Multidisciplinary management of diabetic kidney disease: a systematic review protocol

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Review question/objective

The goal of this systematic review is to identify the best available evidence regarding multidisciplinary management of diabetes related kidney disease. More specifically, this analysis aims to answer the question: is the multidisciplinary management of diabetic kidney disease effective in improving health-related patient outcomes?

Background

The growing rate of diabetes poses significant practice and economic related challenges to healthcare systems around the world.\textsuperscript{1} Diabetes carries significant risks for negative health sequelae and as such, Diabetic Kidney Disease (DKD) is becoming a global health concern.\textsuperscript{2} Despite pharmacologic advances and disease management strategies, DKD remains associated with high morbidity and mortality.\textsuperscript{3} Non-adherence to the treatment regimen is considered to be the major cause of the poor glycemic control and resultant complications often seen in patients with diabetes.\textsuperscript{4} Systematic reviews

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of the literature focusing on other chronic diseases have suggested that multidisciplinary management of chronic conditions can improve patients’ adherence to treatment and improve health related outcomes.\textsuperscript{5,6} However, the effectiveness of multidisciplinary management in improving or optimizing outcomes of patients with DKD has yet to be established in a systematic manner.

DKD is a progressive disease associated with multiple comorbidities, major complications and increased healthcare costs. It affects approximately 30\% to 40\% of diabetic patients.\textsuperscript{7,8} The prevalence of DKD is projected to continue to rise\textsuperscript{9}, mainly in proportion to the rise in the prevalence of diabetes.\textsuperscript{10} Patients with DKD have the highest risk of morbidity among diabetic patients.\textsuperscript{11} DKD carries a poor prognosis, with increased all-cause mortality and cardiovascular mortality; a risk of progressive renal function decline and acute renal failure, leading to end-stage renal disease.\textsuperscript{12,13,14} DKD is the most common cause of end stage renal disease in both the United States and Europe.\textsuperscript{15} In fact, patients with DKD account for half of dialysis cases.\textsuperscript{3} Disease progression is associated with frequent hospitalizations and dialysis, events that increase healthcare costs considerably.\textsuperscript{16} Moreover, decreased kidney function is also associated with compromised health related quality of life. As the rate of kidney function declines, disease burden increases concurrent with diminished quality of life measures.\textsuperscript{17} These findings have been further supported by a cross sectional study demonstrating that patients with stage four and five kidney disease have a compromised quality of life, with similar levels to patients on dialysis.\textsuperscript{18}

Accordingly, targets for interventions aimed at improving the management of DKD have included: improving patient outcomes such as functional status, quality of life and adherence to treatment\textsuperscript{19}, and preventing the progression of the disease and the occurrence of cardiovascular complications.\textsuperscript{8} The treatment of DKD typically involves controlling blood pressure, glycaemia and lipids. Additional management steps include screening for retinopathy or neuropathy, along with patient education, training in self-management and lifestyle modification coaching.\textsuperscript{20} This is important as patients with multiple chronic diseases, such as DKD, often live at home and are expected to manage a wide range of daily selfcare activities including monitoring of blood glucose levels, adjusting nutrition, engaging in physical activity, adhering to medication regimens, recognizing symptoms of deterioration in status and responding accordingly, and to reduce their risk of complications and adjust psychologically to their treatment and lifestyle changes.\textsuperscript{21} Patients are often unable to suitably interpret the multitude of instructions received from various health care professionals and to process the complexity of the treatment regimens.\textsuperscript{22} These challenges can pose barriers for adherence and non-adherence is thought to be the major cause for the poor control of diabetes and a significant contributor to the occurrence of complications.\textsuperscript{4}

