, right? "*

## Category 3 Professional diet self-management skills

### (1) Recommend individual recipes

To improve patients' dietary compliance, within a reasonable diet if allowing patients to freely match foods according to their preferences is necessary, both patients and caregivers, clinical professionals emphasized the function to generate individual recipes. For example, Patient 1: *"Each person set up a health file, and then according to each person's medical history, and put on regular blood tests, and then it generated a recipe, and after a while, I updated new biochemical data and that (recipe) changed"*. Caregiver 1: *"From the doctor's point of view, to recommend what to eat each day, or a weekly recipe, that kind of information was better"*. Doctor 8: *"Recommend recipes was the most direct and practical for patients and calculate each food nutrients and the number of servings to be eaten based on the patient's personal information, but that should base on the patient's dietary preferences"*. Due to modern diet

tends to be fast paced, one nurse mentioned that the recipes may also include take-out, drinks, nurse 1: "*recipes, including take-out, desserts and drinks which we may eat outside, that is to say, to keep up with the recent popular trend*".

## (2) Diet record and analysis

In clinical practice, 3-day paper diet diary is commonly used to assess the patient's dietary intake. The disadvantage is that patients often fail to clearly write the amount of food and lead to inaccurate estimation of actual dietary intake. Therefore, a function of visual and quantitative diet record is necessary. For example, doctor 9: "*3-days diet review, the traditional way was to write down, and then assessed, but recorded it in the MP may be relatively more accurate, and analysis may also be more targeted. In fact, for normal people, many Apps were available for diet record, now this was a trend*". Dietitian 2: "*I hope to have a function that let the patient to see this dish intuitively and knew how much weight this dish and with an analysis of the recorded meal*". In addition, it is requested for statistical analysis. For example, caregiver 1: "*Something like a date manager, for example, what had consumed today, and you can easily record it in, and then every month I got a summary and statistics data.*"

## (3) Recommend disease-specific foods

Most patients thought make CKD diet is complicated and troublesome, especially low-protein staple foods, and for patients with advanced CKD even require a very low-protein diet, so they are recommended to buy low-protein ingredients to facilitate diet preparation and control protein intake. For example, patient 1: " In the future, I hope the MP can suggest us where to shop for low-protein products, or which nearby supermarket are available, and be precise about what brand to choose, or even the price, because we were a special group". Nurse 7: "*Low protein rice, noodles, these low-protein foods, you can make a shopping link and jump to WeChat store by directly clicking in and order them*".

## Category 4 Provide emotional support channels

### (1) Consult professionals

For clinical professionals, the best emotional support for patients is to provide practical dietary guidance when they need. The MP has an advantage for patients to consult with professionals remotely without leaving home. For example, Patient 1: "*The hospital can*

*provide an additional service (access to their doctors) to manage patient's health without additional charges."* Patient 5: *"Once my disease condition changed, if I can consult a doctor about it"*. Clinical professionals also hope to provide doctor-patient interaction. For example, Dietitian 2: *"A consultation function, some patients who would encounter some problems, if they able to contact the medical staff to give him guidance"*. However, clinical professionals also suggested that the potential safety issues, e.g., Nurse 6: *"online consultation can be provided, but safety issues shouldn't be ignored, because sometimes it was not possible to get the patient's comprehensive condition"*. Furthermore, busy clinical work and limited human resources, doctor-patient interaction had better carry out in the message area, for example, doctor 5: *"We usually busy with clinical work, set aside a fixed time every day to answer questions online, or real-time answer questions were difficult, but the patient can ask, then a professional team would answer regularly, this was possible"*. Nurse 7: *"An area where patients could leave messages or asked questions, and other patients also had the right to read these messages. In that case, if patients found their questions had been asked or answered, there was no need to ask again. And a professional team gave answers regularly, or a robot assistant to reply some common fixed answers"*. It is important to note that, all the clinical professionals at this interview indicated that nutrition counselling should be reasonably charged.

Interestingly, one doctor mentioned using the MP to promote CKD-nutrition joint clinic to benefit more CKD patients. For example, doctor 5: *"We need patients to know that they needed diet control after CKD stage 3 and came for regular follow up, and we had this specialized clinic, but many patients may not know what this clinic. If the MP was well promoted, many patients would know that hospitals with CKD- nutrition clinic services, and what hospital can be consulted"*.

## (2) Promote family participation

Family support is important for CKD patients, especially family caregivers who prepare and make patient's diet, and clinical professionals should encourage them to participate in diet management. For example, Nurse 1: *"Family also had something to do with it (dietary compliance), if their family were not aware and cooperative. For example, they fried very greasy and salty, then the patient had to eat this, because he usually didn't say no, so the whole family had to have this consensus of CKD diet. In fact, we should encourage the family to participate in diet education."*. One caregiver wanted the MP to report the patient's status

that monitored by others when he was not around, e.g., caregiver 3: "*Provide the function of photograph, such as how much she ate and took a photo before eating and after eating, so that the family got to know today's situation, and the nurserymaid would be more dedicated.*"

### (3) Communication among patients

Because clinical professionals are not accessible for immediate communication, experience sharing among patients can also obtain relevant information to enhance their confidence. For example, patient 1: "*It was very necessary to communicate with these old patients, which was very beneficial, they were experienced people who had come through for many years*". Doctor 8: "*Word of mouth among the patients, they exchanged their eating*". Even some patients and family spontaneously established WeChat group to communicate, caregiver 2: "*When we were hospitalized last time, we joined a WeChat group (the patients spontaneously created it, including patients and their families, without medical staff), to talk about what to eat daily*".

### (4) User feedback

Medical-related applications not uncommon on the market, but the users are not so wide, thus interaction with the user is essential to continuously improve services. For example, doctor 5: "*It also needed to get user feedback to know what they really needed, what different groups of people needed, I thought the platform should set up such a side, for example, after watching the video to get patients' feedback, like a questionnaire star or something like that can be scored. It was not the patients opened it to watch, and then no communication without interaction.*"

### (5) Intelligent reminder

Intelligent reminder plays a supervisory role, enhancing patients' attention to diet management and reminding them some important matters at regular intervals. For example, Nurse 7: "*A function of reminder to remind patients to pay attention something*". Caregiver 3: "*Remind patients when to take their medication, what time to test their blood sugar, when to drink water, what to do at what time, all can be set up in advance*".

## Theme3 Performance requirements for this MP

### (1) Easy to use and learn

Clinical professionals, patients and caregivers indicated that this MP should focus on practicality and avoid tedious and complicated operations. For example, patient 6: *"For us, convenient to use was the best, if it was too cumbersome and inconvenient, then we may not be happy to use it, for different age groups, video was definitely more convenient, or at least presented with attractive pictures and texts, that is, it should not be too monotonously. A large paragraph of text, people wouldn't like to read these "*. Caregiver 4: *" After all, it was for the public, so it should be simple and easy to learn"*.

## (2) Interface concise

User interface (UI) is expected to be as simple and friendly as possible, to optimize user experience and improve user viscosity. For example, patient 8: *"The interface should be simple and not so fancy, because after all, most of patients were elderly people"*. Nurse 7: *" Friendly user interface, several main modules, and then several sub-modules which directly clicked into, and then back was also very convenient, including the switch between the modules should also be very convenient."*

### 2.1.4 Discussion

Through this interview, we found it necessary to design and develop a specialized MP to assist CKD patients manage diet at home. Both patients and caregivers have positive attitude toward this MP, and clinical professionals expressed their willingness to recommend it to patients if there is such a professional MP, and the attitude of patients and caregivers is that they are expecting to try it. The possible reason is that, on the one hand, clinical professionals hope that the MP can make up for the shortcomings of traditional diet education and improve diet management in CKD patients. On the other hand, today, when both cell phones and WeChat are highly popular nationwide, using MP to assist patients in their home diet, which is an acceptable solution to balance work and life. It should be noted that patients and caregivers in this interview said that they never use or even know that some similar diet management MPs are available on the market, and some clinical professionals mentioned that they know that some MPs for CKD patients, which indicates that the usage of existing MPs on the market are not optimistic, and diet management tools have not yet reached most CKD patients.

Demand is the driving force to develop new product. To satisfy users, the MP for CKD patients should have diverse functions and simplify the operation as much as possible to avoid

resulting in poor user experience. Through this interview with stakeholders, it is suggested that the functions of this MP could include, providing reliable dietary knowledge and food nutrient query to support patients and caregivers with professional and comprehensive dietary management information; individualized dietary advice and monitoring dietary nutrient intake to provide basis for patients to make reasonable dietary decisions; recommending individual recipes and disease-specific foods, and diet record and analysis to give patients with more autonomy in food choices and improve their dietary compliance; the provision of professional consultation, promotion of family participation, communication among patients, user feedback, and intelligent reminder to improve patients' social support and promote their mental health. At the same time, attention should be paid to the issue of user information security, strengthening the privacy protection to prevent leakage; and system updates and maintenance are also important issues to be considered.

## **2.2 Design and Expert Evaluation of the Mini Program**

### **2.2.1 Objective**

Multidisciplinary experts were invited to evaluate the feasibility of this written MP design and gave feedback on its improvement, to prepare for prototype development

### **2.2.2 Method**

#### *2.2.2.1 Preliminary written design of this MP*

Through literature review to clarify the content and requirements of diet management for CKD patients, and market survey to learn and innovate existing diet management MPs and Apps on the market. Then combined with requirements analysis of stakeholders to complete the first draft of the written MP design, named Kidney Disease Diet Bao (KDDB), which has 5 modules with 28 functions, and the diagram of modules and functions is shown in Figure 2.

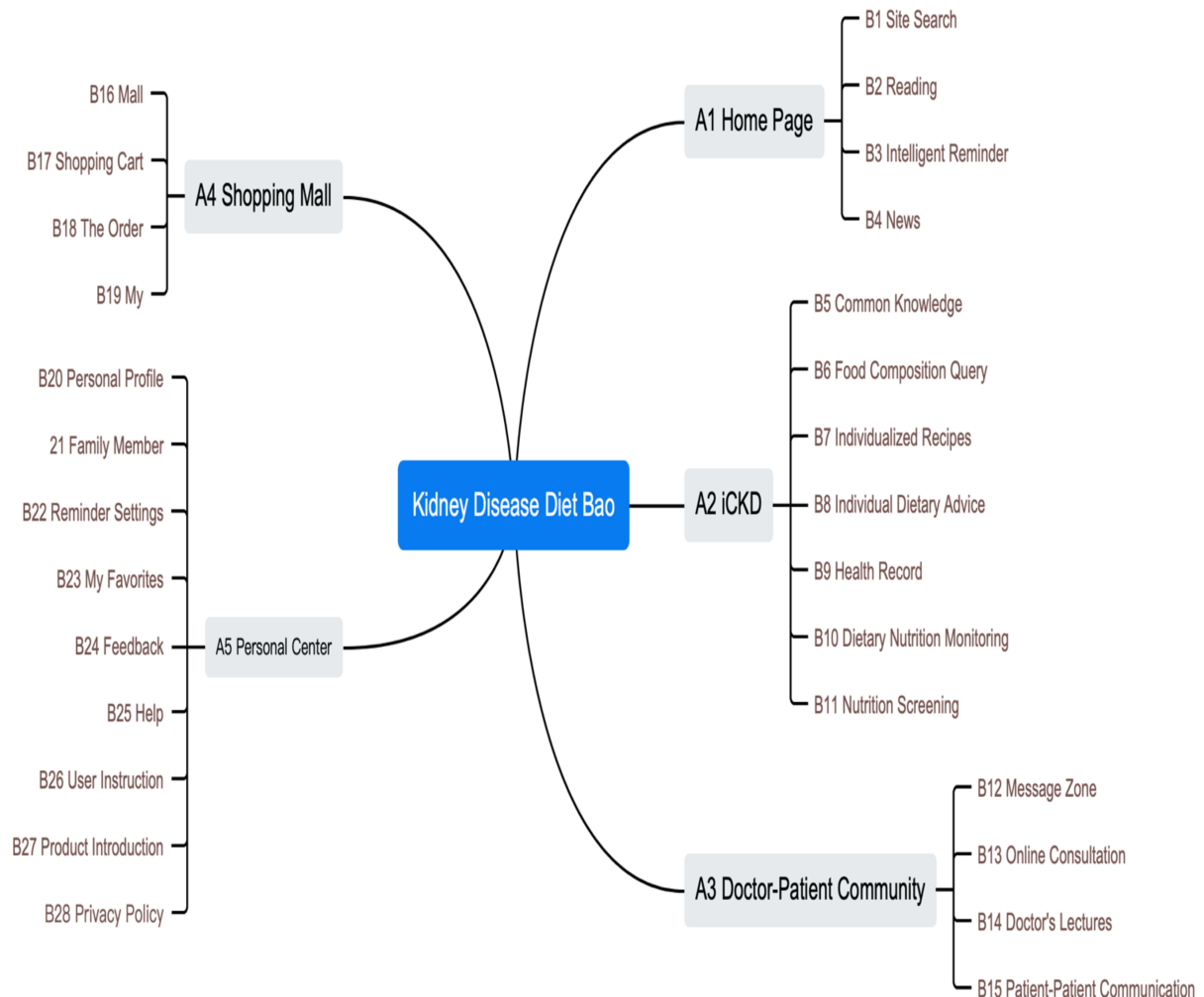


Figure 2 Diagrammatic sketch of Kidney Disease Diet Bao (Version1)

### 2.2.2.2 Expert evaluation group

#### (1) Number of experts

Expert membership is closely related to the scientific and authoritative research findings, and experts are usually not chosen at random, but are familiar with the study and have profound knowledge. The number and diversity of experts depends on several factors such as the purpose of the study, time, and funding, and the general number is 10-15. In this study, we invited 10 experts to form the expert panel, 3 nephrologists and 2 specialist nurses, 3 renal dietitians, and 2 MP development technicians.

#### (2) Eligibility of experts

- i. Medical expert field: physicians engaged in the treatment of chronic kidney disease, with a master's degree or above, intermediate title or above, and working life  $\geq 10$  years.



- ii. Nutrition expert field: clinical dietitians engaged in CKD diet management, with a bachelor's degree or above, and national intermediate or above dietitian qualification certificate, working life  $\geq 10$  years.
- iii. Nursing expert field: specialist nurses engaged in clinical care in department of nephrology, with a bachelor's degree or above, title of competent nurse practitioner or above, working life  $\geq 10$  years.
- iv. Technicians: engaged in the development of WeChat Mini Program, with a bachelor's degree or above and working life  $\geq 5$  years.
- v. Voluntary participation in this study and continue to participate in this study until the end of the expert evaluation phase.

### 2.2.2.3 Expert Evaluation Form

The Expert Evaluation Form of Diet Management Mini Program for CKD Patients (hereinafter referred to as The Evaluation Form) (see **Appendix 3** for the template), which was self-made and consisted of two parts, the first part is Expert Information and the second part is Assessment Table, which described the detailed contents of modules and functions of this written MP design, the templates of which are shown in **Table 5 and Table 6**, the written MP design was evaluated in four dimensions: scientific, important, appropriate, and practical, using Likert 5 scale method and assigned values from high to low, i.e. 5=strongly agree, 4=agree, 3=neutral, 2=disagree, 1=strongly disagree, and the higher score represents the better the feasibility of this written MP design.

Table 5 Module assessment table

Modules	Description	Scientific	Important	Appropriate	Practical	Suggestions
		5,4,3,2,1	5,4,3,2,1	5,4,3,2,1	5,4,3,2,1	
A						
Add other modules:						

Table 6 Function assessment table

Modules	Functions	Description	Scientific	Important	Appropriate	Practical	Suggestions
			5,4,3,2,1	5,4,3,2,1	5,4,3,2,1	5,4,3,2,1	
A	B						
Add other functions:							

#### 2.2.2.4 Principles for module & function revision

Based on the feedback from the experts, and combined the following criteria<sup>[233]</sup> for quantitative screening, and the research group discussed to decide the final deletion, addition, and modifications of the module and function

- (1) Retention: the scoring of mean value (MV)  $\geq 3.5$  and coefficient of variation (CV)  $\leq 0.25$  of each dimension of the module function.
- (2) Deletion: the scoring of MV  $< 3.50$  and CV  $> 0.25$  for each dimension of the module function.
- (3) Discussion: the scoring of MV  $< 3.50$  or CV  $> 0.25$  for each dimension of the module function.

#### 2.2.2.5 Expert evaluation process

- (1) The researcher distributed the Expert Evaluation Form to the expert on the spot or via WeChat, explained the background, purpose of the study and instructions for filling it out to the expert to obtain the expert's support, and agreed with the expert on the time to take it back.
- (2) The researcher retrieved the Expert Evaluation Form and checked the completeness and validity and contacted the expert again if there was incomplete filling or doubt about the feedback.
- (3) The researcher collated the scores and feedback given by the experts, the research group discussed, and the researcher modified the written MP design to form the second version of the written MP design.
- (4) The researcher developed a second round of Expert Evaluation Form, which was distributed again 14 days later.

#### 2.2.2.6 Data analysis

Microsoft Excel 2019 and SPSS 28.0 software were used for statistical analysis, and the specific statistical methods were described as follows.

- (1) Expert enthusiasm: the effective recall rate of the evaluation form represented the degree of positivity of the expert, which is generally considered to be  $\geq 70\%$ <sup>[233]</sup>.

