Glycemic Control Using Mobile-based Intervention in Patients with Diabetes Undergoing Coronary Artery Bypass – Study Protocol for A Randomized Controlled Trial

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Abstract

Background

Applying technology through the use of the Internet and mobile phones can help provide education and trained peer support for patients with diabetes after coronary artery bypass (CABG). We are conducting randomized controlled trial to evaluate the efficacy and feasibility of mobile-based coaching intervention in improving risk-factor control and secondary prevention in patients with diabetes after CABG.

Methods

The Glycemic control Using miniprogram-based Intervention in patients with Diabetes undergoing coronary artery bypass to promote self-management (GUIDE ME) Study is a multi-center, randomized controlled trial of mobile intervention versus standard treatment with 6 months follow-up conducted in 2 hospitals in China. The interventions are education and reminder system based on Wechat mini-program. Participants in the intervention groups receive 180 videos (including lines) about secondary prevention education for 6 months as well as the standard treatment. Behavioural change techniques, such as prompting barrier identification, motivational skills, goal setting are employed. A total sample size of 820 patients would be adequate for the GUIDE ME study. The primary outcome is the change of glycemic haemoglobin (HbA_{1c}) at 6 months. Secondary outcomes include a change in the proportions of patients achieving HbA_{1c}, fasting blood glucose, systolic blood pressure, low-density lipoprotein cholesterol (LDL-C) and medication adherence.

Discussion

This trial is the first to investigate the efficacy of mobile phone Wechat-based video coaching and medication reminder mini-program system to improve self-management in patients with diabetes and coronary heart disease (CHD) after CABG and have the potential to be applied in resource-limited setting across diverse populations. If successful, such mobile intervention could be used and scaled up to improve care for this high-risk group of patients.

Trial registration:

ClinicalTrials, NCT 04192409. Registered December 10, 2019.
https://clinicaltrials.gov/ct2/show/study/NCT04192409?cond=NCT+04192409&draw=2&rank=1

Background

Diabetes mellitus (DM) is associated with increased mortality and morbidity in patients undergoing coronary artery bypass grafting (CABG) specifically[1]. It is recommended that secondary prevention including long-term glucose control should ideally be optimized for this high-risk group of patients[1]. In low- and middle-income countries (LIMCs), including China, only one-third of individuals nationwide have adequate glycemic control and over two-thirds of patients with coronary artery disease (CHD) take no medication[2 3]. CABG patients with DM should receive coordinated medical care from a diabetes mellitus monitoring team. However, it is difficult to generalize and implement such interventions of patient-centered care given that limited access to education, consultation and high costs of organization[4]. Given that the high-risk profile of this subgroup among CHD patients, cost-effective and scalable interventions to enhance secondary prevention are urgently needed.

Applying technology through the use of the Internet and mobile phones can help provide education and trained peer support for patients after CABG, even for those who are unable to access cardiac rehabilitation because of geographic barriers[1]. As of August 2016, China had the largest number of mobile phone owners in the world. Wechat had become the most popular messaging communication app in China, which had a monthly-active-user of 549 million[5]. As such, Wechat has the potential to be a scalable and powerful tool to deliver health information.

There are thousands of mobile applications for supporting diabetes mellitus self-management, serving primarily as tracking and reference apps. In fact, <1% of mobile applications have been evaluated through research and even fewer have demonstrated outcomes[6]. Prior studies showed inconsistent results. Evidence indicated that most trials to date have been designed to target a single condition and have not been based on behavioural change techniques (BCTs). Most of studies were limited to single-center studies and were underpowered[6 7]. Thus, issues remain about the authentic role of mobile health. Most importantly, none of studies specifically enrolled diabetic patients who had undergone CABG which are regarded as high-risk populations and usually manage multiple conditions, requiring several lifestyle and treatment recommendations[1].