One approach to address these problems in patients with DKD involves multidisciplinary management of different comorbidities to slow the progression of the disease and prevent complications. Black and colleagues (2010) have recommended the shifting of multidisciplinary management of end stage kidney disease to the management of patients with evidence of early stage chronic kidney disease.\textsuperscript{23} Stamm, Burnier and Zanchi (2011) have noted the need for comprehensive multidisciplinary care that would optimize the care of patients with DKD.\textsuperscript{24} They advocate for a multidisciplinary nurse led team composed of an endocrinologist, nephrologist, clinical nurse specialist, dietitian, pharmacist and podiatrist. In relation to other chronic diseases such as heart failure and diabetes, systematic reviews of the literature and meta-analyses support the effectiveness of multidisciplinary management.
programs such as nurse led clinical management programs, multidisciplinary home visit management programs and multidisciplinary home telemanagement programs. These approaches have demonstrated enhanced patient outcomes in terms of reducing costs, re-hospitalization rates and mortality, increasing health literacy and adherence to treatment, and ameliorating patients’ functional status, self-care abilities and quality of life.\textsuperscript{25-30} While, these systematic reviews support the benefit of multidisciplinary management of chronic disease, only a paucity of studies exist in nephrology regarding the care of DKD patients. DKD is a chronic disease similar to diabetes. However, patients with DKD have specific needs that differ from patients with diabetes. A study using the Kidney Disease Quality of Life Questionnaire and the generic Health Related Quality of Life Questionnaire-SF-36 in 38 patients with DKD on dialysis aimed at describing the quality of life as compared to 40 non-diabetic patients on dialysis and 38 patients with long term diabetes but with normal kidney function. The self-rated physical function and physical health were significantly lower in the DKD group as compared to the non-diabetic dialysis control and to the diabetic control patients with no kidney disease. The physical role, general health, vitality and emotional role were also scored lower in this group as compared to the diabetic controls. The DKD patients on dialysis exhibited reduced physical health, limitations in the activities of daily living and compromised social roles.\textsuperscript{31} A review of the literature of 118 studies on health-related quality of life among patients with type two diabetes highlights the heterogeneity of the results, which is predominantly due to heterogeneity of the diabetic population.\textsuperscript{32} A recent study confirmed the significantly impaired physical health perception in the DKD patients on dialysis as compared to their non-diabetic on dialysis control.\textsuperscript{33} It can therefore be surmised that the DKD population is unique and cannot simply be considered to be a subpopulation of the group of diabetic or kidney disease patients. Therefore, transferability of findings from previous systematic reviews to the DKD patient population, which is challenged by complex multisystem complications, is questionable. None of these chronic disease management strategies have been specifically assessed in terms of their impact on the outcomes of patients with DKD. A recent systematic review of multidisciplinary approaches in the management of patients with chronic kidney disease pre-dialysis included four articles; two randomized clinical trials and two observational studies. This review highlighted the effectiveness of this type of care management in delaying the progression of the disease based on the results of both randomized controlled trials and observational studies, each with equal input. The included studies focused primarily on educational interventions and none involved a targeted self-management approach, home visit follow up or technology based (e-health) follow up.\textsuperscript{34} In light of this gap in the literature, there is a need to examine the existing evidence regarding multidisciplinary approaches specific to the management of DKD.

DKD presents multiple medical management challenges and has a significant impact on the daily lives of patients living with this condition. Considering the global trends and predicted increase in the prevalence of DKD, healthcare systems are faced with major financial ramifications that demand novel management strategies for delaying the progression of the disease, enhancing self-care activities and improving the patients’ health-related outcomes.

The authors propose a systematic review of multidisciplinary management of DKD involving the structured care plans provided and elaborated in collaboration by more than one healthcare discipline, including physicians, nurses, pharmacists, dieticians, or health educators. Such a review is a fundamental initial step that will help to evaluate whether multidisciplinary disease management can contribute to preserving kidney function and delaying disease progression. Such a review will enable: i)
identification of the gaps in knowledge and research in this area; ii) identification of targets for implementing an effective multidisciplinary approach to managing DKD; and iii) development of recommendations for the implementation of an appropriate multidisciplinary approach in a clinical practice setting.

**Keywords**

Diabetic nephropathies; Diabetic Kidney Disease; multidisciplinary; interdisciplinary; patient care team; collaborative approach; nurse-led

**Inclusion criteria**

**Types of participants**

This review will consider studies that include:

1. Adults aged ≥18 years old

2. Diagnosed with type 1 or type 2 diabetes, according to the WHO criteria (WHO 2006): fasting plasma glucose ≥ 7.0 mmol/L and two hour plasma glucose ≥ 11.1 mmol/L.  

3. Diagnosed with CKD stage one to five, based on the urine albumin excretion ratio (UAER) according to the KDOQI 2007 criteria.

**Types of intervention(s)/phenomena of interest**

This review will consider studies that include the following types of interventions:

1. Multidisciplinary management programs or programs that include an approach or intervention from more than one medical or allied health discipline (for example nurses, pharmacists, dieticians, or health educators) for the management of DKD, that aims to prevent the decline in kidney function, control the progression of kidney disease, improve glycemic and/or blood pressure control or improve patients’ quality of life.

2. Comparison of multidisciplinary programs with any other treatment (including standard disease management approaches) or with retrospective (historical) outcome data.

3. Structured care plans provided by more than one healthcare discipline including physicians, nurses, pharmacists, dieticians, or health educators.

4. Multidisciplinary intervention conducted in an outpatient setting defined as an ambulatory clinic, home care/work place setting or a combination of both (hybrid).

**Types of outcomes**

This review will consider studies that include the following health-related outcomes: in the absence of validated objective or subjective self-report instruments, unvalidated self-report data will be included as the lowest level of data assessing outcomes among DKD patients.

A. Primary clinical outcomes:

1. Changes or decline in kidney function evaluated through the measurement of creatinine clearance and/or glomerular filtration rate and/or serum creatinine and/or proteinuric.
2. Incidence of kidney failure evidenced by the start of renal replacement therapy either by hemodialysis or peritoneal dialysis.

