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Improving outcomes in patients with coexisting multimorbid conditions—the development and evaluation of the combined diabetes and renal control trial (C-DIRECT): study protocol

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ABSTRACT

Introduction: Diabetes mellitus (DM) is the most common cause of end-stage renal disease (ESRD). Patients with diabetes on dialysis have worse clinical outcomes and increased psychological burden. The need to manage the combined treatment demands for both conditions is particularly challenging yet there is paucity of data of the barriers preventing optimal management to combined therapy for diabetes and kidney failure. The study aims to explore needs of patients and develop an intervention to enable people with diabetes and ESRD to better manage both their conditions.

Methods and analysis: A two-phase study comprising a mixed method observational study (phase I) and a feasibility trial (phase II). Phase I will seek to document outcomes and needs of the population (patients with DM-ESRD) and seek input on preferred delivery/implementation for the programme. Data will be collected with in-depth interviews with patients, caregivers and healthcare providers (N=50), and from a questionnaire-based survey (N=170). Phase 2 will build on these data to design and test the feasibility of a practical, low-intensity, clinic-integrated intervention using a self-management paradigm. The intervention will primarily seek to support behavioural change so as to improve adherence and clinical outcomes for DM as well as for ESRD. For the feasibility trial, we will be evaluating acceptability, retention and completion rates of the programme.

Ethics and dissemination: The study protocol has been approved by the local ethics committee and written informed consent is required from every participant. Findings will be disseminated through journals, conferences and will be used to create a fully manualised intervention (materials) and training course for facilitators.

Strengths and limitations of this study

- Focus on population with complex health needs with a view to develop an intervention for patients with coexisting diabetes and end-stage renal disease.
- Triangulation of perspectives of all parties (patients, family members and healthcare professionals) using in-depth interviews and questionnaires to guide the development of the combined diabetes and renal control trial (C-DIRECT) intervention.
- Recruitment of ethnically and language diverse population with assessments available in English, Mandarin and Malay.
- Use of newly developed instruments that may need further linguistic validation.
- Potential difficulty in prioritising the targets and content of C-DIRECT intervention in brief and clinic-integrated format.

INTRODUCTION

Increased life expectancy is accompanied by an increase in the prevalence of chronic conditions, and combinations of chronic conditions are common.[1] The presence of multiple chronic conditions increases the burden of disease and negatively influences health status beyond the sum of the effects of each single condition.[2 3] The importance of managing coexisting chronic conditions in people of all ages is critical to slow progression and prevent associated complications. The evidence on self-care in comorbid conditions suggests that patients with diabetes and also a severe comorbid condition have difficulty with self-management activities and deciding on priorities regarding their care.[4]

Diabetes and kidney disease are rapidly escalating global health problems.[3] The total number of people with diabetes is projected to rise from 285 million in 2010 to 438 million in 2030.[5] Diabetes is also the most common cause of end-stage renal disease (ESRD).[6] Patients with DM-ESRD are the fastest growing segment of the dialysis

population[7 8] and also represent the segment most at risk for poor clinical outcomes. More than 50% of diabetic dialysis patients die within 2 years of initiating dialysis.[7 8] Overall, the coexistence of diabetes and ESRD leads to synergistic adverse effects: mortality is higher mainly due to cardiovascular complications, quality of life is worse and the burden on healthcare services is increased.[3 9] We would expect this to be reflected in poor self-management behaviours.

Despite the growth of this population, few studies have explored patient outcomes in this group.[10 11] Past work has focused on either ESRD or diabetes, and has documented substantial rates on non-adherence and emotional distress.[12–20] Evidence on how patients integrate and apply the treatment recommendations for multiple conditions and patterns of adherence for the combined diabetic and renal regimes is still largely lacking.

The competing physical and psychological needs of diabetes and ESRD constitute an additional challenge that can potentially result in misregulation, as when treatment demands for one condition conflict with or impede management of the other, or when patients prioritise one condition over another.[21] Managing diabetes and ESRD may benefit from an integrated approach that balances the demands of each condition without neglecting the other.

Clinical care of these patients is complex and the evidence base for intervention programmes to support managing is based largely on trials of interventions for single conditions, which too often exclude patients with multimorbidity. Typically, interventions are designed for a particular condition rather than coexisting diseases. A number of community-based interventions aim to enable individuals to manage their diabetes, however, these do not formally address self-management of behaviour change nor have they been developed to address the compound effect of diabetes and ESRD. Further concerns include limited data on racially diverse populations and the use of rather intensive, non-pragmatic programmes all making applicability for the complex synergistic effects of diabetes mellitus (DM) and ESRD difficult to assess.