Given the public health significance of poor diabetes management, high-risk profile in patients with concomitant diabetes after CABG and problems with previous studies, we designed and conducted the Glycemic control Using miniprogram-based Intervention in patients with Diabetes undergoing coronary artery bypass to promote self-management (GUIDE ME) Study (NCT04192409). The primary objective of this study is to evaluate the efficacy and feasibility of mobile-based coaching intervention, based on BCTs, in improving risk-factor control and secondary prevention in this high-risk group of patients.

Methods

Study overview

The ongoing GUIDEME study is a multi-center randomized controlled trial of an automated mobile phone miniprogram-based intervention with 6 months of follow-up. We hypothesize that education and medication reminder for patients can help reduction of A1c over 6 months. This RCT was registered at http://www.clinicaltrials.gov (NCT 04192409). The central ethics committee of Fuwai Hospital approved the study (No.2019-1151, June 2019). The recruitment and the last follow-up are expected to finish in June 2022 and December 2022, respectively. All participants provided written informed consent at the initial trial visit.

Patient and public involvement

No patient involved.

Inclusion and exclusion criteria

Patients must meet all of the following criteria to be recruited for the study: 1) Type 2 diabetes diagnosed by a physician prior to study enrollment; 2) documented coronary artery disease and isolated coronary artery bypass is recommended and performed; 3) access to a mobile phone with Wechat and ability to operate on the miniprogram. Patients are excluded if they could not read the materials, had cognitive or communication disorders, unable to provide informed consent or die before discharge.

Patient recruitment

We identify patients in the surgical ward who have been hospitalized with CHD and DM and who have undergone coronary artery bypass. The diagnoses of CHD and DM and the indication for surgical revascularization are adjudicated centrally, based on reviews of the patients' medical charts. Once identified, study staff explained the study face-to-face and that they may be eligible to participate. A 'screening log' of basic demographic information and reasons for not participating in patients deemed ineligible or declined to participate has been recorded. Individual patient signature informed consent is obtained by the China National for Cardiovascular Disease independent of clinical office involvement.

Based on previous experience[8], we estimated that surgical practice would provide an average of 1300 patients with CHD and DM undergoing CABG in Beijing Fuwai Hospital annually and 100 patients in Qingdao Fuwai Hospital.

Randomisation and blinding

Participants were randomly allocated to enter the intervention or the control arm in a 1:1 ratio using a computerized randomization system. In order to achieve a balance of participants' characteristics in both arms, a stratified randomization approach is employed, based on age, gender, education degree, acute myocardial infarction history and medical insurance type. Statisticians and clinic staff are blinded to treatment allocation.

Trial intervention

The interventions are education and reminder system for patients with CHD and DM, using mobile phone to allow transmission (Figure 1). Participants in the intervention groups receive video (including lines) about CHD and diabetes risk modification education for 6 months as well as the standard treatment. The control group receive standard treatment without risk factor modification support. All patients in the intervention groups receive the study treatment mobile phone mini-program software which is anchored in Wechat (Figure 2). A training session is held by the research staff on enrollment that participants in the intervention group are registered in the system so that they have access to the web-based individual patient portal and they are capable of receiving and reading system-driven coaching video material. In addition, participants in the intervention receive medication regimen reminder. Prior to commencement, the system is tested to confirm functioning effectively. Researchers at the China National for Cardiovascular Disease could monitor the visiting frequency of the system. Participants are also informed that they could withdraw from the study by sending text messages to the research staff. Outbound patient phone calls by the research staff are discouraged.

Intervention development

A cluster of 180 videos were developed by a multidisciplinary team of cardiac surgeons, cardiologists, endocrinologists, psychologists, nurses and public health researchers using a two-phase systemic and iterative approach. Coaching videos cover a range of secondary prevention after coronary artery bypass graft surgery in addition to diabetes self-management topics based on current guidelines[19–13] including: (1) general education on CHD and DM, (2) postoperative antiplatelet agents; (3) lipid-lowering therapy; (4) b-Blocker Therapy; (5) glucose monitoring and control, (6) blood pressure control, (7) smoking cessation; (8) cardiac rehabilitation; (9) lifestyle recommendations such as weight loss, physical activity, diet. Other self-care behaviors including monitoring, self-management problem solving, reducing risks and healthy coping are considered as essential bahaviors for improving diabetes mellitus self-management and incorporated into video development accordingly[1415]. All videos are in Chinese and are less than 2 minutes. The captions of the videos are affiliated and are also developed into text.