B. Primary patient reported outcomes:

1. Generic or specific health-related quality of life (including assessment of depression, anxiety and coping using validated instruments).
2. Patient self-care abilities measured by objective validated instruments or self-report.
3. Adherence to treatment recommendations or goals, such as adherence to medication taking, increased physical activity, dietary modifications or any other treatment assessed using objective measures, validated instruments or self-report.

C. Secondary clinical outcomes:

1. Mortality rates secondary to DKD.
2. Changes in blood pressure control, glycemic control or lipid profile.
3. Incidence of cardiovascular disease or events.

D. Secondary patient reported outcomes:

1. Level of knowledge about diabetes and/or DKD, evaluated using objective measures or self-report.
2. Level of patient empowerment or self-efficacy assessed using objective measures or self-report.
3. Generic (unvalidated patient-reported outcomes related to satisfaction with care) or specific instruments measuring patient satisfaction with care (previously validated metrics/questionnaires).
4. Patient healthcare utilization measured objectively or through self-report.

Types of studies

This review will consider any experimental study design including randomized controlled trials, randomized cross-over and quasi-experimental studies, before and after studies and non-randomized controlled trials, for inclusion.

Search strategy

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken, followed by analysis of the text words contained in the title and abstract and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be
undertaken across all included databases. Thirdly, the reference lists of all identified reports and articles will be searched for additional studies. Reviewers are fluent in English, German and French. Therefore, studies published in these languages will be considered for inclusion in this review. Studies published from the time of the respective database inception to July 2014 will be considered for inclusion in this review.

The databases to be searched include:

1. Medline using MeSH terms and keywords together. MeSH terms (Diabetic nephropathies, patient care team, collaborative approach, multidisciplinary).

2. CINAHL using Subject Headings terms and keywords together. Subject Headings terms (Diabetic nephropathies, patient care teams).

3. Embase using EMBASE terms and keywords together.

The search for unpublished studies will include:

1. Searching clinical trials registry platforms namely:
   - International clinical trials registry platform search portal: www.who.iht/trialsearch
   - International standard randomized controlled trial number register: www.controlled-trials.com/isrctn
   - European Medicines Agency: www.emea.europa.eu/index/index1.htm
   - Australian clinical trials registries: www.australianclinicaltrials.gov.au
   - UK clinical trial gateway: www.controlled-trials.com/ukctr

2. In the event that unpublished studies are retrieved, letters will be sent to the corresponding author requesting further information and/or data from the identified studies.

Initial keywords to be used will be:

Diabetic nephropathies; Diabetic Kidney Disease; multidisciplinary; interdisciplinary; patient care team; collaborative approach; nurse-led

**Assessment of methodological quality**

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using the standardized critical appraisal instrument, the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix V). Any disagreements that arise between the reviewers will be resolved through discussion or with a third reviewer.

**Data collection**

Data will be extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI (Appendix VI). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.
Data synthesis
Quantitative data will be pooled where possible, for statistical meta-analysis using JBI-MAstARI. Effect sizes (expressed as an odds ratio for categorical data) and weighted mean differences (for continuous data) with a 95% confidence interval will be calculated for analysis. Results will be tested for heterogeneity using Chi-square and in the case of significant heterogeneity a random effects meta-analysis will be conducted. In circumstances whereby statistical pooling is not appropriate or possible, the findings will be presented using narrative and tabular form.

In the event that multiple combinations are identified in the literature related to composition of the multidisciplinary team or the structure of multidisciplinary interventions, the authors will construct tabular matrices depicting the variable results for each respective combination (for example group composition or structure of treatment plan).

Conflicts of interest
Authors disclose no conflict of interest.

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References


Appendix I: Appraisal instruments
MAStARI appraisal instrument

JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer ............................... Date ..................................
Author ................................. Year .......................... Record Number ..........................

1. Was the assignment to treatment groups truly random?  Yes ☐ No ☐ Unclear ☐ Not Applicable ☐
2. Were participants blinded to treatment allocation?  ☐ ☐ ☐ ☐
3. Was allocation to treatment groups concealed from the allocator?  ☐ ☐ ☐ ☐
4. Were the outcomes of people who withdrew described and included in the analysis?  ☐ ☐ ☐ ☐
5. Were those assessing outcomes blind to the treatment allocation?  ☐ ☐ ☐ ☐
6. Were the control and treatment groups comparable at entry?  ☐ ☐ ☐ ☐
7. Were groups treated identically other than for the named interventions?  ☐ ☐ ☐ ☐
8. Were outcomes measured in the same way for all groups?  ☐ ☐ ☐ ☐
9. Were outcomes measured in a reliable way?  ☐ ☐ ☐ ☐
10. Was appropriate statistical analysis used?  ☐ ☐ ☐ ☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

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Appendix II: Data extraction instruments
MAStARI data extraction instrument

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