(2) Expert authority: it refers to the authority of the expert in a certain research issue or direction, which has a significant impact on the reliability of the research results, so the degree of expert authority needs to be calculated quantitatively. The degree of expert authority is expressed by coefficient of expert authority (Cr), which comes from the expert's self-evaluation. Cr is determined by two factors: the expert's judgment basis for the problem and the expert's familiarity with the problem. The judgment basis is expressed by Ca, and the degree of familiarity is expressed by Cs. The coefficient of expert authority  $(Cr) = (Ca + Cs) / 2$ ,  $Cr \geq 0.70$  is suggested that research results are reliable<sup>[233]</sup>. The expert's judgment basis is divided into four dimensions: practical experience, theoretical analysis, reference to domestic and foreign materials, and intuition, and the degree of influence of the judgment basis on the expert's evaluation is divided into three levels: large, medium, and small; the quantitative assignments of the large, medium, and small levels of different dimensions are: practical experience (0.5, 0.4, and 0.3), theoretical analysis (0.3, 0.2, and 0.1), reference to domestic and foreign materials (0.1, 0.1, 0.1), and intuition (0.1, 0.1, 0.1). The experts' familiarity with the evaluation contents and their quantitative assignments were very familiar (0.9), familiar (0.7), generally (0.5), unfamiliar (0.3), very unfamiliar (0.1).

(3) The scores of the module and function of the MP were described using mean, standard deviation (SD), and coefficient of variation (CV).

(4) Experts' feedback and feedback processing were presented with descriptive content analysis.

## 2.2.3 Results

### 2.2.3.1 Expert Member Information

#### (1) Basic information

In this study, 10 experts participated in two rounds evaluation of the written MP design, including 3 renal dietitians, 3 nephrologists, 2 specialist nurses and 2 MP developer (technicians), the information is shown in **Table 7**.

Table 7 Basic information

Members	Gender	Working life (years)	Education background	Professional title	Professional field
1	male	27	PhD	associate chief physician	chronic kidney disease
2	female	20	PhD	associate chief physician	chronic kidney disease
3	female	16	PhD	associate chief physician	chronic kidney disease
4	female	14	master	physician-in-charge	renal diet
5	female	11	master	physician-in-charge	renal diet
6	female	10	master	physician-in-charge	chronic diseases
7	female	13	master	nurse-in-charge	specialized nursing
8	female	28	bachelor	nurse-in-charge	specialized nursing
9	male	8	bachelor	/	Mini Program development
10	male	6	bachelor	/	Mini Program development

## (2) Expert enthusiasm

Two rounds of expert evaluation were conducted in this study, and all the Expert Evaluation Forms were returned in both rounds, and all of them were valid forms, and the validity recovery rate was 100%, indicating that the experts involved in the evaluation were well motivated.

## (3) Expert authority

Two rounds of expert evaluation were conducted in this study, and the results of experts' self-evaluation on their judgment basis and familiarity with the content of the design are shown in **Table 8** and **Table 9**, respectively, and the calculated  $Ca=0.92$ ,  $Cs=0.76$ , and  $Cr=(0.92+0.76)/2=0.84$ , indicating that the results of expert evaluation in this study are reliable.

Table 8 Expert judgement based on self-evaluation

Judgment basis	Number (N=10)		
	Large	Medium	Small
Practical experience	7	3	
Theoretical analysis	5	5	
Reference to domestic and foreign materials	4	6	
Intuition	2	3	5

Table 9 Self-evaluation of expert's familiarity

Degree of familiarity	Very familiar	Familiar	Generally	Unfamiliar	Very unfamiliar
Number (N=10)	4	5	1		

### 2.2.3.2 First round of expert evaluation

#### (1) Scoring of modules and functions

The results of the first round of scoring of module and function are shown in **Table 10** and **Table 11**, experts gave feedback on 3 modules and 14 functions with a total of 38 suggestions, the summary of feedback and feedback processing is shown in Appendix 4. In these modules,  $MV \geq 3.5$  and  $CV \leq 0.25$  including A1, A2, A3;  $MV < 3.50$  or  $CV > 0.25$  including A4, A5. In these functions,  $MV \geq 3.5$  and  $CV \leq 0.25$  including B1, B2, B5, B6, B9, B10, B14, B24;  $MV < 3.50$  and  $CV > 0.25$  including B11, B15, B16, B21;  $MV < 3.50$  or  $CV > 0.25$  including B3, B4, B7, B8, B12, B13, B17, B18, B19, B20, B22, B23, B25, B26, B27, B28.

Table 10 First round of modules scoring

Note: coefficient of variation (CV)>0.25 was marked with "\*\*"

Modules	Scientific			Important			Appropriate			Practical		
	MV	SD	CV	MV	SD	CV	MV	SD	CV	MV	SD	CV
A1	4.40	1.075	0.244	4.60	0.516	0.112	4.40	0.699	0.159	4.50	0.527	0.117
A2	4.60	0.516	0.112	4.70	0.483	0.103	4.50	0.527	0.117	4.40	0.516	0.117
A3	4.10	0.568	0.139	4.30	0.675	0.157	4.00	0.943	0.236	4.10	0.876	0.214
A4	3.90	1.197	0.307*	3.50	1.269	0.363*	3.60	1.174	0.326*	3.80	1.398	0.368*
A5	4.40	1.265	0.288*	4.40	0.843	0.192	4.30	1.059	0.246	4.30	0.949	0.221

Table 11 First round of functions scoring

Note: coefficient of variation (CV)>0.25 was marked with "\*\*"

Functions	Scientific			Important			Appropriate			Practical		
	MV	SD	CV	MV	SD	CV	MV	SD	CV	MV	SD	CV
B1	4.50	0.707	0.157	4.80	0.422	0.088	4.40	0.699	0.159	4.60	0.699	0.152
B2	4.80	0.422	0.088	4.20	1.033	0.246	4.30	0.949	0.221	4.60	0.516	0.112
B3	4.40	1.075	0.244	4.50	0.972	0.216	4.10	1.197	0.292*	4.30	1.059	0.246
B4	3.90	1.101	0.282*	3.50	1.354	0.387*	3.50	1.179	0.337*	3.60	1.430	0.397*
B5	4.80	0.422	0.088	4.70	0.483	0.103	4.60	0.516	0.112	4.50	0.707	0.157
B6	4.80	0.422	0.088	4.50	0.707	0.157	4.40	0.699	0.159	4.60	0.699	0.152
B7	4.60	0.516	0.112	4.10	0.738	0.180	4.10	0.876	0.214	4.00	1.155	0.289*
B8	4.50	0.527	0.117	4.40	0.516	0.117	4.00	0.667	0.167	3.90	0.994	0.255*
B9	4.40	0.966	0.220	4.50	0.707	0.157	4.20	0.789	0.188	4.40	0.843	0.192
B10	4.30	0.675	0.157	4.20	0.919	0.219	4.10	0.876	0.214	4.20	0.919	0.219
B11	4.30	1.252	0.291*	4.20	0.632	0.150	3.50	1.269	0.363*	3.00	1.414	0.471*
B12	4.10	0.994	0.242	3.70	1.160	0.314*	3.70	1.059	0.286*	3.50	1.269	0.363*

Functions	Scientific			Important			Appropriate			Practical		
	MV	SD	CV	MV	SD	CV	MV	SD	CV	MV	SD	CV
B13	3.80	1.317	0.347*	3.60	1.647	0.458*	3.50	1.269	0.363*	3.50	1.179	0.337*
B14	4.70	0.483	0.103	4.50	0.527	0.117	4.60	0.516	0.112	4.60	0.516	0.112
B15	3.70	1.160	0.314*	2.90	0.994	0.343*	3.50	1.269	0.363*	3.30	1.337	0.405*
B16	3.30	1.252	0.379*	3.20	1.135	0.355*	3.30	1.252	0.379*	3.20	1.398	0.437*
B17	3.80	1.476	0.388*	3.80	1.398	0.368*	3.70	1.418	0.383*	3.80	1.476	0.388*
B18	3.80	1.317	0.347*	3.80	1.317	0.347*	3.80	1.317	0.347*	3.90	1.370	0.351*
B19	4.10	1.370	0.334*	4.20	1.317	0.314*	4.10	1.370	0.334*	4.30	1.337	0.311*
B20	3.90	1.370	0.351*	3.90	1.287	0.333*	4.00	0.816	0.204	4.00	0.816	0.204
B21	3.60	1.578	0.438*	3.00	1.333	0.444*	3.30	1.252	0.379*	3.40	1.430	0.421*
B22	3.70	1.636	0.442*	3.90	1.663	0.427*	3.80	1.619	0.426*	3.90	1.663	0.426*
B23	4.00	1.491	0.373*	4.10	1.449	0.353*	4.00	1.491	0.373*	4.00	1.491	0.373*
B24	4.40	0.699	0.159	4.40	0.699	0.159	4.30	0.823	0.191	4.40	0.843	0.192
B25	3.90	1.101	0.282*	4.10	1.101	0.269*	4.00	1.333	0.333*	3.80	1.317	0.347*
B26	4.20	0.919	0.219	4.10	1.101	0.269*	4.10	1.101	0.269*	4.00	1.333	0.333*
B27	4.30	0.949	0.221	4.10	1.101	0.269*	4.30	0.949	0.221	4.20	1.135	0.270*
B28	4.30	1.160	0.270*	4.10	1.287	0.314*	4.20	1.135	0.270*	4.20	1.229	0.293*

## (2) Revision of modules and function of the MP

Combined with the first round of feedback, the research group discussed, and the researcher modified, or deleted, or added, or integrated or split the modules and functions of the first version of the written design and generated the second version of Kidney Disease Diet Bao, including 5 modules, 21 functions, a diagram in Figure 3. The revision of modules and functions as follows.

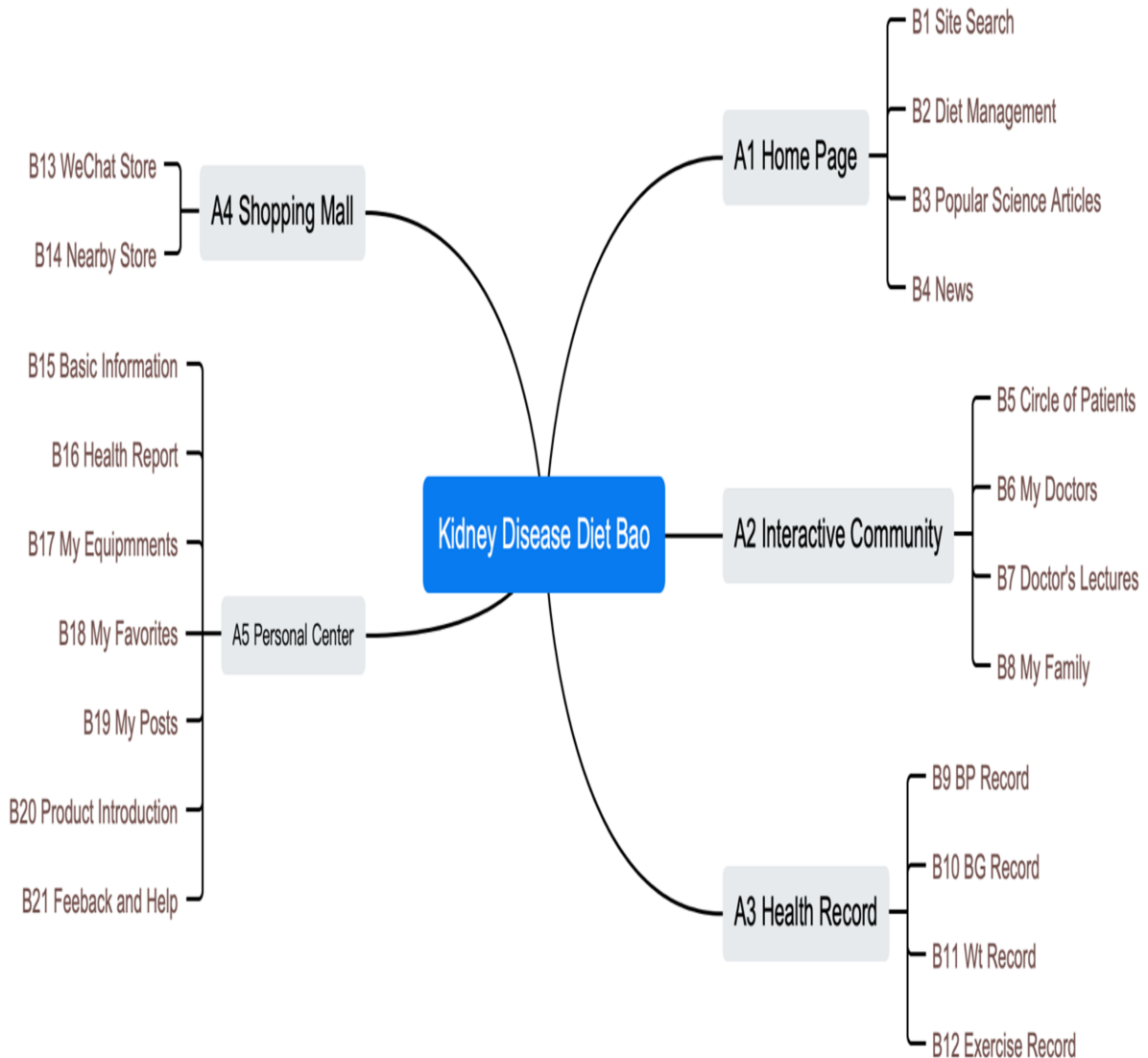


Figure 3 Diagrammatic sketch of Kidney Disease Diet Bao (Version 2)

(1) The deleted modules and functions

- i. Experts believed that home page is the entrance to several major functions, it is suggested to consider the user habits and needs, re-adjust the layout, 1-A2 (iCKD) ( $MV \geq 3.5$  and  $CV \leq 0.25$ ) is mainly used to help patients manage diet, which is the most important and core module function of this MP, so deleted 1-A2 (iCKD), and integrated it into 2-A1 (Home Page).
- ii. Experts believed that 1-A4 (Shopping Mall) should be deleted ( $MV < 3.50$  or  $CV > 0.25$ ) because too many issues need to be considered, such as background support, supervision, logistics. It may be difficult to realize such large shopping platform like Taobao, Pinduoduo in the MP, but considering the real needs of users, 1-A4 (Shopping Mall) was

not completely deleted and 1-B16 (Mail) ( $MV < 3.50$  and  $CV > 0.25$ ), 1-B17 (Shopping Cart) ( $MV < 3.50$  or  $CV > 0.25$ ), 1-B18 (The Orders) ( $MV < 3.50$  or  $CV > 0.25$ ) and 1-B19 (My) ( $MV < 3.50$  or  $CV > 0.25$ ) were deleted from it.

- iii. Experts thought that if users need to set reminders by themselves, which is complex and unnecessary, and it was suggested to delete 1-B22 (Reminder Settings) ( $MV < 3.50$  or  $CV > 0.25$ ).

## (2) The added modules and functions

- i. The experts believed that health records are important, especially the records of blood pressure and blood glucose, so we decided to make 1-B9 (Health Record) ( $MV \geq 3.5$  and  $CV \leq 0.25$ ) as a separate module, i.e., 2-A3 (Health Record). However, the experts thought that the records of hospital examination are not directly related to the purpose of this MP, and the uploaded information involves patients' privacy, so it was suggested to delete it. Therefore, the original 1-B9 (Health Record) was split into 2-B9 (BP Record), 2-B10 (BG Record), 2-B11 (Wt Record), and 2-B12 (Exercise record), all of which are quick windows; and 2-B16 (Health Report) was added as a window for directly viewing various health records.
- ii. Whether patients would be willing to enter health data manually and it was suggested that it would be better to add a function for Bluetooth data upload, so 2-B17 (My equipment) was added as a window for connecting Bluetooth devices.
- iii. As mentioned above, experts believed that the main function of the MP should be placed on the home page, so 2-B2 (Diet Management) is added, which integrated 1-B6 (Food Composition Query) ( $MV \geq 3.5$  and  $CV \leq 0.25$ ), 1-B7 (Individualized Recipes) ( $MV < 3.50$  or  $CV > 0.25$ ), 1-B8 (Individual Dietary Advice) ( $MV < 3.50$  or  $CV > 0.25$ ), and Diet Record in 1-B9 (Health Record) ( $MV \geq 3.5$  and  $CV \leq 0.25$ ), 1-B10 (Dietary Nutrition Monitoring) ( $MV \geq 3.5$  and  $CV \leq 0.25$ ), 1-B11 (Nutrition Screening) ( $MV < 3.50$  and  $CV > 0.25$ , but we decided not to remove it), and presented as functional navigation in 2-A1 (Home Page).
- iv. Experts suggested that the backend should have a shielding function to prohibit post inappropriate or irrelevant statements, and we accepted this suggestion and added 2-B19 (My Posts) for allowing users to delete and modify the published content.