Phase I: Developing videos

Lines of the coaching videos were originally drafted in Chinese based on current guidelines. BCTs were employed to develop short videos including goal setting, providing information on consequences of behavior, self-monitoring, barrier identification and social support[1617]. Table 1 illustrates the BCTs used in the lines of short videos. Videos were developed in form of lectures or dialogues in order to make them more acceptable to patients and compatible with Chinese beliefs and values[18]. Lectures began with a question regarding to the subject and are followed by the response. Videos of dialogue were made in the setting of real-world examples instead of abstract theories[19]. These videos were sent to experts in BCTs and subsequently reviewed, criticized and revised within the research team.

Table 1
Behaviour change technique used in video development

Behavior change technique	Content/explanation	Examples lines of video in English
Provide information about behaviour-health risk	General information about behavioural risk	Aspirin should be continued indefinitely to reduce graft occlusion and adverse cardiac events. In order to convey the most benefit of CABG to you, taking medications regularly.
Provide instruction	Tell the person how to perform a behavior and/or preparatory behaviors	Smoking cessation is critical. Electronic cigarettes (e-cigarettes) have not been demonstrated to improve cessation rates and important concerns has been raised about their potential for adverse health effects. However, nicotine replacement therapy, such as bupropion and varenicline as adjuncts to smoking cessation for stable CABG patients after discharge is reasonable. And you can try this method!
Prompt barrier identification	Identify barriers to perform the behavior and plan ways of overcoming them	b-blockers are often associated with side effects such as weight gain, fatigue, and sexual dysfunction. You may feel upset about this and are reluctant to take it regularly. But if you have hypertention, a history of myocardial infarction or a history of heart failure, keep taking it regularly as this is good for your body. We will remind you to take this medication through mini-program. And you can also set a repeating alarm on your cellphone.
Prompt self-monitoring of behavior	The person is asked to keep a record of specified behavior	Meals, exercise, cold and diarrhoea will make your blood sugar levels fluctuate. Thus, you should perform self-monitoring of blood glucose (SMBG) prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise and prior to critical tasks such as driving. You may as well upload this data through the mini-program. In addition, perform the A1C test three months and six months after surgery even if you have stable glycemic control. Striving to achieve an HbA_{1c} is a reasonable goal for most patients after CABG.
Set graded tasks	Set easy tasks, and increase difficulty until target behavior is reached	Have you ever felt hard to take medicine regularly? All things are difficult before they are easy. However, our mini-program system will help you. You can enter your medication and the system will automatically generate the ratings according to your medication adherence performance. More star you get, more benefit you will gain. Move on to get the most stars and it will make a great difference in the future!

Behavior change technique	Content/explanation	Examples lines of video in English
Plan social support or social change	Prompt consideration of how others could change their behavior to offer the person help or (instrumental) social support	Symptoms of hypoglycemia include, but are not limited to shakiness, irritability, confusion, tachycardia, and hunger. Tell your friends and family when you have the symptoms above so that they give you the glucose (15-20g). Fifteen minutes after treatment, if SMBG shows continued hypoglycemia, the treatment should be repeated. Once SMBG returns to normal, the individual should consume a meal or snack. The family members should know where the glucagon is and how to administer it in case of blood glucose <54 mg/dL.
Stress management	May involve a variety of specific techniques (eg. Progressive relaxation) that do not target the behavior but seek to reduce anxiety and stress	Relaxation is something we need to learn and practice. Listening to music, reading or talking to friends and family can ease stress.
Motivational interviewing	Prompt the person to provide self-motivating statements and evaluations of their own behaviors to minimize resistance to change	Does your A1C decrease in value three months after CABG? If so, it is something worth celebrating. We are sure that you have put a lot of effort into taking medications and lifestyle modification. Keep up the good work and you can make a difference. If A1C remains less than 7%, it is supposed that you achieve the target of glycemic control. However, less stringent A1C goals (such as <8%) may be appropriate according to recent guidelines. Thus, glycemic target must be individualized to the needs of each patient and his or her disease factor.

