A physical activity intervention feasibility study for renal inpatients: a basic research protocol

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ABSTRACT

Background: Low physical activity levels and poor physical functioning are strongly associated with poor clinical outcomes and mortality in adult End Stage Kidney Disease (ESKD) patients, regardless of treatment modality. Compared to the general population, individuals with chronic kidney disease are physically inactive, have reduced physical abilities and difficulties performing routine daily tasks, lower health-related quality of life, higher cardiovascular morbidity and mortality. In addition, frail ESKD patients have higher hospitalization and mortality rates than other ESKD patients. Evidence suggests that assessment and recommendations for physical activity should be part of standard care for ESKD patients. Structured exercise can improve physical function and quality of life in frail older adults and may be used specifically for management of frailty in ESKD. However, research is needed to determine best practices

for implementation of physical function measurements and physical activity promotion in standard ESKD care.

Objective: The proposed Move More study will assess the feasibility of a physical activity intervention offered to the ESKD inpatients in Calgary, Alberta. Specifically, this study is designed to examine the effects of an early physical activity/mobility intervention led by a kinesiologist (KT), and supported by the clinical care team including physiotherapists (PT) and nurse clinicians.

Methods: The Move More study is a single-arm pilot intervention examining feasibility and preliminary efficacy. ESKD inpatients at the Foothills Medical Centre will be recruited to participate. Patients will receive an individualized in-hospital physical activity/mobility intervention. Frailty and physical function will be assessed at baseline and post-intervention prior to hospital discharge.

Conclusions: Evidence needed to support the inclusion of mobility and physical activity as part of standard care will be gathered, with knowledge gained used to help direct future physical activity programming for ESKD inpatients.

INTRODUCTION

Chronic Kidney Disease (CKD) prevalence is now as high as 71.9 per 1000 individuals in Canada [1]. CKD is associated with high morbidity, mortality and poor clinical outcomes, leading to challenges for patients, families, and health care providers [2]. As CKD progresses to end-stage kidney disease (ESKD) these issues are exacerbated, and healthcare costs for inpatient care increase due to required dialysis, long transplant waiting times, and high hospitalization rates [2, 3]. Individuals with ESKD are often physically inactive, have reduced physical abilities and difficulties performing routine daily tasks, lower health-related quality of life (QOL), and higher cardiovascular morbidity and mortality compared to the general population [4–6]. Due to frailty and reduced physical function, many are unable to return home, leading to high admission rates to long-term care facilities, prolonged lengths of stay, and frequent re-admission to the hospital [7].

Evidence suggests that physical activity (PA) assessments and recommendations should be included in standard ESKD care [8]. PA can improve blood pressure [9, 10], insulin sensitivity, maximal exercise

capacity, physical performance and self-reported functioning [11] in renal patients. Additionally, PA has been shown to improve QOL and cognitive function while reducing symptoms of depression [10]. A randomized-controlled PA intervention for elderly medical inpatients demonstrated improved physical function and reversed the typical functional decline associated with hospitalization [12]. In addition, researchers measured positive changes in cognitive and mood status, QOL, length of stay, falls, and readmissions three months after discharge [7]. Evidence suggests, critically ill patients who undergo PA interventions have enhanced functional capacity, strength, mobility, QOL, reduced length of stay, and a higher probability of being discharged home [13].

Due to general deconditioning and increased muscle wasting, the prevalence of frailty and limited physical function in ESKD patients is high [11]. More than 60% of ESKD patients are considered frail, compared to only 11% of older adults [14]. Frailty increases risk of health complications such as falls, cardiovascular events, hospitalization, disability, reduced QOL, and mortality [10, 15–17]. Therefore, the management of frailty is central to ESKD care. PA interventions show promise for managing frailty in geriatric populations [18]. A systematic review of PA for frailty found high adherence and no adverse events in most studies, concluding that PA is safe and feasible for an aging population, with greater impact during early stage frailty [18]. Due to the high prevalence of physical function limitations and frailty in ESKD patients regardless of age, PA interventions are warranted [13, 19]. Furthermore, ESKD patients are interested in increasing PA and improving their physical function [2]. Research is thus needed to identify optimal strategies to implement physical function assessments and promote PA in ESKD care [11].

The purpose of the proposed study is to assess the feasibility and preliminary efficacy of an early-PA intervention in the care of ESKD inpatients. It is hypothesized that the intervention will be feasible to administer and for patients to participate in.

METHODS

Study Design

The Move More study is a single-arm pilot intervention examining feasibility and preliminary efficacy. An overview of study procedures is shown in Figure 1. Ethical approval was obtained through the Conjoint Research Ethics Board of the Faculties of Medicine at the University of Calgary (REB18-2134).