### (3) The modified modules and functions

- i. 1-B2 (Reading) ( $MV \geq 3.5$  and  $CV \leq 0.25$ ) for the daily updated science articles, experts believed that the name of Reading was not very clear, patients may not understand, so we integrated 1-B2 (Reading) and 1-B5 (Common Knowledge) ( $MV \geq 3.5$  and  $CV \leq 0.25$ ) for 2-B3 (Popular Science Articles).
- ii. 1-B3 (Intelligent Reminders) ( $MV < 3.50$  or  $CV > 0.25$ ) is used to remind various messages, including abnormal data of health record, user-set reminder, activities (such as online doctor' lecture), user feedback, personal information reset and received messages reminder, which experts considered inaccurately named and inconsistent with the function description, due to the deletion of 1-B22 (Reminder Settings) ( $MV < 3.50$  or  $CV > 0.25$ ), and 1-B4 (News) ( $MV < 3.50$  or  $CV > 0.25$ ) is for chatting, therefore integrating 1-B3 (Intelligent Reminders) ( $MV < 3.50$  or  $CV > 0.25$ ) and 1-B4 (News) ( $MV < 3.50$  or  $CV > 0.25$ ) as 2-B4 (News).
- iii. Experts believed that even if teaching videos of anthropometric measurements are provided, it is difficult to guarantee that patients will measure correctly and it should be measured by professionals; and it is not suitable for patients to use Subjective Global Assessment (SGA) for nutrition assessment by themselves, and nutrition risk screening can be performed, such as Malnutrition Universal Screening Tool (MUST) or Nutrition Risk Screening 2002 (NRS2002), so anthropometric measurements and SGA were deleted from 1-B11 (Nutrition Screening) ( $MV < 3.50$  and  $CV > 0.25$ ), and NRS2002 was added.
- iv. Experts suggested that to solve the problem of purchasing, shopping links can be set up to purchase products or directly list the sold products, to ensure the authenticity of the products, it should be stated that it is not promotion, so split part of 1-B16 (Mall) ( $MV < 3.50$  and  $CV > 0.25$ ) into 2-B13 (WeChat Store) and 2-B14 (Nearby Store).
- v. Experts believed that online medical visits can only be carried out on Internet hospitals, which requires strict approval and supervision, the MP is not suitable, and the rights of both doctors and patients cannot protect on 1-B13 (Online Consultation) ( $MV < 3.50$  or  $CV > 0.25$ ), and it is difficult to ensure the qualifications of the settled medical personnel, it was suggested to delete – When considering the high popularity of Internet and mobile phones in China, and COVID-19 pandemic, undoubtedly, mobile telemedicine is

convenient for patients to review, prescribe medication and access to higher quality medical resources. When it comes to the problems of medical personnel source, which can be solved by cooperation with hospitals. Besides, Internet hospital based on Mini Program are already available on the market. Therefore, if strictly according to Management Measures for Internet Diagnosis and Treatment issued by the nation, the online medical visits can be realized, so this suggestion was not accepted. Furthermore, experts suggested that it is unrealistic for clinical professionals to answer questions for free in 1-B12 (Message Zone) ( $MV < 3.50$  or  $CV > 0.25$ ), and they thought that communication among patients is not always needed. In contrast, we believe that patients not always be able to access to free medical resources (e.g., free Q&A from doctors), communication among CKD patients is necessary and should also promote family participation in patients' diet management, which helps improve their confidence in disease treatment, enhance social participation and improve social support, and is beneficial to their mental health. Therefore, 1-A3 (Doctor-Patient Community) ( $MV \geq 3.5$  and  $CV \leq 0.25$ ) was renamed as 2-A2 (Interactive Community), 1-B12 (Message Zone) ( $MV < 3.50$  or  $CV > 0.25$ ) and 1-B15 (Patient-Patient communication) ( $MV < 3.50$  and  $CV > 0.25$ ) were integrated as 2-B5 (Circle of Patients), 1-B13 (Online Consultation) ( $MV < 3.50$  or  $CV > 0.25$ ) renamed 2-B6 (My Doctors), and 1-B21 (Family Member) ( $MV < 3.50$  and  $CV > 0.25$ ) renamed 2-B8 (My Family) and integrated into 2-A2 (Interactive Community).

- vi. Experts suggested that there is no need to collect too much irrelevant personal information, such as place of origin, so 1-B20 (Personal Profile) ( $MV < 3.50$  or  $CV > 0.25$ ) was simplified and renamed 2-B15 (Basic Information).
- vii. Experts believed that the MP should be simplified as much as possible, so integrated 1-B24 (Feedback) ( $MV \geq 3.5$  and  $CV \leq 0.25$ ) and 1-B25 (Help) ( $MV < 3.50$  or  $CV > 0.25$ ) into 2-B21 (Feedback and Help); integrated 1-B26 (User Instruction) ( $MV < 3.50$  or  $CV > 0.25$ ), 1-B27 (Product Introduction) ( $MV < 3.50$  or  $CV > 0.25$ ) and 1-B28 (Privacy Policy) ( $MV < 3.50$  or  $CV > 0.25$ ) into 2-B20 (Product Introduction).

### 2.2.3.3 Second round of expert evaluation

#### (1) Scoring of modules and functions

10 experts continued to participate in the second round of expert evaluation, the scoring of modules and functions are shown in **Table 12** and **Table 13**, experts gave feedback on 4 functions, a total of 8 suggestions, feedback and feedback processing summary is shown in **Appendix 5**. In these modules,  $MV \geq 3.5$  and  $CV \leq 0.25$  including A1, A3;  $MV < 3.50$  and  $CV > 0.25$  including A4;  $MV < 3.50$  or  $CV > 0.25$  including A2, A5. In these functions,  $MV \geq 3.5$  and  $CV \leq 0.25$  including B1, B2, B3, B6, B7, B9, B10, B11, B12, B16, B21;  $MV < 3.50$  and  $CV > 0.25$  including B13;  $MV < 3.50$  or  $CV > 0.25$  including B4, B5, B8, B14, B15, B17, B18, B19, B20.

Table 12 Second round of module scoring

Note: coefficient of variation (CV)>0.25 was marked with "\*\*"

Modules	Scientific			Important			Appropriate			Practical		
	MV	SD	CV	MV	SD	CV	MV	SD	CV	MV	SD	CV
A1	4.00	0.943	0.236	4.60	0.699	0.152	4.60	0.843	0.183	4.60	0.843	0.183
A2	3.70	0.949	0.256*	3.90	1.101	0.282*	3.90	0.994	0.255*	4.00	1.054	0.264*
A3	3.90	0.876	0.225	4.10	0.994	0.242	3.80	0.919	0.242	3.80	0.919	0.242
A4	3.40	1.350	0.397*	3.50	1.269	0.363*	3.50	1.179	0.337*	3.50	1.269	0.363*
A5	3.70	1.160	0.314*	3.90	1.287	0.330*	4.10	1.101	0.269*	4.20	1.135	0.270*

Table 13 Second round of function scoring

Note: coefficient of variation (CV)>0.25 was marked with "\*\*"

Functions	Scientific			Important			Appropriate			Practical		
	MV	SD	CV	MV	SD	CV	MV	SD	CV	MV	SD	CV
B1	4.50	0.850	0.189	4.80	0.422	0.088	4.70	0.483	0.103	4.80	0.422	0.088
B2	4.50	0.707	0.157	4.60	0.516	0.112	4.60	0.516	0.112	4.40	0.699	0.159
B3	4.50	0.527	0.117	4.30	1.059	0.246	4.50	0.707	0.157	4.40	0.966	0.220
B4	4.10	1.101	0.269*	4.10	0.876	0.214	4.10	0.876	0.214	4.30	0.949	0.221
B5	3.60	1.174	0.326*	3.90	0.994	0.255*	4.00	1.054	0.264*	4.00	0.943	0.236
B6	4.00	0.816	0.204	4.00	0.816	0.204	3.70	0.675	0.182	3.70	0.675	0.182
B7	4.40	0.699	0.159	4.30	0.823	0.191	4.50	0.707	0.157	4.40	0.843	0.192
B8	3.70	0.949	0.256*	3.90	0.876	0.225	4.10	0.738	0.180	4.00	0.816	0.204
B9	4.60	0.699	0.152	4.40	0.699	0.159	3.90	0.876	0.225	4.10	0.994	0.242
B10	4.40	0.843	0.192	4.30	0.823	0.191	4.10	0.876	0.214	4.20	0.919	0.219
B11	4.60	0.699	0.152	4.60	0.699	0.152	4.40	0.699	0.159	4.60	0.699	0.152
B12	4.20	1.033	0.246	4.30	0.949	0.221	4.00	0.816	0.204	3.80	0.789	0.208

Functions	Scientific			Important			Appropriate			Practical		
	MV	SD	CV	MV	SD	CV	MV	SD	CV	MV	SD	CV
B13	3.40	0.699	0.206	3.50	1.080	0.309*	3.90	0.876	0.225	3.90	1.197	0.307*
B14	3.90	1.101	0.282*	3.70	1.059	0.286*	3.70	1.059	0.286*	3.70	1.059	0.286*
B15	3.90	1.524	0.391*	4.00	1.491	0.373*	4.10	1.287	0.314*	4.20	1.229	0.293*
B16	4.30	0.823	0.191	4.40	0.843	0.192	4.40	0.843	0.192	4.30	1.059	0.246
B17	4.10	0.876	0.214	4.40	0.843	0.192	4.00	1.054	0.264*	4.10	1.101	0.269*
B18	3.80	1.135	0.299*	4.00	1.247	0.312*	4.20	0.919	0.219	4.20	0.919	0.219
B19	3.50	1.179	0.337*	3.80	1.229	0.323*	3.90	1.287	0.330*	3.80	1.229	0.323*
B20	4.10	0.876	0.214	4.10	0.994	0.242	3.90	1.287	0.330*	3.70	1.418	0.383*
B21	4.00	0.943	0.236	4.40	0.843	0.192	4.30	0.823	0.191	4.30	0.823	0.191

## (2) Revision of modules and functions of the MP

From the results of second round, now most of modules and functions were scored excellent by multidisciplinary expert. The scoring of modules and functions with  $MV < 3.50$  or  $CV > 0.25$  mainly focus on the interaction of doctor-patient and patient-patient in Interactive Community and Online Shopping, and some basic functions of this MP in Personal centre.

Therefore, relevant modifications were made to the second version of Kidney Disease Diet Bao, including,

- i. delete 2-A4 (Shopping Mall) ( $MV < 3.50$  and  $CV > 0.25$ ), and its subordinate 2-B13 (WeChat Store) ( $MV < 3.50$  and  $CV > 0.25$ ) and 2-B14 (Nearby Store) ( $MV < 3.50$  or  $CV > 0.25$ ).
- ii. 2-B6 (My Doctor) ( $MV \geq 3.5$  and  $CV \leq 0.25$ ) was modified, users can ask questions online instead of the original online consultation, which will be regularly answered by the settled clinical professional team.
- iii. Expert suggested to merge Diet Record and Dietary Nutrition Monitoring in 2-B2 (Diet Management) ( $MV \geq 3.5$  and  $CV \leq 0.25$ ), so in 3-B2 (Diet Management) that is Diet Record & Dietary Nutrition Monitoring.
- iv. In addition, expert doubted the validity and accuracy of Dietary Survey in Nutrition Screening [2-B2 (Diet Management)], which is considered need to be confirmed by clinical research, and it was said that should calculate directly via Food Database,

because that only provide rough results and cannot generate meaningful reports, so it was suggested to delete, therefor Dietary Survey was removed and only retained NRS2002.

#### 2.2.3.4 Final written design of the MP (V3)

Through two rounds of multidisciplinary experts' evaluation and feedback, the final version of the written design of Kidney Disease Diet Bao was finished, including 4 modules and 19 functions, and the schematic diagram is shown in Figure 4, the specific content of the designed modules and functions as follows.

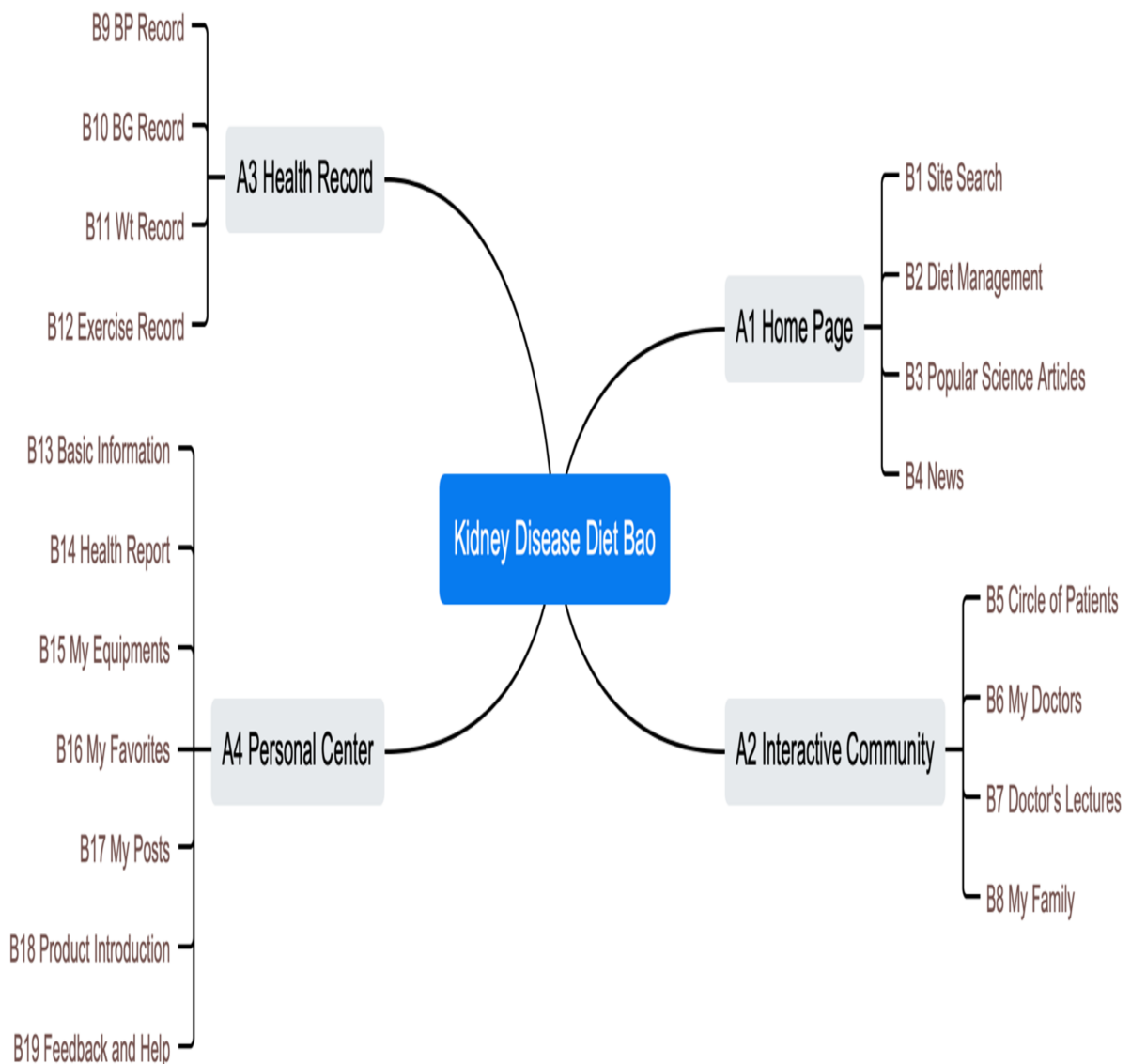


Figure 4 Diagrammatic sketch of Kidney Disease Diet Bao (Version 3)

## (1) Login and disease information setting

### 1) Login

Login through WeChat account, prompting the user that the MP is for adults with chronic kidney disease stage 1-5 clinically stable non-dialysis patients (not applicable to patients on peritoneal dialysis, haemodialysis, kidney transplantation, kidney cancer, etc.), and will verify and bind the cell phone number after the first login, prompting the user to select the identity category, including patients, family, clinical professionals, others.

### 2) Disease information settings

- i. After logging in, users need to set up basic information and disease information of the patient, including gender, date of birth, height, weight, activity intensity, serum creatinine (Scr), cystatin (Cys), serum potassium and phosphorus, whether to take keto acid preparations, whether to take calcium or calcium-phosphorus binder, whether to combine diabetes, hypertension, hyperuricemia/gout, hyperlipidaemia, daily urine volume and oedema.
- ii. Setting prompt: to make accurate dietetic-nutritional plan, please fill in the following information truthfully and update the information regularly, we guarantee the strict confidentiality of your information. (If there are obvious mistakes, such as height is 16cm, or part of the information is missing, the MP will automatically remind the user to fill in again).
- iii. The MP will remind the user to reset the above information every month, and the user can also reset the information at any time according to the actual situation.