Phase II: Expert review

The 180 videos were reviewed with a different focus by an expert panel consisting of clinicians and academics in the field of cardiology, endocrinology, epidemiology, psychology and linguistics. First, the clarity, accuracy and feasibility of each video was checked and verified. Second, linguists reviewed all videos and focus on the acceptability and readability of the video education material. Issues regarding to videos were addressed and the corresponding education videos were shoot again in order to achieve the desired target which the expert panel had proposed.

Frequency and timing of education video delivery

180 coaching videos in total were push forward to the participants in the intervention group across a 6-month timeframe. The videos were sent to the participant portal every 2 days in the morning. The theme of coaching video covers a range of recommendations from the recent guidelines. Participants in the intervention group will receive the update text message and log into the Wechat-based miniprogram to read the updated educational video material. Initially, only one education video is available. To evaluate the engagement in the miniprogram system, participants are required to finish the question at the end of

every video, “Do you think that the information is easy to understand? Do you think that information is useful?”. The logbook data are analyzed at the completion of the study intervention. Through the 6-month follow-up, research staff call participants if they do not finish the questions for two consecutive weeks and only one call is made per patient during the intervention period, so as not to confound the intervention. Patient communication is delivered by automated feedback on the mobile phone Wechat-affiliated miniprogram and messaging through the message center in the patient web portal.

Data collection and management

Patient characteristics are collected from self-reported interviews with trained research staff and medical chart reviews including basic information, baseline clinical variables, biochemistry information, coronary angiography, echocardiographic outcomes, diabetes-related variables, surgical details, postoperative complication and socioeconomic status (Supplementary materials).

Additional assessments of baseline medication adherence, health status (EuroQol five-dimensional questionnaire: EQ-5D) are also conducted in person[20]. Biochemistry test will be analysed at the central laboratory. The process of recruitment is monitored and data collection is checked by trained staff from China National for Cardiovascular Disease to improve the quality control.

A specialized software platform was established by the Information Technology team for use in sending coaching video materials to participants and also recording responses. In addition, project progress can be supervised and 24-hour management support is provided through this web-based platform. Predesigned onscreen case report form is entered by two staff members independently, and data are then securely transmitted to the central server through automatic electronic transfer. Continuous checks are run to ensure that data being entered are complete and meet predefined data formats and ranges to ensure the reliability and validity of the data. The database is regularly backed up and password protected so that only a limited number of approved staff members can access the data. Data confidentiality policies of NCCD on data collection, storage and analysis have been strictly imposed to ensure the confidentiality.

Outcomes

The primary outcome is the change in glycaemic HbA_{1c} by the central blood sample. Secondary outcomes include blood pressure, blood glucose, low density lipoprotein, a change in proportion of patients achieving HbA_{1c}<7% of patients, graft patency, major adverse cerebrovascular and cardiovascular events (MACCEs), change in medication adherence, mini-program behavior adherence, changes in antihyperglycemic medications during the intervention and health status (EQ-5D). MACCEs include death, non-fatal myocardial infarction, stroke and any repeated revascularization and cardiac rehospitalizations. HbA_{1c} is determined using a high-performance liquid chromatography technique with ADAMS A_{1c}HA-8180 (ARKRAY, Japan). Graft outcomes are assessed by multislice computed tomographic angiography (MSCTA) or catheter coronary angiogram (CAB) at 6 months after coronary artery bypass grafting. The examinations are conducted according to standardized radiology and

cardiology procedures. Digital images from a ≥64-slice CT scanner are analyzed with software (Intellispace portal Version 6.0, Phillips Healthcare). Members of the independent Image Data Review Centre reviewed the images and adjudicated the patency of the grafts blinded to treatment assignments.