Figure 1 – Flowchart of Study Design

Participants/Study population

ESKD inpatients on Unit 37 at the Foothills Medical Centre in Calgary, Alberta will be invited to participate. Eligibility criteria are: 1) ESKD inpatients on maintenance dialysis (hemodialysis or peritoneal dialysis), 2) Anticipated Date of Discharge (ADOD) greater than 7 days, and 3) deemed

medically stable to participate in PA by a nurse or nurse clinician. Exclusion criteria due to medical instability are defined as 1) unstable vital signs, poor oxygen saturation on room air, 2) decreased level of consciousness, confusion, 3) febrile (temperature $>38.3^{\circ}\text{C}$), 4) chest pain or shortness of breath at rest, 5) signs of GI bleed, 6) pain which can be potentially exacerbated by physical activity intervention, or 7) a permanent negative change in medical status (ex. change to palliative care). Patients will remain enrolled if there is a temporary decline in medical status that prevents participation if the patient is expected to recover. Due to the variability in medical care for maintenance dialysis patients, patients will remain enrolled in the study if there is a temporary transfer off the renal inpatient unit to another unit for procedures or other medical interventions. Patients who are permanently transferred to another unit will be discharged from the study.

Study Procedure

Eligible participants will be identified by nurse clinicians or the research coordinator. The patient will then be presented with a consent to contact by unit staff before receiving further information about the study from the research team. Those who agree to participate will sign an informed consent form before completing a baseline assessment and exercise education session to learn how to perform tailored exercises with a kinesiologist. The kinesiologist will supervise exercise with the patient 1-3 times per week and the unit staff will monitor and record all exercise sessions.

Physical Activity Intervention

Inpatients will receive an individualized physical activity intervention according to baseline measures. Table 1 specifies measures collected at baseline and discharge. Patient mobility is determined by a review of charts and nursing/ physiotherapy (PT) notes to determine level of assist. There are three intervention phases, 1) bed-bound (two-person assist/full lift), 2) moving around room (one-person assist), and 3) moving out of room (independent), each with its own exercise protocol (Table 2). Exercise will be tailored based on phase and participant's exercise preferences.

Participants will complete prescribed exercises daily and progress as determined by the Kinesiologist.

Strength exercises will be selected from the Vivifrail Multi-Component Physical Exercise Program that

has shown positive effects in elderly inpatients [20]. A target exercise intensity of 2-3 on the 10-point Borg rating of perceived exertion scale will be used, which is considered best practice in advanced renal disease settings [21, 22]. In addition, participants will be encouraged to perform exercises beyond their daily prescription as tolerated.

	Baseline Assessment			Discharge Assessment		
	1 Bed-bound, two-per- son assist	2 Moving around room, one-person assist	3 Moving out of room, independent	1 Bed-bound, two-per- son assist	2 Moving around room, one-person assist	3 Moving out of room, inde- pendent
Fried Frailty In- dex	✓	✓	✓	✓	✓	✓
Grip strength taken seated in bed	✓	✓	✓	✓	✓	✓
15ft. walking (if safe)		✓	✓		✓	✓
30 sec chair stand (if safe)		✓	✓		✓	✓
Fatigue	✓	✓	✓	✓	✓	✓
Shrinking	✓	✓	✓	✓	✓	✓
GLTEQ	✓	✓	✓	✓	✓	✓
KDQOL	✓	✓	✓	✓	✓	✓
Patient satisfac- tion question- naire				✓	✓	✓

Table 1: Baseline and Discharge Assessment Overview

GLTEQ- Godin Leisure Time Exercise Questionnaire

KDQOL- Kidney Disease Quality of Life Instrument

Phase	Resistance exercises	Aerobic Exercise
1 Bed-bound or two-person assist	5min or more of selected exercises with or without resistance bands • Chest press • Rows • Bicep curls • Triceps extensions • Buttocks squeeze • TA activation • Heel slide • Straight leg raise • Ankle pumps	5 mins or more, bed bike
2 Moving around room, one-person assist	10 mins or more of selected exercises with or without resistance bands: • Chest press • Rows, • Biceps curls • Triceps extensions • Glute squeeze • Knee extensions • Calf raises- seated or standing • Standing hip abduction • Seated hip abduction • Hamstring curl seated or standing • Quarter squat	10 mins or more, bed and/or leg bike
3 Moving out of room, independent	15 mins or more of selected exercises with or without resistance bands: • Chest press • Rows • Biceps curls • Triceps extensions • Glute squeeze • Knee extensions • Calf raises- seated or standing • Standing hip abduction, • Seated hip abduction • Hamstring curl seated or standing • Quarter squat • Sit to stand.	15 mins or more, leg bike and/or walking

Table 2: Physical activity intervention

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Measures

Primary Outcomes

The primary outcome of the study is the feasibility of administering an individualized early exercise/mobility intervention. Feasibility measures include: (a) recruitment: those eligible, approached, consent/no consent, reasons for refusal, numbers participating, numbers recruited from advertising; (b) completion of the prescribed exercise/mobility intervention and reasons for non-completion/withdrawal (recorded on the Electronic Medical Record (EMR)); (c) participant and healthcare practitioner (HCP) satisfaction with the exercise intervention, measured by satisfaction surveys; (d) HCP completion of clinical charting for FITT prescription (date, frequency, intensity, duration, type of exercise; progression through strengthening exercises) and level of assist needed (if any); (e) participant assessment; and (f) reporting of adverse events related to participation in the in-hospital exercise program. Feasibility will include 60% recruitment rate, 50% assessment completion, no adverse events related to the intervention, and high satisfaction as reported by both the participants and HCPs.