## (2) Description of modules and functions

**A1 (Home Page), including B1 (Site Search), B2 (Diet Management), B3 (Popular science articles) and B4 (News)**

### # B1 (Search Engine)

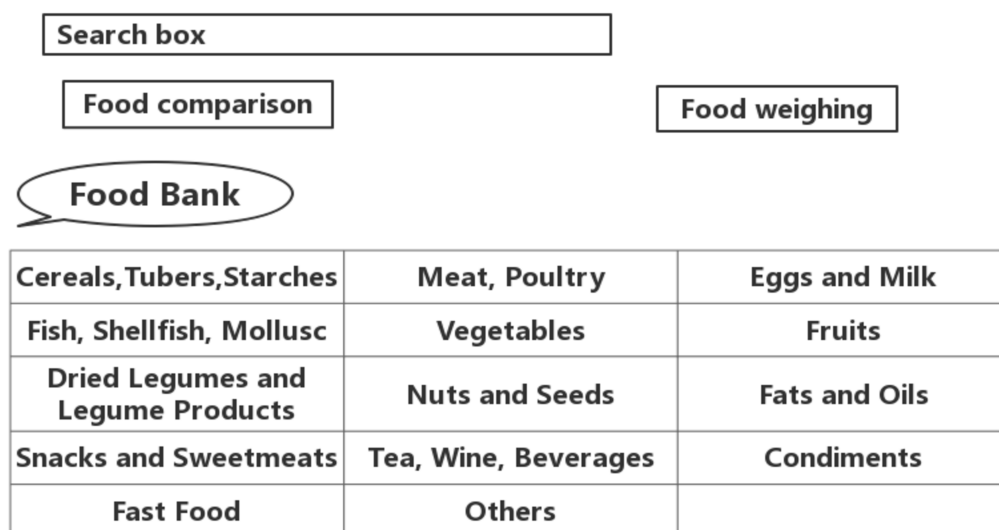
Search for information in this MP, with keyword intelligent matching.

### #B2 (Diet Management)

It assists users in self-management on diet, and presented in the form of functional navigation



\*Food Composition Query



- i. Search box: Enter the name of food to quickly check the nutrient content of a certain food.
- ii. Food comparison: 2-5 kinds of food can be added from Food Bank to compare their nutrient contents.
- iii. Food weighing: provide actual quantitative illustration of ingredients, will use plates and bowls of different sizes as measuring tools, and combine various forms such as measuring tape, palm, fist, spoon, to provide an intuitive visual quantification (i.e., change with the number or weight size) of the recommended intake of each raw food ingredient, provided that the technology is achievable will combined with 3D as well

as virtual reality (VR) technology, the visual sense will be more realistic so that users can accurately estimate the weight of ingredients, i.e., the actual picture of the raw food ingredients + the name of the ingredients + the quantity (in grams). (Meat and fish may be 10g, 20g, 30g, 40g, 50g, 60g per serving, and other foods may be 90kcal per serving, or a complete serving of itself to represent each serving).

- iv. The foods in each food category are partitioned so that users can filter according to their needs, including protein (high quality protein zone/non-high quality protein zone), potassium (<150mg/100g=low-potassium zone, 150-250mg/100g=medium-potassium zone, >250mg/100g=high-potassium zone), phosphorus (<100mg/100g=low-phosphorus zone, 100-300mg/100g=medium -phosphorus zone, >300mg/100g=high-phosphorus zone), phosphorus/protein (<5mg/g=low-phosphorus/protein ratio, 5-12mg/g=medium-phosphorus/protein ratio, >12mg/g=high-phosphorus/protein ratio), purine (<50mg/100g=low-purine zone, 50-150mg/100g=medium-purine zone, 150- 1000 mg/100g=high-purine zone), and glycaemic index /GI (<55=high GI, 55-70=medium GI, >70= high GI), and the high/medium/low zone are marked by red, yellow and green respectively.
- v. Each food mainly shows the content of the following nutrients: calories, protein, carbohydrates, fat, cholesterol, saturated fatty acids, unsaturated fatty acids, dietary fibre, water, phosphorus/protein ratio, glycaemic index, sodium, potassium, phosphorus, calcium, iron, vitamin D, folic acid; if users want to check the content of other nutrients, can click More to check the content of other nutrients, including vitamins (vitamin A, vitamin B1 and B2, vitamin B6, vitamin B12, vitamin C, vitamin E, vitamin K, niacin), minerals (magnesium, copper, selenium, zinc)

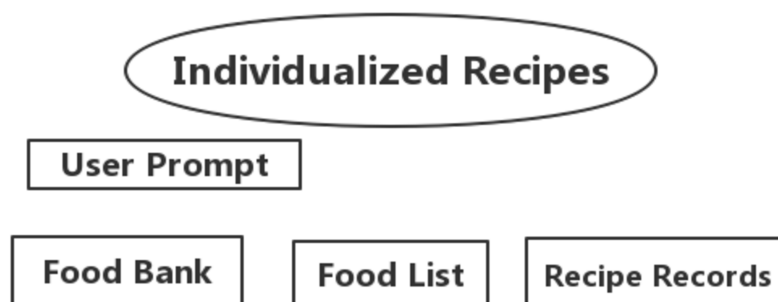
\* Individualized Recipes (note: renal dietitian administrator will be allocated)

- i. User interface will display the reference sources: Clinical Practice Guidelines for Nutritional Treatment of Chronic Kidney Disease in China (2021 Edition) and the national Dietary Guidelines for Patients with Chronic Kidney Disease (WS/T 557-2017), and the background settings will continue to update according to the national guidelines.
- ii. Set user instructions: select today's ingredients in [Food Bank] and add them to [Food List], then click Today's Recipe at the bottom of this window to automatically



jump to [Recipe Records] to view today's individualized recipes. (Note: Users are allowed to go back to each window to retry as needed).

- iii. Setting the guideline for ingredient selection, according to Dietary Guidelines for Chinese Residents (2016) and the Clinical Practice Guidelines for the Nutritional Treatment of Chronic Kidney Disease in China (2021 Edition), it is recommended that you should include in your daily balanced diet at least 1) staple foods, i.e., whole grains, tubers, starches ( at least 1-2 kinds per day), high-quality protein from animal foods such as meat, eggs and dairy, and soybean products, preferably to eat fish and poultry meat, and milk and eggs in moderation; and fruits and vegetables, animal fats are not recommended. 2) For people with hyperkalaemia (serum potassium >5.5 mmol/L), foods with high potassium content are not recommended. 3) For people with hyperphosphatemia (serum phosphorus >1.9mmol/L), foods with high phosphorus content are not recommended. 4) For those with hyperuricemia/gout, foods with high purine content such as seafood (mainly deep-sea fish, shrimp, crab, shellfish) are not recommended. 5) For people with hyperlipidaemia, foods such as animal offal and fatty meat are not recommended. 6) For patients with combined diabetes, foods with high glycaemic index (GI) are not recommended.



#### 1) Food Bank

Prompt users to read these tips carefully before selecting ingredients, so according to the disease information set by users, if the selected ingredients do not meet the above requirements, the MP will remind users to modify the food list before submission.

- i. It includes a search box, and food categories, display the nutrient content of foods and partitions, just as mentioned above.

- ii. User selects today's diet ingredients and click Add then it will automatically go to [Food List].

## 2) Food List

- i. The user will view the selected ingredients, be allowed to delete the selected ingredients, and return to the [Food Bank] to select food again.
- ii. After determining today's ingredients, the user clicks Today's Recipe at the bottom to generate the customized recipe, if the selected ingredients do not meet the disease requirements, such as the lack of high-quality protein, the user will be prompted that they should continue to add the corresponding food types and jump to [Food Bank], if the selected ingredients meet the requirements of the disease, it will jump to [Recipe Records].

## 3) Recipe Records



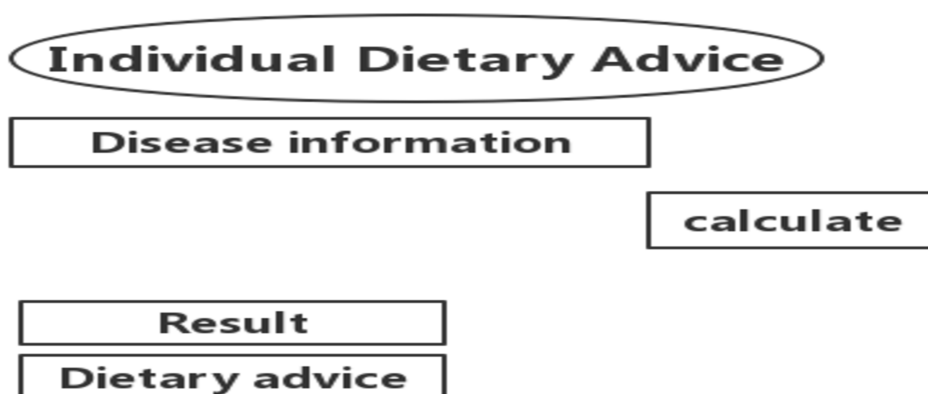
- i. To facilitate users to freely match the types of food and portion sizes for each meal, the recipes are presented in the form of food categories, which provide the recommended weight of intake of the selected ingredients by the user. The format is as follows.

Food Category	Recommended Intake (g)	Food Weighing
Cereals, Tubers, Starches	? ----? g	food1(g)+food2(g)
Meat and Poultry		
Eggs and Milk		
Fish, Shellfish, Mollusc		
Vegetables		
Fruits		
Nuts and Seeds		
Fat and Oils		

Condiments		
------------	--	--

- ii. When users click on Food Weighing, it will jump to the actual quantitative graph of ingredients, same as mentioned above.
- iii. [Recipe Records] is displayed in the form of a calendar, so that users can quickly view all the previous recipe records, or they can search the date directly in the search box to check the historical recipe records.

\* Individual Dietary Advice (note: renal dietitian administrator will be allocated)



- i. Once entering this window, the user interface displays the disease information set by the user, and after the user checks or changes and confirms the information, click Calculate at the bottom to jump to Result and Dietary Advice.
- ii. Result: Your estimated glomerular filtration rate (eGFR) is? ml/min/1.73m<sup>2</sup>, currently in CKD stage? (See the formula). Your standard weight is? kg, body mass index is? kg/m<sup>2</sup>, body type belongs to (see the formula)?
- iii. Dietary advice: Your recommended energy intake is? kcal, protein intake is? g, carbohydrate intake is? g, fat intake is? g. The recommended intakes of various food are as follows (Note: When users click on View Details, it will jump to [Food Bank] to view the specific kinds of foods in the food category, showing the nutrient content and partition of each food (same as mentioned above), so that users can match their own diet.

Food category	Recommended Intake (g)	View Details
Cereals, Tubers, Starches	? ----? g	<a href="#">Click Here</a>
Meat and Poultry		
Eggs and Milk		
Dried Legumes and Legume Products		
Fish, Shellfish, Mollusc		
Vegetables		
Fruits		
Nuts and Seeds		
Fat and Oils		
Condiments		
Water		

### \*Diet Record & Nutrition Monitoring

**Diet Record & Nutrition Monitoring**

+ Breakfast
Photos
Voices
Food Weighing

food1(g) , food2(g).....  
Remark(there are cooking methods for the user to choose

+ Lunch

+ Dinner

+ Extra meals

+Seasonings (oils, salt,..... )

Dietary Nutrition Analysis

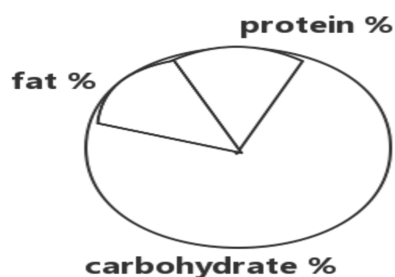
Dietary Suggestions

Diet Record Review

- i. once the user enters into this window, a prompt is displayed: In order to accurately analyse your dietary nutrition intake, all foods eaten orally need to be recorded, including three meals a day, additional meals, cooking oil, salt, seasonings and snacks (such as peanuts, candy, melon seeds, cookies), liquids (such as water, tea, beverages, wine,), and the record is the name and weight of raw food ingredients consumed or processed foods

and fast food. For example, scrambled eggs with tomatoes, the record is a few grams of tomatoes and a few grams of eggs.

- ii. When the user clicks to add record, such as +Lunch, it will automatically jump to [Food Bank], find the food consumed in the search box or food category, and click on the selected food, it will provide a visual quantified food weight weighing diagram (same as mentioned above), so that the user can accurately estimate the weight of the food. In addition to adding diet record manually, users can also take photos and upload pictures of diet (unlimited number of pictures) and record today's diet with voice to facilitate communication with dietitians during follow-up visits.
- iii. [Dietary Nutrition Analysis] is to generate a report of nutrition of the current food intake (to inform the user that the data is for reference only), which provides the basis for the user's next meal. If the actual intake of nutrients > recommended intake, it is marked with red arrow upwards, and the actual intake < recommended intake, it is marked with red arrow downwards. The report only shows some major nutrients (including energy, protein, carbohydrates, fat, cholesterol, dietary fibre, water, sodium, phosphorus, potassium, iron, calcium, vitamin D, folic acid), users can click View More to display other nutrients. The format is as follows.



Nutrients (unit)	Actual Intake	Recommended Intake
Protein (g)		
High-quality protein (%)		
Carbohydrate (g)		
Fat (g)		
Energy (kcal)		

Nutrients	Actual Intake	Recommended Intake
Energy (kcal)		
Protein (g)		
Carbohydrate (g)		
Fat (g)		
Cholesterol (mg)		
Dietary fibre (g)		
Water(g)		
Sodium (mg)		
Phosphorus (mg)		
Potassium (mg)		
Iron (mg)		
Calcium (mg)		
Vitamin D (ug)		
Folic Acid. (ug)		
View More		
Saturated Fatty Acid (g)		
Unsaturated Fatty Acid (g)		
Vitamin A(ug)		
Vitamin B1 (mg)		
Vitamin B2 (mg)		
Vitamin B6(mg)		
Vitamin B12 (ug)		
Vitamin C (mg)		
Vitamin E (mg)		
Niacin (mg)		
Magnesium (mg)		
Zinc (mg)		
Selenium (mg)		
Iodine (ug)		

- iv. When the user clicks on [Dietary Suggestions], it will recommend a series of food for the user to choose according to the results of the user's dietary nutrition monitoring, and then will recommend the intake amount for the user after the user selects the food.

- v. [Diet Record Review] is displayed in the form of calendar, which is convenient for users to check the past diet records, and users can also select a specific time to analyse the trend of dietary nutrients (such as protein, calories, carbohydrates, sodium.) intake, and the analysis results are displayed in line graphs or bar graphs.

#### \*Nutrition Screening

Using a simple survey, Nutritional Risk Screening 2002 (NRS2002).

User instructions: NRS2002 can only determine whether there is a nutritional risk and cannot determine whether the patient has malnutrition and the degree of malnutrition, the score is not determined the degree of nutritional risk. The result  $\geq 3$  points, indicating the presence of nutritional risk and prompting users to visit a medical nephrology nutrition department;  $< 3$  points, prompting users to regularly re-examine.

#### #B3 Popular Science Articles

This is to release articles related to diet and nutrition treatment for users to read, classified as Diet Control Skills, Low-protein Diet, Hypertensive Nephropathy Diet, Diabetic Nephropathy Diet, CKD & Gout Diet, CKD & Anaemia Diet, Exercise Rehabilitation, Common Dietary Problems, and How to Protect Kidneys. (Note that the published scientific articles should be illustrated and colourful and should support voice broadcast to meet the needs of different users).

- i. Invite clinical professionals (renal dietitians, nephrologists, and nurse specialists) to write scientific knowledge about diet and nutrition for CKD patients; and to write articles on the frequently asked/searched diet issues by users through statistical background data.
- ii. Allow users to comment, rate (5-star rating), like, favourite or forward to their family/friends in WeChat address book.
- iii. To improve the transparency of information, it displays the information of article writers (work unit, department, professional title, expertise), release time, number of reads, user ratings, comments, favourites and likes.

#### #B4 News

This is used for users to receive messages, clicking the link inside the message will automatically jump to the corresponding operation.



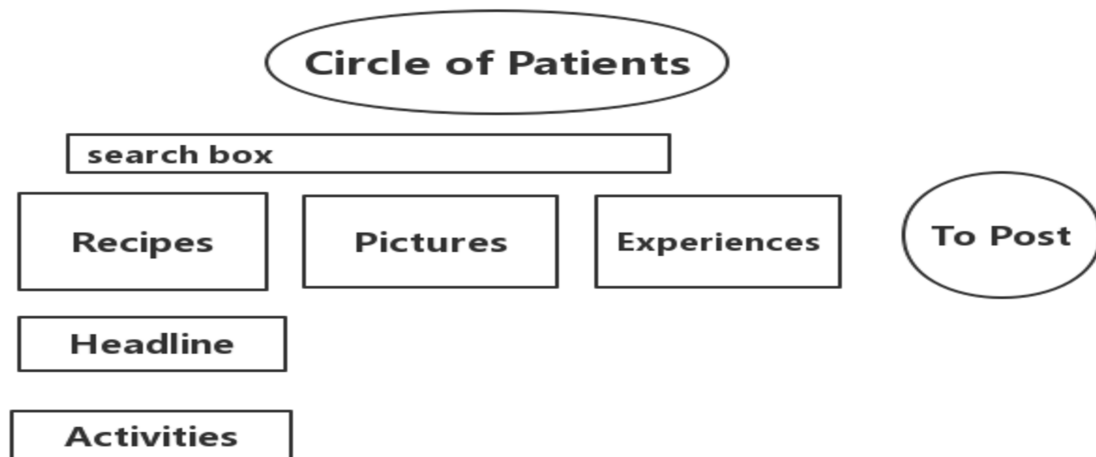
- i. System messages: including notification of the activities of doctor's lecture (such as clicking on the message and automatically jumps to the page of appointment and will send a message to remind the registered user when the lecture starts); user feedback reminder (regularly remind users can give feedback), abnormal health data reminder.
- ii. Interactive messages: user's publication gets answered or commented, users can view and reply in this window.
- iii. Answer questions: All questions asked by users, questions are presented in a list, sorted by posting time. View and choose whether to answer the questions asked by other users can be operated in this window.