Graft patency is defined according to FitzGibbon criteria[21]. In our trial, graft patency is defined as FitzGibbon grade A[22 23]. Quality of life is measured using the short version of EQ-5D.

The institutional follow-up protocol requires that patients who are discharged alive visit our outpatient clinic three and six months after coronary artery bypass graft. If adverse events are reported, the patient medical records in the outpatient clinic were checked cautiously. When the patients visited another hospital, they are asked to send copies of their medical records by mail. If the patient dies at home without any evidentiary material, a structured summary of death conversation with family members would be reported. All information is sent to NCCD for central adjudication according to prespecified criteria by trained clinicians.

Statistical analysis

All analysis will be conducted according to the intention-to-treat principle. Baseline patient characteristics are represented as the means with standard deviations (SDs) for continuous variables and proportions for categorical variables. The primary analysis used analysis of covariance. For categorical secondary outcomes, log-binomial regression is used to compare groups and calculate relative risk of outcomes at 6 months (ie, proportions of patients achieving HbA_{1c}<7.0%). A generalized estimating equation model including terms for treatment is used to estimate between-group difference in graft patency and 95% confidence intervals (CIs). For the (time-to-event) secondary outcomes, hazard ratios (HRs) and corresponding 95% CIs are determined with Cox proportional hazards regression analysis. Kaplan-Meier curves are used to depict the occurrence of secondary outcomes over time. Follow-up of event-free patients with incomplete follow-up will be censored at the last clinical contact. Additionally, we performed prespecified subgroup analyses of outcomes by age (<60 and ≥ years), sex (male and female), area (urban and rural), education (≤12 and >12 years) and tertile of baseline HbA_{1c}. Subgroup results are presented as mean differences with 95% CIs. All tests of significance are 2 tailed, with an a of 0.05.

We estimate that a sample size of 820 would provide 80% power at the 5% significance level to detect a 0.3% absolute difference in HbA_{1c} change in the intervention group at 6 months, compared with the control group, assuming a mean HbA_{1c} level of 7.0% at baseline (SD 1.4%) based on data from studies involving similar populations[24], using PASS, version 11.0 (NCSS, Kaysville, UT), for sample size calculation. This sample size allowed for a 20% loss to follow-up during the study period. We used the SPIRIT checklist when writing our report[25].

Discussion

The GUIDEME Study aims to assess the efficacy of an innovative intervention for improving secondary prevention by using mobile-based video-coaching miniprogram among patients with diabetes and CHD

after coronary artery bypass in China. To the best of our knowledge, this is the first to investigate the efficacy of video coaching and medication reminder system to improve self-management in a high-risk group of patients with diabetes and CHD undergoing coronary artery bypass and have the potential to be applied in resource-limited setting across diverse populations.

The GUIDEME study has several strengths. Up till now, there is a paucity of large RCTs of mobile diabetes mellitus management. With regard to smaller studies, the type of mobile technologies used for diabetes mellitus self-management research interventions include mobile platforms with diabetes mellitus-specific software apps or short message service[6]. Meta-analysis showed that mobile phone interventions significantly reduced HbA_{1c} by a mean of 0.5% over a median follow-up of 6 months[26]. However, most clinical trials examined change in HbA_{1c} during a 3-month intervention and it may be inaccurate to assume that a significant change in HbA_{1c} in the intervention group is attributable to technology instead of other nonspecific benefits of participants considering a report from a 2011 survey that 26% of downloaded health apps are used only once and 74% are abandoned by the 10th use[27]. In view of shortcomings of software apps or short message service above, our study employ video coaching approach based on Wechat miniprogram. Wechat is the most popular social media platform in mainland China, with over 1 billion active users[28]. Patients place more value on health service delivery and intervention program using Wechat has been effectively applied in a range of clinical settings[29–32]. Considering the fact that our patient population are more of older adults and the majority of adults prefer learning by following directive rules and guidelines[33], patient education and management in form of video is prioritized instead of text message or software apps. This has the potential to improve system adherence.