Most intervention studies on populations with coexisting conditions focused primarily on the management of polypharmacy without consideration of the important lifestyle aspects of treatment.[22 23] Recommendations related to lifestyle and health behaviours are key to all chronic conditions. These become increasingly complicated for those with coexisting conditions and complex health needs. Compared with other chronic medical illnesses, diabetes and ESRD self-care place significant demands on patients, including dialysis procedures as well as dietary, exercise, glucose monitoring, fluid control and medication requirements. Besides dialysis, medication and dietary modification are the two key components in the management of coexisting diabetes and ESRD. Medication alone without dietary modification cannot guarantee good clinical outcomes such as good glycaemic and phosphate control in patients with DM-ESRD. Diet may be particularly challenging for patients with DM-ESRD, as patients are called to reconcile complex and often incompatible dietary recommendations for these two conditions.

In addition, there is a great psychological cost associated with making the necessary lifestyle changes. Rates of depression and distress are high and these have been shown to be associated with worse clinical outcomes and lower adherence and self-care.[24] Another important consideration is that patients with DM on dialysis are by definition a select group of patients with a 'poor' record with regards to adherence and self-management. These are patients who have a history of poor self-management decisions, self-care behaviours and metabolic control, given the development of diabetic nephropathy and need for dialysis. This may also adversely affect patients' motivation and hope, and undermine their confidence in effecting control and managing their conditions.

Identifying these barriers for patients with DM-ESRD and supporting adherence to treatment help reduce the burden of the coexisting conditions on the individual.

A brief, low-dose intervention developed for ESRD in Singapore (HED-SMART; HEmoDialysis Self-MAnagement Randomized Trial)[25] has been shown to produce improvement in adherence rates immediately postintervention.[26 27] The HED-SMART programme provides skills that can be translated by users to the management of their combined health risks (diabetes+ESRD). Hence, this work will serve as an initial platform for the development of the combined diabetes and renal control trial (C-DIRECT) programme, the intervention to support patients with DM-ESRD.

In recognition of challenges related to design a programme to meet the more complex needs of multimorbid patients and to deliver it in a way to facilitate participation of patients, the proposed study will be undertaken to inform the development of a self-management intervention to promote combined management of DM and ESRD as coexisting conditions (C-DIRECT). In order to achieve this, the study will comprise two phases: an observational mixed methods study (phase I) to identify the important targets for management and support programmes of adults on dialysis with multimorbidity (DM and ESRD), followed by a feasibility trial (phase II) to develop and pilot C-DIRECT intervention.

The main product of this two-phase project (phase I: observational study; and phase II: feasibility study) will be the answers to the following key questions:

1. What are the needs and challenges of patients with DM-ESRD?
2. What are patients' preferences for various means of delivery and implementation so as to guide the development of C-DIRECT?
3. Can sufficient numbers of participants be recruited and retained through the C-DIRECT programme?

A fully powered randomised controlled trial study would necessitate a large sample of patients with DM on dialysis, so it would be critical to get the design of such a study optimised before rolling it out. The two studies (observational study and feasibility study) would allow

methods to be refined so that the main study can be run in an optimal manner to facilitate large-scale recruitment and follow-up.

Specific aims

The specific aims of this study are:

1. To complete an observational study of a representative sample of adult patients with diabetes and ESRD to identify their needs, and evaluate adherence and emotional adjustment outcomes so as to inform the content of the intervention to be developed.
2. To assess patients' preference and readiness for various models and means of delivering the support programme/intervention.
3. To develop a self-management intervention programme for patients with diabetes and ESRD (C-DIRECT) to be a pilot in a subsequent feasibility trial.

METHODS AND ANALYSIS

The study will comprise an observational mixed methods study (phase I) followed by a feasibility trial (phase II).

Phase 1: mapping the needs of patients with diabetes and ESRD

We plan to develop the C-DIRECT intervention as a combined 'top-down and ground-up' approach, integrating the input and expertise of researchers and renal healthcare professionals (HCPs), and service users alike.

Design: mixed methods cross-sectional study to document needs and outcomes in patients with diabetes on dialysis combining a qualitative study and a questionnaire-based patient survey.

Qualitative substudy

First, a qualitative substudy involving interviews with patients, family members, and renal and allied HCPs will be conducted. Qualitative methods were chosen as the first step to help achieve the aims of developing the C-DIRECT, as little is known about patient experience of multimorbidity in the context of diabetes and ESRD/dialysis. In terms of Morgan's[28] mixed method typology, the study will use qualitative methods as the preliminary methodology, although the priority in the proposed research is quantitative.