**A2 (Interactive Community), including B5(Circle of Patients), B6 (My Doctors), B7(Doctor' Lectures), B8 (My Family)**

**#B5 (Circle of Patients)**

An area for all users to interact and communicate, all the posted contents are strictly supervised by the backstage, for inappropriate or unrelated speech, it will issue a red warning to stop users from posting. The posted information will show the publisher (anonymous), posting time, views, likes, favourites, comments. Users are allowed to make comments, favourites, and likes. The top of each window can be filtered by likes, favourites, views, and posting time. To increase the participation and activity of user interaction and sharing, it will regularly release activities in [Activities], such as topic interaction/recipe PK, and can be received in [System Messages], so that users can know the activity in time.

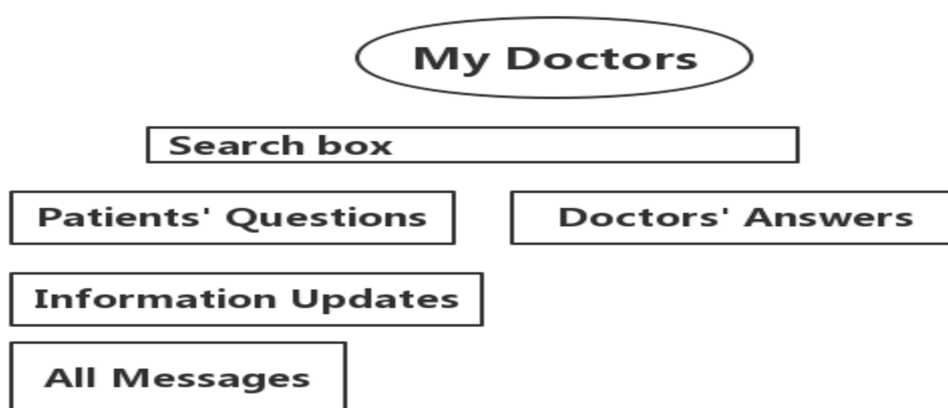




- i. Search box: users can search for the topics or questions that they want to know and is presented intelligently according to keyword matching.
- ii. Recipes: The presentation format is video + picture (referring to the picture of the food done) + text (ingredients and cooking steps) to meet different reading styles of users; recipes are classified according to low-protein diet, diabetic nephropathy diet, hypertensive nephropathy diet, high uric acid diet, diet control tips, etc. (Note: the recipes come from users published, and the background can be captioned for the recipe videos)
- iii. Pictures: the presentation form is picture + text, for users to share the pictures of daily diet.
- iv. Experiences: presented in text, users share their own experience in diet management, or other related content.
- v. To Post: to ask related questions or share related content, supporting formats including text, pictures, videos (in anonymous form). For example, ask questions about how to control dietary potassium intake, make a video of recipes or share experience in diet management, medical experience, disease stories, etc. All users can read and comment.
- vi. Headline: presenting today's updated release and shared information, easy for users to browse.
- vii. Activities: to active users, it should regularly release activities such as topic interaction/recipe PK. Users can read the details of various activities and register for them in this window.

## #B6 My Doctors

This is used for doctor-patient interaction, where users can ask questions anonymously for free (permission is set to 2 times per month), support formats including text + images, and view other users' questions and the corresponding answers, allowing users to comment and rate (using five-star ratings), forward or collect. Teams of clinical professionals are stationed to answer questions, in strict accordance with Internet Diagnosis and Treatment Management Measures (Trial) issued by National Health and Wellness Commission and the State Administration of Traditional Chinese Medicine in 2018.



- i. Search box: Enter a question or keyword to search similar questions asked by other users and responding answers, comments and ratings, number of views, likes, favourites, and users may not need to ask questions again if their questions can be answered.
- ii. Patients' Questions: Patients post their questions according to the uniform format, including basic information, question description, past medical history, uploading hospital examination (pictures). Clinical professionals with permission to post answers within 48 hours.
- iii. Doctors' Answers: set the permission to answer, and the clinical professional team that is enrolled can click on this window to view and reply to the question.
- iv. Information Updates: daily updates of all new questions or answers posted and all unanswered questions (display release time), making it easy for users to quickly browse the information.

- v. All messages: according to the different topics of the questions, it will automatically identify and extract the keywords for classification and naming. Users can view all the questions and corresponding answers, to improve the transparency of information, will display the release time, number of views, likes, favourites, comments, and ratings (5 stars), users can choose to sort by release time, ratings, number of views or comments, likes, favourites.

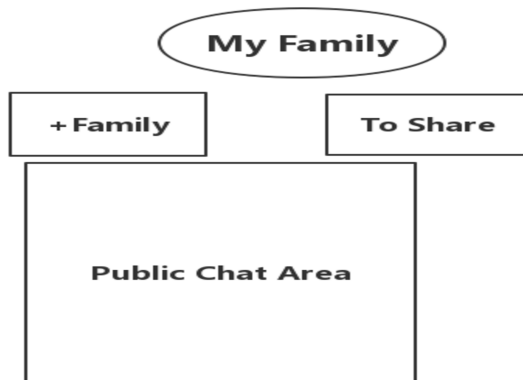
### **#B7 Doctor' Lectures**

Users can watch online videos related to CKD diet and nutrition in this area.

- i. It will regularly invite clinical professionals (nephrologists and specialist nurses, renal dietitians) to conduct online lectures related to the topic of CKD diet and nutrition, and the information of the activities will be notified to all users and published in [News]. Users need to make a reservation to attend, and a reminder notice will be sent to users who have made a reservation when the lecture starts, which will also be published in [News]. Or clinical professionals will be invited to record relevant videos, which will be published in this area, and users can watch them online.
- ii. Attending online lecture, users can communicate and interact with clinical experts online, and they can also review and watch previous lectures in the video list.
- iii. The information provided to the users of the posted videos includes the topic of the video, the presenter information (work unit + department + title + professional expertise), the time of posting, the number of views, comments and likes; users can comment on each video with text or interact with other users' comments.

### **#B8 My Family**

This is used to increase communication and interaction among family members, promote them to participate in and understand the condition of patient's diet, and provide support for the patient's diet management.



- i. +Family: add new family members, add by looking up WeChat ID, cell phone number, or scanning QR Code of WeChat business card.
- ii. Public Chat Area: all added family members can read and post messages (related to patient's diet management), e.g., Family member A: today I will select ingredients and customize recipes for the patient, or I will record diet for the patient, or he has made an appointment for doctor's online lecture.
- iii. To Share: From the list of added family members, select the family members who wish to authorize, and authorize the family members to directly access this MP under the user's account (note that just access to use this MP, any other information of the user is not authorized and cannot be viewed) to jointly view the user's information within this MP (e.g. customized recipes, diet records, dietary nutrition monitoring), with the aim of satisfying the need for different members of the family to understand/participate in the patient's diet management.

**A3 (Health Record), including B9 (BP Record), B10 (BG Record), B11(Wt Record), B12 (Exercise Record)**

## #B9 BP Record

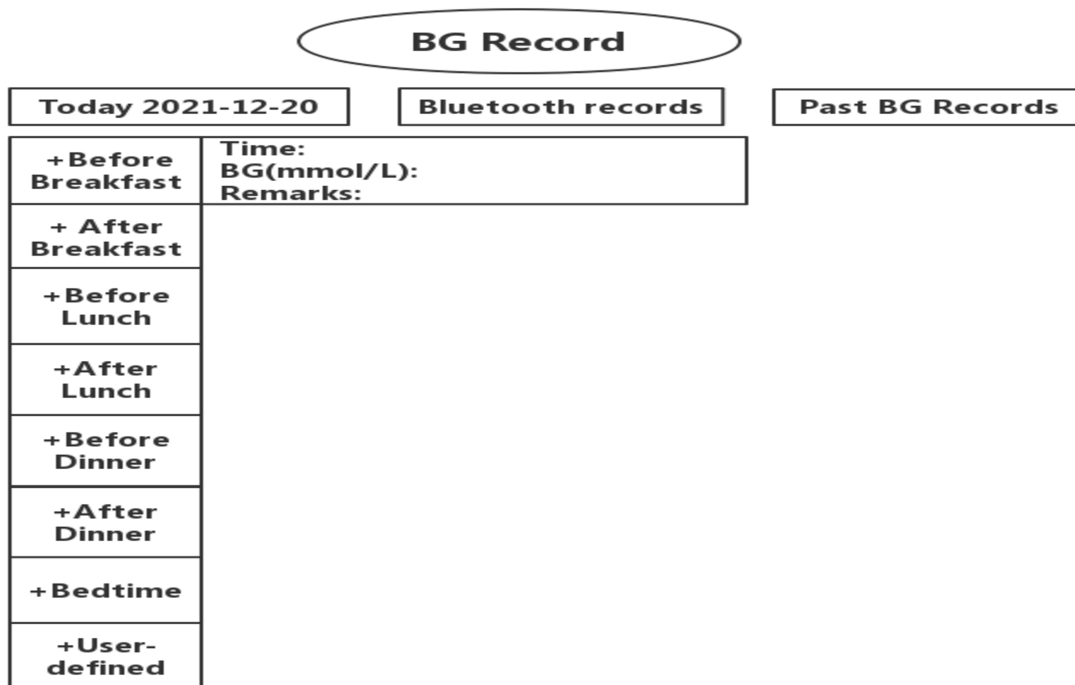
The screenshot shows a mobile application interface for recording blood pressure. At the top, there is a title 'BP Record' in an oval. Below it are three tabs: 'Today 2021-12-20', 'Bluetooth records', and 'Past BP Records'. On the left side, there are five buttons: '+ Morning', '+ Afternoon', '+ Evening', '+ Bedtime', and '+ User-defined'. To the right of these buttons is a form with three fields: 'Time:', 'BP(mmHg) :', and 'HR(times/min )', followed by a 'Remarks:' label.

- i. Setting prompt: Before measuring BP, you need to rest for 10-15 minutes in a quiet state. Please manually record BP in time or check BP uploaded by Bluetooth, so that we can find abnormal BP for you in time.
- ii. Users can manually record BP and measurement time; or use Bluetooth electronic blood pressure monitor, the measured result can be directly uploaded to Bluetooth Records.
- iii. Remarks: Users can describe the measured BP (e.g., higher than usual), the measurement arm (left/right arm) and measurement location (home/clinic/hospital), and mood (happy, sad, angry).
- iv. If the recorded/uploaded BP is significantly higher or lower than normal, such as BP greater than 180/120mmHg or lower than 90/60mmHg, the user will be prompted if it is wrong, and if it is not, a red alarm will be displayed to remind the user of the corresponding symptoms and self-treatment measures (**note, I won't describe the details here**).
- v. To only view BP uploaded through Bluetooth monitor, users need to enter [Bluetooth Records], but whether recorded manually or uploaded through Bluetooth, can be viewed in [History BP Records].

- vi. [History BP] uses a calendar format to display, so that users can easily view past BP records, and can also select a specific time range and BP measurement time (06:00-08:00, 08:00-10:00, 10:00-12:00, 12:22-14:00, 14:00-16:00, 16:00-18:00, 18:00-20:00, 20:00-20:00). 20:00, 20:00-22:00, 22:00-00:00, select 1 or several of them) to view the trend of BP changes during that time, and the analysis results are presented in the form of a line graph.

### #B10 BG Records

The design idea is the same as the above BP Records, so I won't go into details here.



### #B11 Wt. Record

The design idea is the same as the above BP Record, so I won't go into details here.

**Wt Record**

Today 2021-12-20	Bluetooth records	Past Wt Records
+ Before Breakfast	Time: Wt(kg): Remarks:	
+ Bedtime		
+ User- Defined		

### #B12 Exercise Record

**Exercise Record**

Manual Records	Intelligent Monitoring Start      End	Bluetooth Records
History Exercise		
Circle of Exercise		

- i. Manual record: When recording, users need to choose the exercise date, exercise mode and exercise duration. This mode requires background setting of calories consumed per hour for each type of exercise, and it is recommended to use the formula:  $\text{calorie (kcal)} = \text{METs} \times 3.5 \times \text{exercise time (min)} \times \text{body weight (kg)} / 200$ , to consider individual differences. (Note: METs, also known as Metric values, indicate the intensity of physical activity and are based on energy consumption in a quiet, seated position, i.e., 3.5 ml of oxygen per kg of body weight is consumed for 1 minute of sitting still, so that the intensity of exercise is 1 METs).
- ii. Intelligent Monitoring: users need to click start when exercising, and click end when exercising is over, it can automatically jump to the record column, users only need to fill

in or select the exercise mode, the format of exercise record: exercise mode + exercise duration + energy consumption, that is, this mode can automatically monitor calorie consumption.

- iii. Bluetooth records: when users wear the sports monitoring bracelet, they can upload the data to [Bluetooth records], users only need to fill in or select the sports mode, click save to generate exercise records.
- iv. Users can record multiple exercises per day and can view the total amount of exercise for the day in [History Exercise].
- v. [History Exercise]: it adopts the calendar format; users can select a specific time range to view the past exercise records.
- vi. After the user finished the exercise record of the day, in [History Exercise], he can click Share to [Circle of Exercise], and view the exercise shared by other users in [Circle of Exercise] (exercise mode + exercise duration + energy consumption), and its exercise ranking (can choose to sort by exercise duration or energy consumption).
- vii. When setting the type of exercise in the background, the specificity of the user group needs to be considered. Exercise items can include doing housework, gardening, walking, jogging, stair climbing, rope skipping, social dancing, square dancing, aerobics, yoga, tai chi, bowling, table tennis, tennis, badminton, golf, swimming, mountain climbing, biking, etc.

**A4 (Personal centre), including B13 (Basic Information), B14(Health Report), B15(My equipment), B16 (My Favourites), B17 (My Posts), B18 (Product Introduction), B19 (Feedback and Help)**

#### **#B13 (Basic Information)**

To set up personal information, including virtual avatar and nickname, gender, date of birth, place of residence, hospital visited, dietary preferences.

#### **#B14(Health Report)**

Including BP report, BG report, Wt report and exercise report, and the reports can be forwarded to facilitate communication between doctors and patients. The user clicks on a report type, it will automatically jump to History window in [BP Record], [BG Record], [Wt



Record], and [Exercise Record], and as mentioned above, where can generate trend charts of health data within the selected time range.

### **#B15(My equipment)**

To connect Bluetooth electronic smart devices, including weight scales, blood pressure monitors, blood glucose meters, sports bracelets, which can be added by searching for device models

### **#B16 (My Favourites)**

To save the user's favourite content in this MP, sorted by time by default, also can enter keywords in the search box at the top of this window.

### **#B17 (My Posts)**

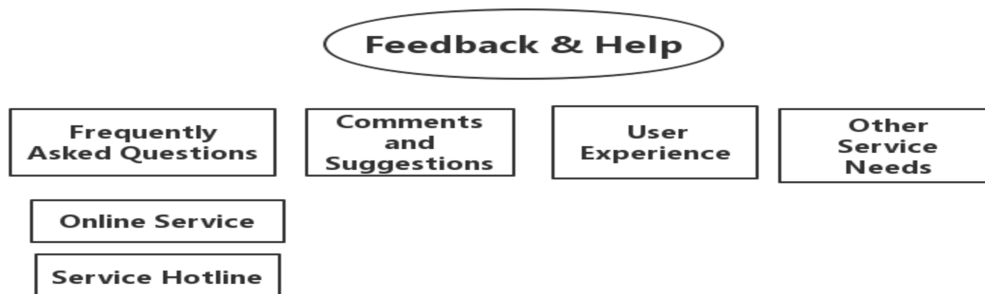
Save all the posts published by the user in this MP, sorted by time by default, allowing the user to delete and modify the published content.

### **#B18(Product Introduction)**

- i. Developers: Describe the development process of this MP, the people involved, including information technology companies, clinical professionals, CKD patients and family caregivers.
- ii. References: including professional books, medical literatures, medical websites. Considering the large number of references, links can be set up so that users in need can view it by clicking on the links.
- iii. Suitable for people: for patients aged 18-70 years with chronic kidney disease in stages 1-5 (non-dialysis) and stable condition (not suitable for groups with combined tumour, severe cardiac insufficiency/acute and chronic heart failure, cerebrovascular disease, haematological system disease, cirrhosis, liver failure, post-gastrectomy, hyperthyroidism, acute trauma or surgery, mental illness, pregnancy or lactation).
- iv. Product functions: dietary knowledge, individual recipe customization, individual dietary advice, food composition inquiry, diet record and dietary nutrition monitoring, health record, doctor-patient interaction, patient communication, family support.
- v. Privacy and security: explain Privacy Policy of this MP, mainly including how this MP uses user' personal information and how it protects user' personal information.

User guide: provide instructions on the use of Kidney Disease Diet Bao in the form of text, screenshots, and video.

### #B19 (Feedback and Help)



- i. Collect problems, comments and suggestions or other service needs encountered by users, and regularly update and maintain the system to provide better services.
- ii. Set up frequently asked questions and answers, provide online service and service hotline to solve problems for users in a timely manner.
- iii. Users click into the corresponding window to operate according to their actual needs, supporting formats of text, pictures, and videos.
- iv. If users are willing, it should promptly call to users who leave feedback to fully understand them and solve their problems.