Our study is further distinguished by management of multiple risk factors. Prior studies evaluated the effectiveness of mobile computing and communication technologies among patients with one risk factor. Few studies focus on high-risk populations. In addition, the efficacy of mobile technology in the management of multiple risk factors has not been fully explored, which is a reality for many patients. One such group of patients pertains to diabetic patients undergoing coronary artery bypass who carry a high-risk profile. It is emphasized that such group of patients require multifaceted strategies[34]. In addition, patient-centred cognitive behavioural strategies are recommended to help patients achieve lifestyle changes and practice self-management[34]. Thus, targeting multiple risk factors using mobile technology hold the promise for achieving this purpose. More importantly, lack of evidence exists pertaining to the effectiveness of mobile intervention in high-risk of patients with concomitant diabetes and coronary artery disease requiring surgical revascularization.

Furthermore, the content of coaching video in our study is theory-driven and culturally sensitive. It evaluates a coaching system using mobiles phones to deliver treatment recommendations and behavior support based on evidence-based guidelines. Two systematic reviews concluded that interventions were more likely to be successful if they selected and combined theory-based behavior change strategies[3536]. However, very few studies specified a theoretical rationale on this specific population. The GUIDEME

study is further distinguished by the large sample size and multicenter research. The study enrolls patients from a range of geographically diverse country which will reflect the real-world practice across China.

Several limitations need to be acknowledged. First, patients with vision or touch disability or those who have no access to mobile technologies are excluded from our study which leads to selection bias. However, our study aims to assess the efficacy of mobile technology. When the efficacy is justified, measures will be taken to meet the needs of specific population groups above. Second, behavior factors are not included in the study that may influence the initial engagement and ongoing use of mobile technology and its associated impact on outcomes. And medication adherence is measured by self-report which carries the possibility of recall bias and social desirability bias. However, we believe that any such factors would be balanced across the treatment and control groups.

The GUIDEME study has paramount public health implications. Patients with diabetes and coronary artery disease requiring surgical revascularization are at high risk for mortality and major vascular events. Provider coaching and reminders are associated with improvement in adherence to guidelines and with clinically significant improvements in patient outcomes[37]. The widespread distribution of mobile phones, across China, combined with their unique ability to process and communicate data in real-time, make them an ideal platform to create simple and effective diabetes management programs. The GUIDEME study may serve as important models for evidence-based public health interventions and could convey benefit to a diverse population in China.

Conclusion

The on-going GUIDEME study is a multicentre, randomized controlled trials and will testify the efficacy of mobile coaching and reminder intervention to improve secondary prevention in patients with diabetes and coronary artery disease requiring surgical revascularization in China. If successful, such mobile intervention could be used and scaled up to improve care for this high-risk group of patients.

Abbreviations

CAB Gcoronary artery bypass grafting

CHD coronary artery disease

DM diabetes mellitus

LIMCs low- and middle-income countries

glycemic haemoglobin HbA_{1c}

Declarations

Ethics approval and consent to participate

The ethics committee of Fuwai Hospital approved the GUIDEME study (No.2019-1151, June 2019). Written, informed consent to participate will be obtained from all participants.

Consent for publication

We are willing to provide a model consent form on request.

Availability of data and materials

The data and statistical code are not available to be shared at this time as no datasets are analysed during the current study.

Competing interests

The authors declare that they have no competing interests.

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Author contributions

Wei Feng is the Chief Investigator. Dr. Feng conceived the study, led the proposal and protocol development.Yangwu Song and Yifeng Nan contributed to study design and to development of the proposal. All authors read and approved the final manuscript.

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Not applicable.

Trial status

Protocol version number 1. Date: October 5 of 2021. The recruitment began in January 2020. The study ceased in February 2020 due to COVID-19 until September 2020. The recruitment will be completed approximately in June 2022.