Sample

Potential participants (ie, patients, family members/caregivers) will be identified by the nurse case manager in the respective dialysis centres following medical chart review to confirm eligibility (patients only), or case notes to identify next of kin/caregiver for patients (family members). Participants will be recruited using a purposive selection strategy to increase diversity across respondents from a range of ages and gender, years on dialysis or caring for patients on dialysis, years of experience and range of disciplines (HCPs only).

There will be a total of N=50 in-depth interviews with patients (N=20), family members/caregivers (N=20) and HCPs involved in care of patients with DM-ESRD (N=10). Exact numbers per group may vary and will be determined in a process of concurrent analysis by theoretical saturation.

All study participants have to meet the following criteria: (1) diagnosed with diabetes (either type I or type II DM) and established on haemodialysis (HD) for more than 3 months (patients only); (2) family member of a patient who has been diagnosed with diabetes and ESRD for more than 3 months (family members); (c) or HCPs involved in care for the patient group for more than 3 months.

Participants who speak only dialects, those with speech difficulties or a comorbid diagnosis of dementia or severe cognitive impairment and those unwilling or unable to consent will be excluded.

Procedures

Following informed written consent, arrangements for the interviews will be made as per respondents' preference and convenience. A research associate (not involved in patients' care) will conduct all the interviews, which will be digitally recorded, transcribed verbatim and entered into NVivo8 qualitative software for analysis and data management.

The three interview topic guides (1 for patient interviews, 1 for family member interviews and 1 for interviews with HCPs) will be informed by the aims of the research, literature review and discussion with research team. The interview guides will be field tested for flow and clarity of questions with N=3 participants.

The interview topics will cover perceptions of the relation between their conditions (diabetes and kidney disease), their experiences of living with/or caring for patients with diabetes on dialysis, their needs and the challenges they are facing, their own self-management/coping strategies (for individual conditions as well as for multimorbidity), their perceptions of healthcare and support, satisfaction with current care, and their views and preferences on different formats for support.

The interviews and survey questionnaire (see section below) will also include questions to elicit feedback on the format, implementation and methods of delivering the intervention from the perspectives of patients, family and HCPs. In delineating the delivery of the programme, we will therefore bring together the input of different parties in the process of planning the specific content and delivery of the intervention so as to facilitate implementation/planning and optimise recruitment and retention for the subsequent feasibility trial.

Data analyses

Concepts will be documented inductively, grouping similar or overlapping themes, patterns, relationships and common or divergent perspectives.[29]

To enhance the analytical framework and ensure rigour, two coders will be coding independently first and interpretation of the data and emergent themes will subsequently be discussed with members of the research team.

Quantitative survey

Sample

A range of 100–500 participants is recommended for subsequent factor analyses to investigate the psychometric properties of a self-administered questionnaire (ie, Health Literacy Questionnaire (HLQ)); however, a sample size of 100–200 may be practically achievable and feasible for the duration of this study. Thus, we aim to eventually recruit a minimum sample of 170 participants with diabetes and ESRD from National Kidney Foundation (NKF) Singapore community dialysis centres (inclusion exclusion criteria as per qualitative substudy described above). We will purposefully target patients from all ethnic groups and language proficiencies to ensure a better representation of the spectrum of patients, rather than a limited perspective from an English-speaking cohort and presumed different socioeconomic status.

Measures

All participants will be administered the following questionnaires on one occasion:

1. Sociodemographic Questions (eg, age, employment, education, marital/relationship status, income, housing).
2. A subset of six items from the Brief Illness Perception Questionnaire (B-IPQ)[30] to assess consequences, personal control, treatment control, identity, concern and illness comprehensibility separately for diabetes and kidney disease.
3. The treatment burden and prioritisation subscales from the Multimorbidity Illness Perceptions Scale (MULTIPleS)[31] to assess the perceived impact of multimorbidity. Responses are given on a 6-point Likert scale from 0 'strongly disagree' to 5 'strongly agree'.
4. Emotional distress will be measured using the Hospital Anxiety and Depression Scale (HADS).[32] The HADS is a well-established, standardised, 14-item self-report questionnaire. Its omission of somatic items makes it an appropriate measure for a chronically ill population. The measure rates the patient's experience of anxiety (7 items; score range, 0–21) and depression-related (7 items; score range, 0–21) symptoms within the past week. Higher scores indicate greater emotional distress.
5. Health Literacy Questionnaire (HLQ):[33] A measure of health literacy developed to comprehensively assess the different dimensions of health literacy needs and challenges[34] across nine subscales—feeling understood and supported by HCPs; having sufficient information to manage my health; actively managing health; social support for health; appraisal of health information; ability to actively engage with HCPs; navigating the healthcare system; ability to find good health information; and ability to understand health information.
6. Short version (6 items) of Health-Care Climate Questionnaire (HCCQ)[35] to measure patients' perceptions of the degree to which they experience their HCPs to be autonomy supportive versus controlling in providing treatment. They are scored on a 7-point Likert-type scale ranging from 1 (strongly disagree) to 7 (strongly agree) scale with higher scores signifying higher perceived autonomy support.
7. Short-form UCLA Loneliness Scale (ULS-8):[36] Comprising eight items of the revised ULS[37] to measure feelings of loneliness and social isolation. Items are answered on a 4-point Likert scale ('never' to 'always') with higher scores indicating greater loneliness.
8. Beck Hopelessness Inventory (BHI)—Short version.[38] Items are rated on a 4-point Likert scale (0–4) with higher scores indicating higher hopelessness.
9. Nutrition-Specific Quality of Life (NSQOL):[39] The NSQOL is a 15-item questionnaire developed based on items from Appetite and Diet Assessment Tool (ADAT) and the Food Enjoyment in Dialysis tool. It provides a measure of appetite-related quality of life in patients on HD.