#### 2.2.4 Discussion

Because most of the clinical experts think that it is difficult to carry out online medical visits, the reliability and validity of patient-patient communication to obtain information is unknown, and online shopping and basic function of a MP are not important, and the overall scoring of modules and function were in our expectation, but the concentration of experts' opinion was low, resulting in the scoring of some modules and functions were  $MV > 3.5$ , and  $CV > 0.25$ . Therefore, the finalized written MP design removed online shopping because the current shopping platforms are convenient in China, such as Taobao, Jindo. We believe that basic functions are indispensable for a MP, but most of the experts involved are clinical professionals, so they are probably not taken basic functions seriously. In addition, it already existed online medical visits platforms, such as Good Doctor, Dr. Chunyu, and Weimed to provide convenient and paid online consultation service, considering the working time and

workload limitations of clinical professionals, we narrow the original design of online consultation function, users can ask questions in the message area, and the clinical professional team will reply regularly. However, the function for patient interaction is saved, and in the future, we may consider inviting CKD patients and caregivers to work for the management of this MP, which will help this MP work well, to ensure that this MP is a suitable tool to assist patients manage CKD diet at home.

Overall, through multidisciplinary experts to evaluate feasibility of this MP, and improve the written design, to ensure it can be a scientific and practical tool for patients. Furthermore, it lays the foundation for the next step of prototype development and avoids the repeated revisions and upgrade after the development. resulting in a waste of resources.

## **2.3 Prototype Development and Evaluation of the Mini Program**

### **2.3.1 Objective**

Using Mocking Bot to develop a prototype of this MP, the prototype was tested by recruiting clinical professionals, patients, and caregivers. From the perspective of the target users, to expose the shortcomings of the design and potential usability issues to guide the design iterations in the future, and further confirm whether this MP is an eligible tool for patients in home diet management.

### **2.3.2 Method**

#### *2.3.2.1 Prototype development*

Prototyping is a way for designers to express their ideas and conception, which can be used in the early stage of the product development to test the feasibility of the product, and facilitate other stakeholders to view, discuss and adjust them. Prototype evaluation is regarded as an irreplaceable usability practice in user-centred interaction design, which can better judge the design and make timely adjustments, which is crucial to the success of the final product.

Using Mocking Bot (<https://modao.cc/>) as the development tool, it is an online prototyping and remote collaboration platform that allows to build and demonstrate product prototypes, making it easy to collect feedback from customers. The prototype for this study was made by the researcher herself, and it was high-fidelity and interactive, which means it was as real as possible, as similar as possible to the actual product, and very close to the real product in

terms of visuals, interactions, and user experience, including all the content in the final design. (i.e., its interface was colourful and dynamic, with corresponding page jump when clicked it). It gives a clear understanding of how the product works, meaning that in usability testing, the testers are more likely to behave naturally, as if they were interacting with the real product. Below are some screenshots of the prototype interface, and more prototype images of the MP can be found in **Appendix 6**.





### 2.3.2.2 Prototype evaluation

#### 2.3.2.2.1 Study design

Regarding the design of usability evaluation of prototypes, most of them adopt a mixed study design<sup>[234]</sup>. Think-aloud protocol (TAP) was used for the testing, and the testers are interviewed after the testing to collect their feelings about the prototype and a usability questionnaire was used to collect quantitative data. This combination of quantitative and qualitative data is more comprehensive and increases the credibility of usability testing.

#### 2.3.2.2.2 Sample size and sampling

A sample size of at least 10 users can ensure to detect potential problems and reduce product recall<sup>[49]</sup>. Therefore, in this study, a convenience sampling method was used to recruit 5 CKD patients and 5 caregivers for a total of 10 target users from Huashan Hospital, Fudan University, Shanghai. In addition, to further ensure the professional and scientific nature of this MP, 5 clinical professionals were also recruited to participate in the test, so a total of 15 testers experienced the prototype, and the inclusion criteria for the testers were the same as the above mentioned, see Requirements analysis of diet management Mini Program.

#### 2.3.2.2.3 Research tools

(1) Quantitative tool: Chinese version of the interactive mHealth app usability questionnaire (MAUQ) (see **Appendix 7**) was used in this study to collect usability ratings of the prototype

from patients and caregivers, and the content validity of the MAUQ is 0.952 and Cronbach's alpha coefficient is 0.912, indicating that the questionnaire has good reliability in Chinese cultural context<sup>[235]</sup>. The questionnaire has 21 entries, including 3 dimensions, namely usability and satisfaction (8 items), system information arrangement (6 items), and efficiency (7 items). The questionnaire is a Likert 7-point scale, i.e., 1=strongly agree, 2=agree, 3=somewhat agree, 4= neither agree nor disagree, 5- somewhat disagree, 6- disagree, and 7- strongly disagree, and the corresponding score for all entries is calculated and their mean is determined, with the closer the mean to 1, the better the usability of the MP.

(2) Qualitative tool: A self-made interview outline based on the research purpose, which was used to explore the overall feelings of the target users (CKD patients and caregivers) toward the MP, the perceived benefits, and the willingness to use the MP, and the shortcomings of the design and suggestions for improvement. Questions including: 1) How do you feel about the MP? Do you think it is easy to use? 2) Is it useful for you or your family to manage diet at home? 3) Would you like to use this MP for home diet management? 4) What do you think are the shortcomings or inconveniences of the MP? How do you suggest improving it?

#### 2.3.2.2.4 Prototype testing process

##### (1) Clinical professionals in testing

- i. 1 renal dietitian, 2 nephrologists, and 2 specialist nurses were recruited, who had participated in Requirements analysis of the MP in the first stage of this study.
- ii. The prototype testing was conducted in doctor' office, the researcher introduced the prototype to the clinical professionals before testing and explained the purpose of the test and the testing process.
- iii. The researcher provided the clinical professionals with the QR code of the prototype so that they operate the prototype on their own smart phones, and the clinical professionals were asked to browse and enter each module and function to operate, and to think out loud during the testing, i.e., they could make any comments and suggestions, questions at any time.
- iv. After the testing, the researcher conducted a group focus interview to ask them about their feelings about the prototype, and the shortcomings and suggestions for improvement.

- v. The researcher recorded the entire testing, and observed their nonverbal behaviours, and explained or answered their questions if necessary.

(2) CKD patients and caregivers in testing

- i. Through their attending doctors introduced the researcher to the tester, who introduced herself and the prototype, explained the purpose and the testing process, as well as the potential benefits and risks, and signed an informed consent form (see **Appendix 8**).
- ii. The testers tested the prototype in the iPad provided by the researcher. Considering that the usability test in this study was a primary prototype, moreover, we wanted to understand the comprehensive evaluation and feedback from patients and caregivers, so instead of setting typical tasks, each tester was required to operate all modules and functions of the MP, and encouraged them to think out loud during the testing, i.e., to express ideas, opinions, comments, or ask questions at any time, and the researcher answered.
- iii. After the testing, the testers were interviewed in a face-to-face one-on-one format.
- iv. After the interview, the basic information of the testers was collected, and the testers filled out the MAUQ, which was collected on the spot and checked the validity of the completed questionnaire.
- v. The whole process was sound recording and the testers' non-verbal behaviours were recorded, and the researcher observed the whole testing process and provided necessary instructions and guidance to ensure that the testers experienced all modules and functions but did not provide operational support.

2.3.2.2.5 Data analysis

(1) Quantitative data: SPSS 28.0 was used for data analysis, and the scoring of the questionnaire was statistically described using mean, standard deviation (SD).

(2) Qualitative interview data were transcribed within 24 hours, and the data were analysed using content analysis, with the following steps: repeatedly and carefully read the transcribed text to get a sense of wholeness; breaking up the data and analysing them line by line to identify significant statements and coding them; coding and categorizing recurring statements, things, and phenomena to generate themes; finding associations between themes to form

thematic clusters; and so on until saturation, i.e., no more new themes and sub-themes are presented.

### 2.3.3 Results

#### 2.3.3.1 Testers Information

A total of 15 testers participated in the prototype evaluation, including 5 clinical professionals, 5 CKD patients, and 5 caregivers. 5 clinical professionals were female; 2 with a PhD degree and 2 with a master's degree; and had 13-28 years of work experience, with an average of 18.2 years working life. Among the target users (CKD patients and caregivers), 5 were male and 5 were female; the age range was 23-66 years and average age was 40.2 years; 4 had a high school degree or less, 2 had a college degree, and 4 had a bachelor's degree. The information of the testers is shown in **Table 14**, **Table 15**, and **Table 16**, respectively.

Table 14 Information about Clinical Professionals

Note: D=doctor, RD=renal dietitian, N=nurse

No.	Education	Title	Working life (Years)	Professional field
D1	PhD	Associate Chief Physician	20	Chronic kidney disease
D2	PhD	Associate Chief Physician	16	Chronic kidney disease
RD3	Master	Attending Physician	14	Renal diet
N4	Master	Nurse in charge	13	CKD Outpatient nursing
N5	Bachelor	Nurse in charge	28	Nursing Management

Table 15 Patients information

No.	Gender	Age (Years old)	Education	Occupation	Marital status	Residence	Staging/ duration of CKD	Complication & comorbidities	Economic burden
P1	Male	28	Bachelor	Engineer	Married	Jiangsu	CKD3/1month	None	Mild
P2	Female	29	Primary school	Worker	Married	Shanghai	CKD3/2month	None	Severe
P3	Female	52	Bachelor	Teacher	Married	Anhui	CKD4/3years	Hypertension	Mild
P4	Male	66	College	Retired	Married	Shanghai	CKD4/2years	Hypertension coronary disease	Moderate
P5	Male	34	Junior high school	Monk	Unmarried	Shanghai	CKD3/3years	Hypertension, diabetes, hypoproteinemia	Severe



Table 16 Caregiver Information

No.	Gender	Age (Years old)	Relationship with patients	Residence	Education	Occupation	Financial burden
C1	Male	43	Husband	Anhui	Junior high school	Farmer	Moderate
C2	Male	57	Father-Son	Jiangsu	High school	Worker	Severe
C3	Female	23	Father-Daughter	Heilongjiang	Bachelor	Student	Mild
C4	Female	40	Mother-Son	Shanghai	College	Office worker	Moderate
C5	Female	30	Mother-Daughter	Shanghai	Bachelor	Accountant	Moderate

### 2.3.3.2 Quantitative results

The results of the usability rating of the prototype are shown in **Table 17**. The overall average scoring is 1.39 (SD=0.29); the mean value of the ratings of the usability and satisfaction dimensions is 1.28 (SD=0.31), the mean value of the ratings of the system information arrangement dimension is 1.4 (SD=0.29), and the mean value of the ratings of the efficiency dimension is 1.51(SD= 0.38). The closer of the overall mean value is to 1, the better the usability of the application is, so it can be considered that this prototype is recognized as usable by the target users.

Table 17 Rating of MAUQ

Statements	N=10						
	1	2	3	4	5	6	7
1. The prototype was easy to use	8	2					
2. It was easy for me to learn to use the prototype	9	1					
3. I like the interface of the prototype	4	4	2				
4.The information in the prototype was well organized, so I could easily find the information I needed	7	3					
5. I feel comfortable using this prototype in social settings.	9	1					
6. The amount of time involved in using this prototype has been fitting for me	6	4					
7. I would use this prototype again	9	1					
8. Overall, I am satisfied with this prototype	8	2					
9. Whenever I made a mistake using the prototype, I could recover easily and quickly	5	5					
10. This mHealth prototype provided an acceptable way to receive health care services	8	2					
11. The prototype adequately acknowledged and provided information to let me know the progress of my action	5	5					

Statements	N=10						
	1	2	3	4	5	6	7
12. The navigation was consistent when moving between screens	5	5					
13. The interface of the prototype allowed me to use all the functions (such as entering information, responding to reminders, viewing information) offered by the prototype	4	6					
14. This prototype has all the functions and capabilities I expected it to have	9	1					
15. The prototype would be useful for my/family's health and well-being	8	2					
16. The prototype improved my access to healthcare services	8	2					
17. The prototype helped me manage my/family's health effectively	8	2					
18. The prototype made it convenient for me to communicate with my healthcare provider	5	5					
19. Using the prototype, I had many more opportunities to interact with my healthcare provider	5	4	1				
20. I felt confident that any information I sent to my provider using the prototype would be received	3	6	1				
21. I felt comfortable communicating with my healthcare provider using the prototype	2	5	3				

Note: 1=strongly agree, 2=agree, 3= somewhat agree, 4=neither agree nor disagree, 5=somewhat disagree, 6=disagree, 7= strongly disagree

### 2.3.3.3 Qualitative results

#### 2.3.3.3.1 Results of qualitative interviews with clinical professionals

##### Theme 1 Use experience of the prototype

##### Category 1 The MP is comprehensive and helpful in managing patients' diet

Clinical professionals who participated in the test all said the MP meets the needs of CKD patients and caregivers and will help patients with home diet management. Doctor1: "*Most patients were nervous when diagnosed as CKD and didn't know how to adjust their diets, this MP was very helpful to them*". Dietitian 3: "*This MP was very comprehensive and clearly categorized, so they can find what they need more easily*". Nurse 3: "*Patients and caregivers quite needed this kind of MP, the functions in it were very helpful for them*". Nurse 5: "*The MP was very functional and can support patients from different perspectives.*"

##### Category 2 The MP can reduce the burden of diet education

Clinical professionals said that this MP can reduce the frequency of oral diet education to reduce their workload and compensate for the difference in the effectiveness of diet education that may be caused by their work experience. Nurse 4: *"We taught dietary knowledge to patients, but they (patients) often ran over and asked us some questions that we have talked about, with this MP they can read by themselves, which may reduce our repeated diet education"*. Nurse 5: *"The function of this MP was very comprehensive, most of the nurses in our ward were junior nurses, and because they lack experience, they were unable to do detailed diet education."*

## Theme 2 Shortcomings of the MP and suggestions for improvement

The clinical professionals mainly made three suggestions, including lack of a characteristic logo design for the MP; optimizing the layout to highlight the main functions of diet management and adjusting the colour scheme of UI.

### 2.3.3.3.2 Results of qualitative interviews with patients and caregivers

The purpose of qualitative interview is to explore the target users' overall feelings about this MP, the perceived benefits, and the willingness to use the MP, and the shortcomings of the design and suggestions for improvement.

## Theme 1 Overall feeling after use

Testers all said that the MP is comprehensive, convenient, and easy to use, which is a practical tool, and their overall satisfaction is excellent. Patient 1: *"I think it was okay, if there was 5 points, I would score 4 points, because I still needed to operate the real product. The functions of this MP were relatively comprehensive, and patients can choose the functions they were interested, which can meet the different needs of each user"*. Patient 2: *"All these functions and modules were good for patients, I felt they were all good, and the MP was easy to use, I can use it anytime"*. Caregiver 2: *"I felt it was comprehensive and quite good. It was better than I thought, it would be good if it was developed"*. Patient 5: *"I personally was quite satisfied, it was really quite good and well thought out, it should be quite practical after it hit the shelves"*.

## Theme 2 Perceived benefits of the MP

The testers all indicated that this MP meets the needs of home diet management and will have a beneficial effect on CKD diet management.

### Category1 Easy access to expertise

Most testers (7/10) reported that the MP provided support from several different perspectives and allowed easy access to reliable expertise. For example, Patient 1: *"I was usually too busy at work, the MP can be used anytime, I can take it out when I am free, I can listen to doctors' lectures, read other patients' postings, and learned more information about the disease"*.

Patient 2: *"I just heard from you that the reference materials for dietary knowledge would come from professional books, clinical guidelines, literatures, medical websites, and written by clinical professionals, which I thought is very scientific"*. Caregiver 3: *"I usually used my cell phone Baidu to look up some questions, but so much information on the Internet that sometimes we even got contradictory statements, but we didn't know how to identify the reliable information, this MP was developed by clinical professionals, and the content in it was more reliable"*.

### Category 2 Increase confidence in diet management

Most of the testers (9/10) said that they can get the information they need for diet management from this MP, which helps to control their diet better and makes them more willing to participate in diet management. For example, Patient 1: *"This helped me to pay more attention to my daily diet issues, so that I knew what I should eat and what I should eat less, this was helpful for me. The function of diet record was done in detail and can urge patients to establish dietary habits that met the requirements of the disease, I was interested in it"*. Caregiver 1: *"We didn't know the disease at all, and we didn't know what to eat and what not to eat. If I had this MP, I could use it as a reference, and the questions of how to eat would have answers"*.

### Category 3 Improve social support

A portion of testers (4/10) indicated that they could interact with other patients and doctors through the MP, where they perceived more social support. For example, Patient 4: *"I am a person who usually likes to post friends and share with people, so I can post some of my experience in diet management and hoped to help others"*. Patient 1: *"It was helpful to listen to lectures from doctors and read what patients share, because I learned more about this disease and that reduced my anxiety"*.

### Theme 3 Willingness to use the MP

Except for one elderly patient who expressed reluctance to use it, Patient 4: *“So long treatment has made me learned about diet management and I was able to control my diet by myself, it was not very helpful for me now. Also, for older people, this MP may not be that easy to promote.”* Other testers (9/10) said they would like to use this MP. Patient 1: *“I would like to use it, mainly in three functions: one was that I can read in the interactive community, because if I was not sure, I can read some postings that were issued by doctors and patients to get more comprehensive information about the disease, another was that I can record my daily diet. And another was that I was in the early stage of the disease, so I was interested in the food composition query, which was very helpful for my daily diet management, so I can know what was more reasonable to eat”*. Caregiver 1: *“I would use it, I felt that this MP was quite useful, and it was developed by clinical professionals, so I assured that it can help patients to better control the disease”*.