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Figures

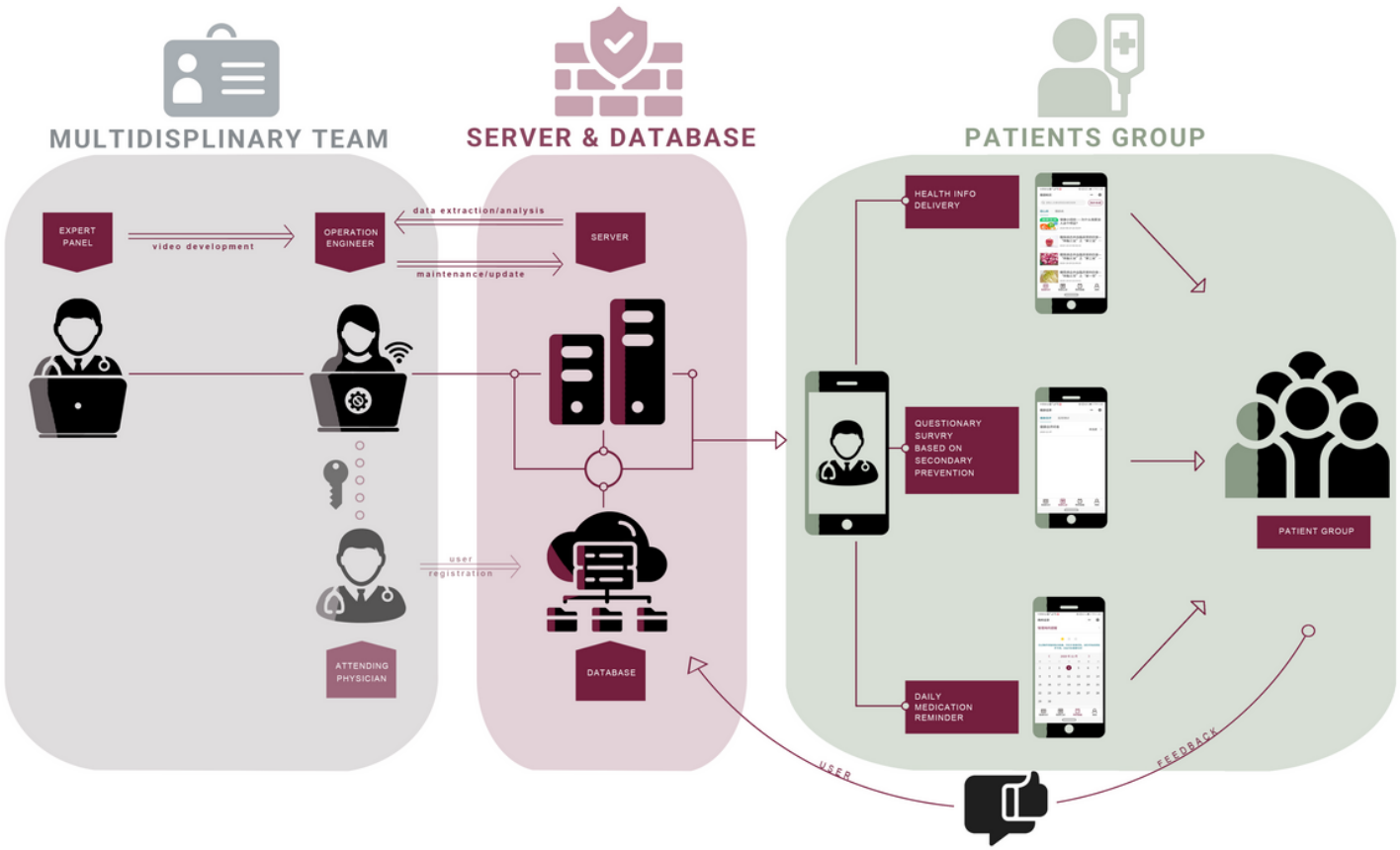

Figure 1

Schematic to show patient mobile connection, patient/physician web portals and servers.

Figure 2

Functional modules of coaching and reminder on the Wechat terminal.

Supplementary Files

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- SPIRITchecklist.docx
- Supplementarymaterials.docx