Secondary Outcomes

Secondary outcomes of this study are frailty, functional measures, QOL, number of falls in-hospital, hospital length of stay (LOS), and 30-day re-admissions. Frailty, functional measures, and QOL will be assessed at baseline and post-intervention prior to hospital discharge. Hospital LOS and 30-day readmissions will be gathered from EMRs.

Frailty

A standardized definition of frailty was established in community-dwelling older adults [23] and utilized in ESKD [17]. According to the Fried Frailty Index, frailty is defined as a clinical syndrome in which three or more of the following criteria are present: unintentional weight loss (10 or more pounds in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, and low PA [23].

If present, each criterion is given one point. A total score of equal to or less than one classifies the patient as non-frail, two points is pre-frail and three or more points is considered frail [24].

Physical Activity behaviour

As part of the Fried Frailty Index, the Godin Leisure Time Exercise Questionnaire (GLTEQ) will measure usual PA habits [25]. The GLTEQ was used to assess PA behaviour in many populations, including renal patients [26, 27]. The GLTEQ will be assessed as outlined in Table 3.

Quality of Life

The Kidney Disease Quality of Life Instrument (KDQOL) [28] is a 36-item self-report measure. It is designed to assess the QOL of individuals with CKD and ESKD, including the burden of the disease, symptoms and specific QOL questions.

Musculoskeletal functional measures

Lower body strength will be assessed using the 30-second Sit to Stand Test [29]. Upper body strength will be assessed using a Jamar hand grip dynamometer (Performance Health, Hydraulic, Illinois, USA), which has widely used in various chronic illnesses [30]. Patients will complete three trials per side and the highest value in kilograms from each will be taken and added together to get a cumulative value. Grip strength for frailty will be assessed as outlined in Table 3.

Walk speed will be assessed using the 15 ft. walking test [23]. Patients walk 15 ft. at a normal walking pace and the time it takes for them to complete this is recorded in seconds [23]. Walk speed test scoring is outlined in Table 3. Physical function tests may be skipped if patient medical or functional status prevents assessment.

GLTEQ		
Active	≥ 24 points	
Moderately Active	14 to 23 points	
Insufficiently Active	< 14 units	
Grip Strength		
	BMI	Grip Strength
Men	BMI < 24	<29 kg
	BMI 24.1–26	<30 kg
	BMI 26.1–28	<30 kg
	BMI > 28	<32 kg
Women	BMI < 23	<17 kg
	BMI 23.1–26	<17.3 kg
	BMI 26.1–29	<18 kg
	BMI > 29	<21 kg
Gait Speed		
	Height	Time cut off
Men	< 173 cm	>7 seconds
	Height > 173 cm	>6 seconds
Women	< 159 cm	>7 seconds
	> 159 cm	>6 seconds

If the patients grip strength is below the cut off for their given BMI, then the person receives a 1 for this component of the Fried Frailty Index. If their grip strength is above the cut-off, then the person will receive a 0.

If the patient's gait speed is slower than the cut off, they receive a 1 for Fried phenotype. If it is faster than the cut-off, they receive a 0.

Table 3. Fried Frailty Index Scoring Values

Demographics

Demographics and medical variables will be obtained by study staff via chart review. This includes age, gender, height, date and reason for admission (diagnosis), date of discharge, weight at

admission and discharge, location discharged to, cause of renal disease, type of dialysis, dialysis vintage, if there is a change in dialysis type while in hospital, co-morbidities (e.g. diabetes, hypertension, heart disease, stroke, peripheral vascular disease, neuropathy, retinopathy, chronic infections/wounds, amputations, falls), referral date, withdrawal and reason for withdrawal, and walking/mobility aids utilized. Hospital LOS and re-admission rates over 30 days will be obtained by EMR review after patient discharge.

Sample Size

All ESKD patients admitted to the *Nephrology Inpatient Service* at the Foothills Medical Centre in Calgary requiring dialysis and meeting the inclusion criteria will be approached for participation in the feasibility study. As a feasibility study, no a priori sample size calculation was performed. It is anticipated that 24-36 patients will be recruited over 12 months.

