

Title:

Home-based interventions for FrAilty preveNTion in AdultS with DIabeTes and Chronic Kidney Disease (FANTASTIC)

Principal Investigator:

Dr. Diana Mager

Co-Investigators:

Dr. Patricia Manns

Dr. Peter Senior

Dr. Angela Juby

Dr. Normand Boule

Host Institution:

Alberta Health Services

Description of Study:

The study purpose is to develop and test a home-based lifestyle intervention program focused on optimizing diet and the ability to perform your ADLs in adults with DM and CKD. The goal is to ensure that adults with DM can live healthier lives within the community.

Funding Source: Alberta Health Services, Novo-Nordisk

Project Start Date: March 2020

Project End Date: December 2025

Inclusion Criteria:

Adults (50-85 years) diagnosed with diabetes (Type 2) and stage 1-IV CKD (Glomerular Filtration Rate (GFR) 10-89 ml/min/1.73m²) at risk for frailty.

Exclusions:

- 1) Individuals with functional and cognitive impairments (MMSE scores < 24)
- 2) Individuals with severe, permanent vision loss
- 3) Individuals with a recent history of bone fracture in the last 12 months that precludes ability to perform
- 4) Individuals with a history of skeletal muscular disorders which precludes the ability to perform resistance exercises
- 5) Pregnant women as DXA scans are not recommended during pregnancy
- 6) Individuals on dialysis.

Ethics Approval: Pro00089513

Participation:

Participants will be seen by an RA/trained grad student who will provide education, observe the study participants performing exercises at home visits and provide feedback. Any unusual findings or adverse events are reported to the study Physician (Dr. P. Senior) as well as the participants responsible clinician.

For patients in the treatment arm, the potential benefit includes improvements in muscle strength, flexibility and balance. There are no expected direct benefits to participants allocated to the control arm of the study, it is possible that participants may experience some benefits related to in depth counseling related to activities of daily life. Both groups will receive in-depth counseling regarding activities of daily life which may improve overall sense of health and well being to both groups.

There is a minor potential for discomfort related to muscle strain related to the performance of the resistance exercises. There is a minor potential for mild fatigue related to performance of exercises. There is a minor risk associated with radiation exposure due to the DXA and the risk for an unexpected finding due to DXA.

To protect the confidentiality of the data, all individual identifying patient data will be coded by subject number. All study documents will be kept in a locked filing cabinet/encrypted electronic files on a password protected computer of the PI. Access to this data will only be available to the PI/CI and research personnel (graduate student/research nurse/research dietitian).

Contact Information:

Name: Deanna Ketsa

Phone: 587-926-9461

Email Address: dketsa@ualberta.ca