#### Theme 4 Shortcomings and suggestions for improvement

The MP can meet the needs of patients and caregivers to a certain extent. The testers recognized the MP as a useful tool, and thought it met their needs for home diet management, even better than they expected. Therefore, only a few suggestions for improvement were proposed, such as Patient 1: *“When reset the patient’s information, it was unnecessary to reset all the information, some data won’t change, such as height, gender, age that can be retained, only reset those changes to reduce the duplication of information filling, which was related to user experience”*. Caregiver 2: *“It would be better to add voice lookup when the technology was feasible”*. Caregiver 5: *“For me, I thought this was okay, but the interface and typography may need to be beautified, and some interfaces were too fancy”*.

### 2.3.4 Discussion

#### 2.3.4.1 Usability

The prototype evaluation provides references for optimizing the design by continuously digging into user needs and focusing on user experience to confirm the target users' acceptance of this MP. The results of the study showed that this designed MP meets the expected research purpose and meets the expectations of the target users (patients and caregivers), the interaction design is logical, no obvious usability defects, and the testers consider this MP is functional, ease to use, which is a practical home diet management tool.

#### *2.3.4.2 Shortcomings and suggestions for improvement*

The MP meets the patients' needs in home diet management to a certain extent, but something needs to be improved, mainly including the UI layout and colour matching need to be adjusted, and under the condition that the development technology is feasible, adding voice function to provide convenience for users will also expand the user group to a certain extent.

#### *2.3.4.3 Implication and recommendation for clinical practice*

The needs of diet management for patients at different treatment stages vary from one to another, and support depending on when the needs of diet management for patients occur. In the interviews, it was found that for patients and caregivers who were unaware of CKD diet, they indicated that the MP was very helpful and had a high willingness to use it. In contrast, for patients or caregivers with a long course of disease and regular follow-up in a nephrology-nutrition clinic, their need for the MP is lower. The portability of smartphones and the large number of WeChat users will facilitate the future promotion of the MP. In the future clinical promotion, it should focus on patients (and their caregivers) who are newly diagnosed and unclear about how to manage CKD diet and emphasize the scientific content source of the MP and update it timely manner. It is worth noting that older patients with good health literacy are also important potential users.

### **3 Conclusions**

#### **3.1 Research conclusions**

In this study, we adhere to the human-centred design concept, puts the needs and demands of patients and caregivers in the first place, and invites them to participate in the original design and prototype testing, and finally determines the modules and functions of this MP. This MP would assist CKD patients in home diet management, which including dietary knowledge, food nutrition query, diet record & nutrition monitoring, personalized diet advice and customized individual recipes, online nutrition guidance, communication channels for patient interaction, promoting family participation in diet management, and record various health data (blood pressure, blood sugar, weight, exercise) to facilitate the long-term management of CKD. We believe that this MP will have a positive effect on home diet management of CKD patients. Dietary management compliance is the key to dietetic-nutritional therapy for CKD, and self-efficacy is an important factor affecting their compliance. The results of the prototype evaluation indicated that the MP has got highly recognized among the target users and clinical professionals, the functions met the patients' requirements, and the testing experience was satisfactory, believing that the MP would motivate and urge patients to manage their diet and improve their confidence and effectiveness in home diet management.

#### **3.2 Research innovations**

The innovation of this study is to adhere to the human-centred design concept, take the needs of CKD patients and caregivers and the suggestions of clinical professionals as the starting point, and adapt and change the design to meet the needs of the target users, aiming to design a suitable and practical home diet management MP for CKD patients, which will provide a reference for future development. Also, this study tried to improve the quality of medical application, clinical usability and ensure the user experience, the prototype was developed before the real development, and conducted a prototype evaluation in medical research field.

#### **3.3 Research limitations**

There are three main limitations of this study. First, when interviewing stakeholders about the requirements for the MP, the sampling population of patients may not have met the expected maximum variability due to the significant reduction in patient traffic in foreign provinces due to the impact of the COVID-19 pandemic, which significantly reduced the flow of patients

from other provinces, with most patients originating from Shanghai and Jiangsu. Second, the prototype is not a real product, not many meaningful quantitative data can be collected; besides, the number of participants in the prototype testing is small, and the age and disease stage of patients are unevenly distributed, which may have an impact on the next design iteration of the MP. Third, because this study was not funded, so the cooperation with developers (technical staff) was insufficient, and it is recommended that a suitable IT development company should be actively sought for the real development of this MP in the future.

### **3.4 Research prospects**

For the direction of further future research, the MP is currently highly rated and expected by patients and caregivers, but the prototype is not really a product. In the future, after the MP is truly developed, further clinical usability testing is necessary; it is also necessary to include a large sample size to conduct intervention studies on clinical effectiveness and determine whether this MP can improve patients' dietary compliance, delay disease progression and improve patients' quality of survival, whether patients can adhere to its use, and to further explore its relationship with economic benefits and health care costs.



## **Research Ethics Statement**

The ethical review committee of the hospital where this study was conducted considered that this study did not involve interventions on the study subjects and therefore it is unnecessary to require an application for ethical review. Therefore, the researcher conducted the study with the permission of the head of the nephrology department of the collaborating hospital and the consent of the study subjects, explained the purpose, methods, possible benefits or risks of the study to the study subjects, and allowed them to terminate or withdraw from the study at any time, and that non-participation, termination or withdrawal from the study would not affect any of their interests, and signed the informed consent form. Commitment to code the obtained information anonymously and saved it carefully to ensure that the information is only for research purposes.

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## Appendixes

### Appendix 1 Interview outline on requirements analysis

#### 1. Patients and caregivers

①What are the dietary issues that you are more concerned about and would like to know?

What dietary knowledge do you think is important?

②Have you heard of WeChat Mini Program? Do you usually use Apps or Mini Programs to manage your diet? What do you think about using WeChat Mini Program to help you/family to manage diet at home? Would you like to use it?

③We are going to design a WeChat Mini Program for patients' diet self-management, do you have any suggestions or functional requirements for this Mini Program?

#### 2. Clinical professionals

① How do you think patients should self-manage their diet at home? What dietary information is important for patients/caregivers?

②What is your opinion on using WeChat Mini Program to assist CKD patients to self-manage their diet at home? Would you recommend such a WeChat Mini Program to patients/caregivers?

③What features do you think a home diet management WeChat Mini Program for CKD patients/caregivers should have? Do you have any suggestions or functional requirements for this Mini Program?

### Appendix 2 Informed consent of requirements analysis

Research name: Design and Prototype Evaluation of a Mini Program for Diet Management centered on patients with CKD

This informed consent form will provide you with information about this research. Please read it carefully. If you have any questions, you can ask the researcher, and the researcher will answer you in detail.

#### 1. Research purpose

The purpose of this study is to design a WeChat mini program to assist patients with chronic kidney disease to manage their diet at home. Thereby improving the clinical health outcomes and the quality of life. The aim of this qualitative interview is to identify your functional requirements or suggestions for this diet management platform, to help us better design this mini program and provide a reference for the actual development in the future.

## 2. Research method

The researcher will conduct a short interview with you in the room of the nephrology-nutrition joint outpatient or the doctors' office. The main content is about how to manage CKD diet; what suggestions or functional requirements about the diet management mini program which we will design, the time is about 30minutes. During the interview, the talk between you and the researcher will be recorded, and the researcher will also record the content of the interview in a notebook. Lastly, the researcher will organize the interview data and send it to you to check again.

## 3. Potential benefits

Participating in this study may not bring you direct benefits, but your participation will provide valuable suggestions on our design for diet management mini program, so that this mini program can better serve CKD patients in the future.

## 4. Potential risks

The audio recording and text material that you participated in this study will be safely preserved. The data is only used for this study and are only accessible by the research team. To protect your privacy, the researcher will code your information. When the result of this research is published in the future, your personal information will not be disclosed. This research is basically harmless. If you have any discomfort during the interview, you have the right to terminate the interview or refuse to answer at any time.

## 5. About withdrawing

You can choose not to participate in, or request to withdraw from this research at any time. The information obtained about you will no longer be included in this research, and any of your interests will not be affected.

If you have any questions about this research, you can directly contact the researcher.

Study participants

I have carefully read this informed consent form.

I can ask questions and all questions have been answered.

I understand that participation in this research is voluntary and unpaid.

My personally identifiable information will be kept strictly confidential.

I can choose not to participate in this study, or request to withdraw from this study at any time, and any of my interests will not be affected by my withdrawal.

The Informed Consent Form will be in duplicate, the researcher and I will keep one copy each.

Signature of participants:

Date:

### **Appendix 3 Expert Evaluation Form**

Dear expert:

Thank you very much for being the expert of this research, my research topic is Design and Prototype a Patient-centred Mini Program for Diet Management of CKD. The purpose is to design a professional and intelligent diet management tool for CKD patients to assist them better manage their diet at home, so as to improve their diet behaviours, and the compliance, effectiveness and safety of dietary nutrition therapy. Ultimately, to delay the progression of CKD, and improve clinical health outcomes, as well as to reduce the economic burden of patients and the national medical resources.

To design this mini program, firstly, we reviewed the clinical practice guidelines for nutrition in patients with CKD at home and abroad, to clarify the requirements of diet management for patients with CKD. Secondly, we carried out a market survey in App Store (Android and iOS) and WeChat, to investigate the existing apps or mini programs that related to diet management for CKD patients, to learn about their features, to ensure that our design is innovative. Thirdly, we conducted a qualitative interview to identify the requirements and suggestions from stakeholders, including patients with CKD stages 3-5 (those who received renal replacement therapy were excluded) and caregivers, doctors and nurses in the



department of nephrology and renal dietitians, to ensure that this mini program will meet the needs and desires of users.

At present, we finished this written design of this mini program (Kidney Disease Diet Bao). The purpose of this expert evaluation is to improve this design, so that it can provide comprehensive and professional services, to better assist CKD patients in the future.

This evaluation form consists of two parts, the first part is Information about expert, and the second part is Assessment Table of Kidney Disease Diet Bao. We guarantee the strict confidentiality of your information and feedback. Due to the time constraints of this study, you are kindly requested to provide feedback within 7 days.

### **Part one Basic Information about Experts**

Instructions: In the column of Judgment basis and degree of influence, please first self-evaluate the degree of influence of each judgment basis on your judgment (large, medium or small), and then tick in the corresponding column, and the degree of influence of each basis can only be ticked once. Each basis can only be marked with one tick.

Gender		Age			
Education		Professional title			
Working life		Professional field			
The following judgments are based on the degree of influence on your evaluation					
Judgment basis	Large	Medium	Small		
Practical experience					
Theoretical analysis					
Reference to domestic and foreign materials					
Intuition					
Your familiarity with the content of the evaluation					
Degree of familiarity	Very familiar	Familiar	Generally	Unfamiliar	Very unfamiliar
Expert self-assessment					

### **Part two Assessment table**

Instructions: This study will be rated on four dimensions: scientific, important, appropriate, and practical, using the Likert 5-point scale, i.e., 5=strongly agree, 4=agree, 3=fair, 2=disagree, and 1=strongly disagree. If you think the module or function is not needed or

inaccurate, please indicate it in the column of Suggestions; if you think there is something else, we have not considered, please add it in the column of Add, thank you very much!

Module assessment table

Modules	Description	Scientific	Important	Appropriate	Practical	Suggestions
		5,4,3,2,1	5,4,3,2,1	5,4,3,2,1	5,4,3,2,1	
A						
Add						

Function assessment table

Modules	Functions	Description	Scientific	Important	Appropriate	Practical	Suggestions
			5,4,3,2,1	5,4,3,2,1	5,4,3,2,1	5,4,3,2,1	
A	B						
Add							

#### Appendix 4 First round of expert feedback and feedback processing

Modules& Functions	Feedbacks	Processing
A1	1.Considering users' habits and needs, it was suggested to readjust the layout, and added the functional navigation. 2. The home page was the entrance to the main functions, and it should add more functions;	1 and 2, Accepted
A2	3.What was iCKD and what was the full name, it was suggested to rename it;	3, Accepted
A4	4. It was suggested to delete this module, because there are too many issues that need to be considered, such as backend support, supervision, logistics, etc. 5. It would be difficult to realize such a large shopping platform (such asTaobao and Pinduoduo) in this mini program. It was suggested to set up the shopping links, or goods list;	4, Unaccepted, because the life needs of users should be taken into consideration. 5, Accepted.
A	6.It was suggested to set up medical end;	6.Partially accepted, whether to add the medical end can be considered, when it will cooperate with different hospitals, which would like to set up their own unique medical end.
B2	7.The name of "Reading" was not very clear, and patients would not understand it;	7. Accepted
B3	8.This name was inaccurate and inconsistent with the description;	8. Accepted
B4	9. It was suggested that the backstage should set up the shielding function, and those inappropriate or irrelevant remarks would be prohibited;	9. Accepted

B6	<p>10. It was suggested to delete those nutrients that were not commonly deficient/excessive in CKD patients, and only listed some important nutrients for patients to read.</p> <p>11. The nutritional content of foods should be updated regularly.</p> <p>12. It was suggested to remove the marks of high-, medium-, and low-zone in sodium and water, because the content sodium and water in food were relatively low compared with salt and drinking water.</p> <p>13. It was suggested not to divide the content of protein into high/medium/low zone. Some foods were marked with high protein (&gt;10g/100g), e.g., eggs or meats were high-quality protein, which were suitable for CKD patients. On the contrary, some low-protein foods with low utilization rate marked with "green", which were not encouraged to be eaten by patients. Thus, the use of "traffic lights" to mark protein content would cause ambiguity.</p>	<p>10. Partially accepted, because it would display those nutritional content that users are more concerned about, and hide part of nutrients, so that users can read them if necessary.</p> <p>11, 12 and 13, Accepted</p>
B7	<p>14. It was suggested that users could be allowed to set up their target energy or protein intake by themselves. In case patients had other unconsidered medical conditions, such as surgery, trauma, cancer, and their goals of nutrition needs might be different.</p> <p>15. For some patients in need of special request, the recipe can be customized by consulting the back-end dietitian (paid). Conversely, the recommended recipe would be calculated according to the built-in formula.</p> <p>16. The recommended recipe was the food selected by the user, so it was necessary to prompt users to supplement complete, if there were missing important types of food.</p>	<p>15 and 16, Accepted.</p> <p>14. Unaccepted, it's unnecessary, because this group of patients is not the target users, and most CKD patients (and their families) are not aware of their target nutrition intake.</p>
B8	<p>17. Dietitians should regularly evaluate users' diet and interact with them, to enhance the enthusiasm of users.</p> <p>18. Live dietitians should participate in giving individual dietary advice, to do this all by AI was not feasible.</p>	<p>17 and 18, Accepted</p>
B9	<p>19. Cooking methods should be provided to choose from, it is too general if they were remarked by the patient themselves.</p> <p>20. The hospital examination record was not directly related to the purpose of this mini program, and the privacy of patients were involved, so it is suggested to delete.</p> <p>21. For patients with abnormal blood pressure, did not recommend them to take specific drugs, and just advised the patient to take their prescribed drug.</p> <p>22. For patients with abnormal blood pressure/ blood sugar, it did not pertain to you to instruct them to take drugs, and patients can be advised to visit hospitals in time.</p> <p>23. The suggested processing of glucopenia was: drink sugar water as soon as possible (15-20g white sugar, 150-200ml juice/soda), and re-test blood sugar after 15 minutes. If it still was &lt;4mmol/L, repeat the above, if it was <math>\geq 4.0</math>mmol/L, and within 30 minutes was time to have a meal, they should normally eat the meal; if it was not the time to have a meal, should eat another 3</p>	<p>19, 20, 21, 22 and 24, Accepted.</p> <p>23. Partially accepted, patients are not recommended to eat specific food, they can eat any accessible sugary foods.</p> <p>25. Unaccepted, because It is not directly related to the purpose of this mini program, and the data of users' medication history would be useless.</p>

	<p>biscuits / 1 slice of bread / 0.5 liang of steamed bread (about 40g);</p> <p>24. Whether patients would be willing to manually input health data, when to enter, whether the hypotension / hypoglycaemia reminder was still timely, it was suggested to add the interface to upload Bluetooth data.</p> <p>25. It was suggested to add medication record (such as hypotension, hypoglycaemic drugs);</p>	
B11	<p>26. Even if providing the videos to teach users about anthropometric measurements, it was difficult to ensure that the patient would measure correctly, and it should be measured by clinical professionals.</p> <p>27. It wasn't suitable for patients to use Subjective Global Assessment (SGA), it is possible to do nutrition risk screening by using Malnutrition Universal Screening Tool (MUST) or Nutritional Risk Screening 2002 (NRS2002). If there was a risk of malnutrition, suggesting patients to visit a nutrition department;</p>	26 and 27, Accepted
B12	<p>28. It was impractical for clinical professionals to answer patients for free.</p> <p>29. Similar questions could be uniformly answered;</p>	28 and 29, Accepted
B13	<p>30. The rights and interests of both doctors and patients cannot be protected, and it was difficult to guarantee the qualifications of the healthcare providers who were to enter this platform. So, it was suggested to delete.</p> <p>31. Online medical visits can only be carried out in Internet hospitals, and there were strict approvals and supervisions, this mini program wasn't suitable.</p>	31 and 32, Unaccepted, considering the high popularity of Internet and mobile phones in China, as well as the impact of Covid-19, online telemedicine for users in remote areas is convenient to follow-up and prescribe drugs and get access to excellent medical resources. For the source of healthcare providers, by cooperation with hospitals across the country, and if this mini program can be well promoted in the future, which absolutely can attract excellent medical resources. Moreover, there are already Internet hospital that based on mini programs on the market. Therefore, if it will adhere strictly to Management Measures for Internet Diagnosis and Treatment, which was issued by the national policy, the online consultation in this mini program can be realizable.
B15	<p>32. This mini program was to popularize science diet, patient-patient communication was unnecessary;</p>	32. Unaccepted, because patients cannot always access to free medical resources (for example, doctors can answer questions for free), the interaction among patients is necessary,