Additional items will be included to explore barriers to fluid intake and diet recommendations: four items from ADAT[40] and five items developed for purposes of the study to capture eating behaviour and fluid control in the presence of social cues and symptoms of thirst/dry mouth.

10. The cognitive restraint subscale of Three Factor Eating Questionnaire (TFEQ)[41] will be used to measure control over food intake. Items are answered on a 4-point scale, with higher values signifying greater restraint.

To measure self-report adherence to treatment, three standardised questionnaires will be used:

11. Dialysis Diet and Fluid Non-Adherence Questionnaire (DDFQ)[17] to measure non-adherence to diet and fluid guidelines.
12. The Summary of Diabetes Self-Care Activities (SDSCA) revised version[42] is a well-validated measure of diabetes self-care. It comprises subscales for different domains of diabetes self-care behaviours, including general diet, exercise, blood glucose testing, foot care and medication using the average number of days per week (ie, 0–7) each self-care activity has been performed. Higher total or subscale scores indicate better self-management.
13. Morisky Medication Adherence Scale (MMAS-8)[43 44] to measure adherence to medication. Scores on the MMAS-8 can range from 0 to 8, with MMAS-8 scores of <6, 6 to <8, and 8 reflecting low, medium and high adherence, respectively.
14. Treatment Self-Regulation Questionnaire (TSRQ)[45] to assess autonomous motivation and controlled motivation for taking medications and checking glucose (8 items) and for following dietary and fluid rules (11 items). Items are answered on a 7-point Likert-type scale ranging from 1 (not at all true) to 7 (very true).

15. Views And Preference For Support: This set of questions have been developed for this study to elicit patients' views and preferences for various activities and services. Patients will be required to rate on a scale of 1–10 how useful the suggested services would be for them or other patients with diabetes and on dialysis, if available at no cost.

Phase 2: developing and evaluating the efficacy of C-DIRECT (feasibility trial)

Phase 2 will strategically aim to develop and pilot (feasibility trial) the C-DIRECT intervention. C-DIRECT will be modelled on the UCL Diabetes Self-Management Programme (UCL-DSMP)[46] and the HED-SMART renal programme,[26] but its content and delivery will be tailored/customised to the needs and context of the local population with DM-ESRD (as identified in phase I).

It is anticipated that the programme will build around the principles that patients can learn to take responsibility for daily management of their conditions, and that confident, knowledgeable patients have better health and use fewer health services. Given the challenges in recruiting multimorbid patients who typically tend to be more frail and likely to have mobility issues, the intervention will most likely be delivered on a one-to-one basis while patients are on dialysis (clinic-integrated).

The final content and format for delivery (ie, group based session vs individual sessions, face-to-face and/or use of technology devices to support content) will be determined based on the phase I study. It is generally expected that face-to-face direct intervention sessions may be supplemented by other contact (telehealth: telephone calls or SMS reminders) to reinforce the use of intervention-derived strategies and potentially generalise these strategies to new problem areas. Once exact content and delivery format has been finalised, the C-DIRECT intervention will be presented in fully manualised form to facilitate implementation alongside onsite training for the intervention facilitators.

ETHICS AND DISSEMINATION

All participants will provide written consent and phase I and phase II studies will both adhere to the ethical principles of the Helsinki Declaration (World Medical Association General Assembly 2008).[47] All data will be anonymised and secured off-site for a period of at least 5 years in accordance with the Data Protection Act 1995.

Dissemination strategy is expected to comprise: interim and final year reports to funders (Yen Pei National Kidney Research Foundation); scientific papers prepared for conference presentations and peer review publications; and feedback about the results of the study, which will be provided to study participants and relevant patient groups through third-level sector organisations (eg, NKF Singapore).

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Competing interests None.

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