Analysis

Participant demographics and outcomes will be summarized using descriptive statistics. For continuous variables, means and standard deviation will be calculated. For categorical variables, frequencies and percentages will be presented. Within-group changes in secondary outcomes of frailty, PA, QOL, and physical function will be examined using dependent sample t-tests. Descriptive statistics will be used to provide an overview of additional measures for LOS, in-hospital falls, and re-admission. All analyses will be completed using SPSS statistics, version 26.0 (IBM).

Dissemination

The results for the primary and secondary outcomes will be published upon study completion. Information from the study will be also be disseminated to the staff and management on Unit 37 as well as the Department of Nephrology at the Foothills Medical Centre to encourage knowledge translation into clinical practice.

DISCUSSION

Statement of principal outcomes

The proposed study will examine the feasibility and preliminary efficacy of implementing an early PA intervention with ESKD inpatients. Physical activity training can improve cardiovascular function and outcomes in ESKD patients with limited physical function, which is associated with poor clinical outcomes and increased healthcare expenditures [8, 11]. This work will improve our understanding of the feasibility of PA in ESKD inpatients and its potential ability to improve frailty, QOL, and reduce hospital LOS and rate of re-admissions. Integrating an individualized PA regimen is part of the approach to management of frail patients with ESKD [14]. The current study will also add to current literature on the psychosocial benefits of PA on QOL in ESKD patients [26, 28].

Strengths and Limitations

A key strength of the proposed study lies in the integration of kinesiologists into the already diverse pre-existing therapy team, consisting of physiotherapists, occupational therapists, their assistants. This aids in the establishment of a strong working relationship with clinical staff and management, promoting recruitment and improving patient flow through the intervention. Furthermore, a wide range of existing therapy equipment will be available to the kinesiologist to individualize exercise programming. The presence of a kinesiologist on the unit throughout the week also allows for constant monitoring and adaptation to enhance safety, adherence, and likely intervention effectiveness.

Due to the single-arm nature of the proposed research, we will not be able to discern between intervention effects and natural patient changes. This feasibility study will recruit a small sample of ESKD inpatients, which limits statistical power to detect changes and may result in a homogenous participant population, reducing generalizability. As commonly seen in PA interventions, study participation may be biased

towards highly motivated individuals with a strong history of PA. Although we will assess feasibility of integrating PA into standard renal care, differences between our clinical environment and population compared to other locations may prevent direct translation of our intervention to other clinics. Therefore, the feasibility and optimal implementation of PA interventions must be assessed in various environments, while larger randomized controlled trials will be required to improve generalizability and address the intervention effectiveness.

Meaning of the study: possible implications for clinicians or policy makers

ESKD patients have a higher rate of readmission to the hospital compared to the general population [6]. There are significant financial costs and emotional consequences of admission to the hospital [6]. In Canada, ESKD has an economic burden of \$1.9million, of which 69% is direct health care costs [31]. Management of frailty using the proposed PA intervention has the potential to decrease length of hospital stay and re-admissions for ESKD patients, reducing patient and healthcare burden. Ongoing research aims to better understand the impact of exercise on ESKD inpatients, adding to evidence on the value of early mobilization in critically ill patients for improving physical function at discharge [32]. The proposed study will inform the feasibility of delivering and participating in daily exercise as part of routine ESKD inpatient care. Lastly, physical activity for ESKD in-patients has the potential to improve functioning, enhance patient outcomes, reduce hospital LOS and enhance overall QOL.

Unanswered questions and future research directions

There is a lack of rigorous work examining exercise interventions for critically ill patients as well as limited research in ESKD inpatients [13]. As such, the proposed work will help to establish feasibility of PA interventions in this population and kinesiologist integration within in-patient units. If feasibility is

shown herein, larger randomized controlled trials will be required to examine intervention effectiveness. Multi-site research may be necessary given the size of the ESKD population. The implementation of PA interventions in various clinical settings will help to inform feasibility and best practices for different environments to improve generalizability. Future research is also needed to optimize exercise prescriptions for ESKD inpatients by varying frequency, intensity, time, and type. Finally, explorations of cost-effectiveness for kinesiologist integration in clinical care will determine if and in what capacity such specialists should be included in ESKD clinical teams.

Ultimately, past, present, and future research of PA in ESKD inpatients will challenge the notion that PA is only appropriate outside of critical care environments, benefitting patients long after their discharge from the hospital. As we work to optimize in-hospital PA interventions and shift the culture on inpatient units, patients will continue to benefit in terms of function, QOL and overall health as resources and education on movement become more prevalent.

Contributions

Contributed to conception and design: KW-F, SM, TC, NCR
Drafted and/or revised the article: KW-F, SM, TC, ME, NCR
Approved the submitted version for publication: KW-F, ME

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Data and Supplementary Material Accessibility

Not applicable: All data is provided directly in the manuscript.

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