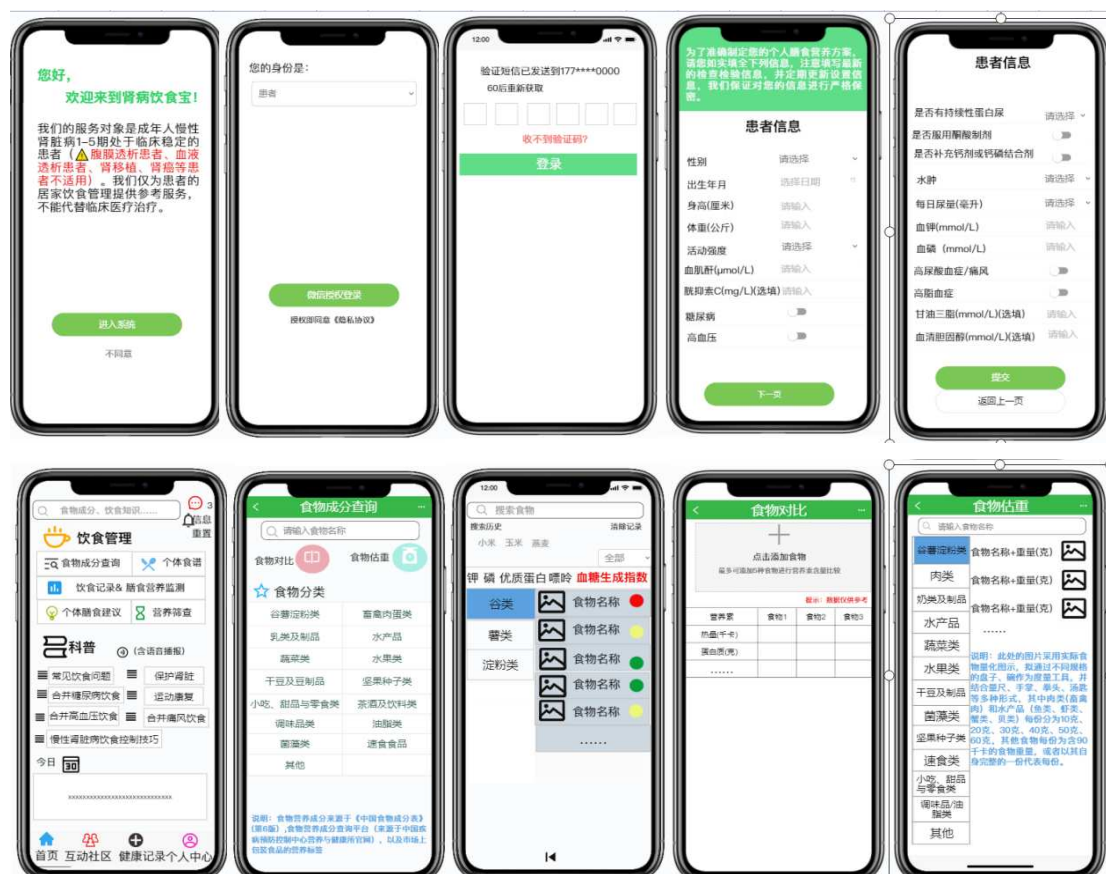
		which is to increase the confidence in treatment, and to enhance social engagement. For patients with chronic diseases, is beneficial to the physical and mental health.
B16	33. It was suggested not to sell medicines. 34. It was suggested to ensure the authenticity of the products, and indicate that they were not sales promotion;	33.Unaccepted, because CKD patients need to take medication for long time, and drugs can already be purchased through online platforms on the market. 34, Accepted;
B20	35.It was suggested not to collect too much irrelevant personal information, such as native place. 36.It was suggested to add the medical history;	35, Accepted. 36.Unaccepted, because the medication history is of no practical use in this mini program;
B22	37. The users needed to set the reminder by themselves, which was unnecessary, and it was suggested to delete;	37, Accepted
Others	38. These functions of this mini program should be as simplified as possible;	38, Accepted

### Appendix 5 Second round of expert feedback and feedback processing

Modules & Functions	Feedbacks	Processing
B2	<p>1. It was suggested to merge Diet Record and Dietary Nutrition Monitoring together and guided the user to record their diets if the user entered Dietary Nutrition Monitoring.</p> <p>2. Patients may not be able to choose the correct type of foods on their own. To consider let them choose from a series of foods automatically recommended by the system based on the results of Dietary Nutrition Monitoring and their dietary preferences.</p> <p>3. The effectiveness and accuracy of Dietary Survey need to be confirmed by clinical research, rather than be calculated directly using food database. Because it only provided extremely rough report and cannot generate meaningful report, it was suggested to delete, and their dietary intake can be assessed through Diet Record to know.</p> <p>4.To consider setting Personalized Recipes and Diet Record as private and paid function, since they were the core functions.</p>	<p>1, 2 and 3, Accepted.</p> <p>4. Unaccepted, because Personalized Recipes and Diet Record are the core functions of this MP, and they are what CKD patients and their families needed. If they are paid, it will overwhelmingly reduce the attraction of this MP for users.</p>
B5	5. Doctor-patient interaction was important, but the interaction of patients was difficult to produce key Opinion leader, and it is necessary to promote their activity.	5. Accepted

B6	<p>6. It is unsuited for a MP to execute online medical visits, which are generally carried out by hospitals.</p> <p>7. It was not easy to realize medical visits, we need to carefully evaluate patient's condition and to prescribe individualized diet plan.</p>	<p>6 and 7, Partially accepted, the interaction between doctors and patients is important and necessary, so we still decided to strictly follow Internet Diagnosis and Treatment Management Measures in China and invite qualified clinical professionals to enter this platform. Online medical visits will be replaced by online message, and the settled clinical professionals will reply regularly.</p>
B15	<p>8. It was suggested to identify user identity (such as patients, family members or clinical professionals), which may improve the transparency of information in this MP.</p>	<p>8. Accepted.</p>

## Appendix 6 Screenshots of the prototype interface

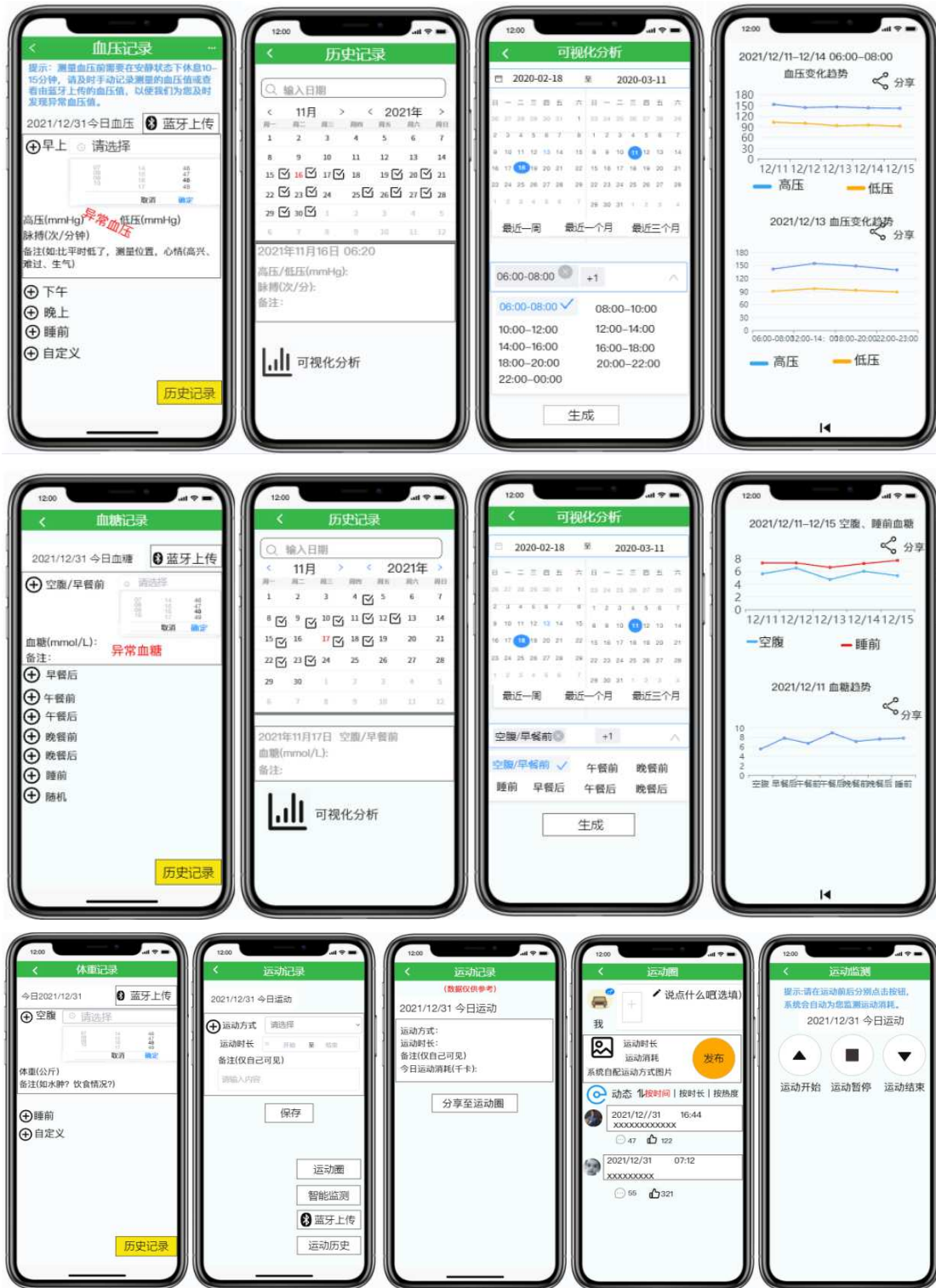


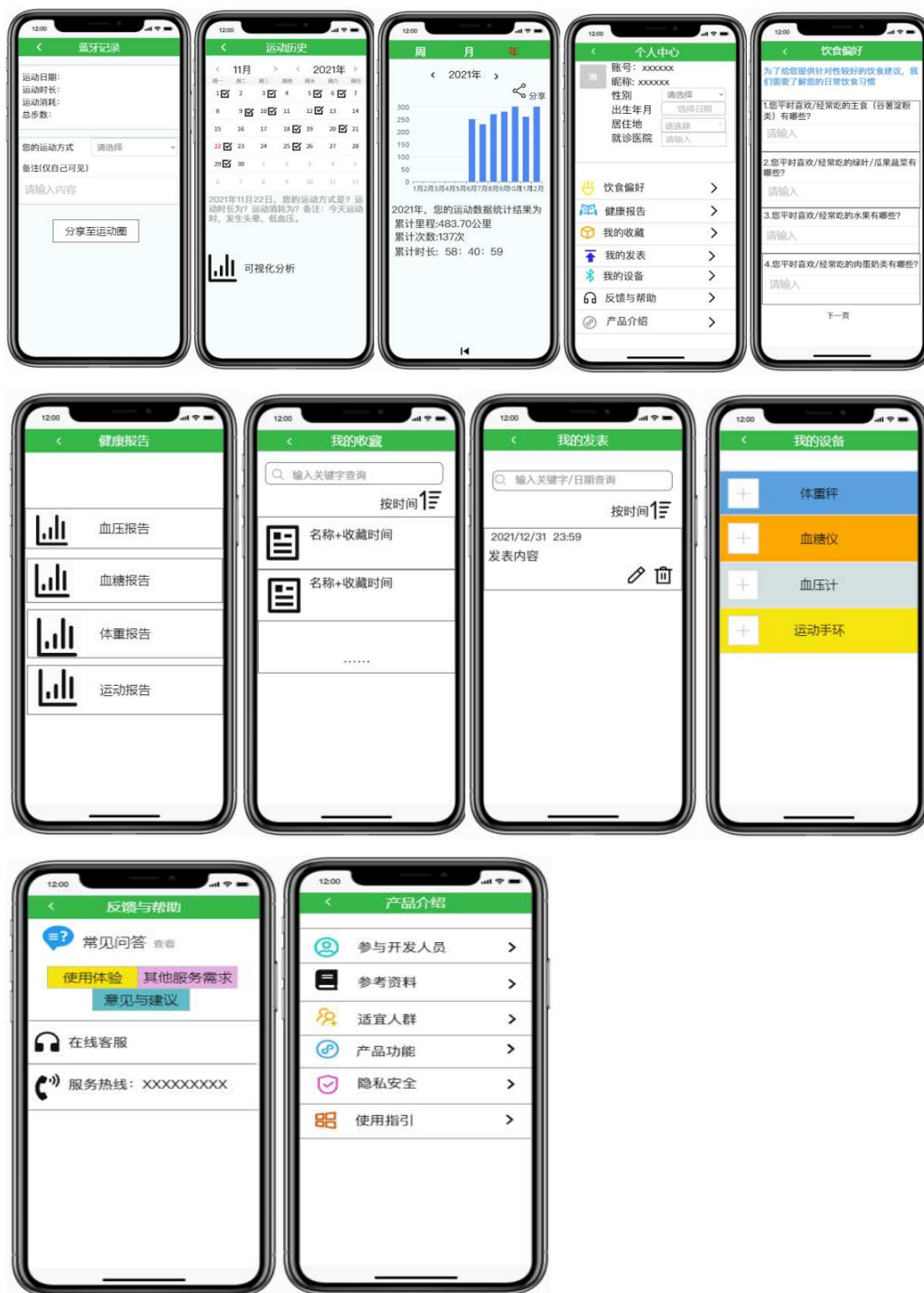












## Appendix 7 mHealth App Usability Questionnaire (MAUQ) for Interactive mHealth Apps Used by Patients

In this questionnaire, 1=strongly agree, 2=agree, 3=somewhat agree, 4=neither agree nor disagree, 5=somewhat disagree, 6=disagree, 7=strongly disagree

statements	1	2	3	4	5	6	7
1. The prototype was easy to use							
2. It was easy for me to learn to use the prototype							
3. I like the interface of the prototype							
4. The information in the prototype was well organized, so I could easily find the information I needed							
5. I feel comfortable using this prototype in social settings.							
6. The amount of time involved in using this prototype has been fitting for me							
7. I would use this prototype again							
8. Overall, I am satisfied with this prototype							
9. Whenever I made a mistake using the prototype, I could recover easily and quickly							
10. This mHealth prototype provided an acceptable way to receive health care services							
11. The prototype adequately acknowledged and provided information to let me know the progress of my action							
12. The navigation was consistent when moving between screens							
13. The interface of the prototype allowed me to use all the functions (such as entering information, responding to reminders, viewing information) offered by the prototype							
14. This prototype has all the functions and capabilities I expected it to have							
15. The prototype would be useful for my/family's health and well-being							
16. The prototype improved my access to healthcare services							

17. The prototype helped me manage my/family's health effectively							
18. The prototype made it convenient for me to communicate with my healthcare provider							
19. Using the prototype, I had many more opportunities to interact with my healthcare provider							
20. I felt confident that any information I sent to my provider using the prototype would be received							
21. I felt comfortable communicating with my healthcare provider using the prototype							

### **Appendix 8 Informed consent of prototype evaluation**

Dear Patients/Caregivers,

To better help you or your family in home diet management, you are invited to evaluate a prototype of our preliminary design, which named as Kidney Disease Diet Bao. We sincerely hope to receive your support and valuable comments! Participation in this research is voluntary, therefore you will not be paid, and you may choose to participate or not to participate. To ensure that your interests are not harmed, please read the following carefully:

1. The prototype will be provided by the researcher, and you will operate it on the researcher's iPad. You are required to express all your thoughts/feelings during the experience at any time.
2. After you experience the prototype, the researcher will conduct a recorded interview with you for 15-30 minutes. The purpose of the interview is to understand your feelings and the satisfaction of this mini program, and the shortcomings and suggestions for improvement.
3. After the interview, you are required to fill in a questionnaire, which takes 5-10 minutes.
4. We assure that this research will not involve your name and will not reveal your personal privacy. After confirming that the data analysis is completed, it will be sealed to ensure that your information will not be leaked.

Sincerely thank you for your support and help!

If you are aware of the above and agree to participate in this study, please sign your name below.

I have read and clearly understood the above, and I voluntarily and agree to participate in this study.

Signature of participant:

Date:

## **Acknowledgements**

My postgraduate study is coming to an end. Looking back on these two years, firstly, I thank my supervisors for their patience to equip me to be here. Secondly, to all those who helped me with kindness, you know who you are, at the risk of leaving anyone out, I can only say thank you. Finally, I thank my families and myself, thank you for your support and love, as well as my own hard-working.