The "Get Moving Trial": A phase I/II RCT of home-based (P)rehabilitation ((P)REHAB) with ExerciseRx in muscle-invasive bladder cancer (MIBC)—Study protocol for a randomized controlled trial.

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Background: Patients with MIBC often have a high burden of frailty, sarcopenia, mobility impairment, and multimorbidity, each of which is associated with reduced treatment tolerability. Prehabilitation programs are designed to improve functional capability prior to treatment to mitigate functional decline and optimize outcomes. Barriers to widespread adoption include cost, time, intensity of in-person interventions, and overly restrictive inclusion criteria which would exclude most patients with MIBC. Here, we describe a randomized controlled trial to evaluate the feasibility, usability, and impact of a pragmatic (P)REHAB exercise intervention delivered via the ExerciseRx app in participants with MIBC undergoing neoadjuvant chemotherapy (NAC) followed by radical cystectomy (RC). The primary objectives are to evaluate the (P)REHAB intervention vs. standard care (SC) to quantify the efficacy of the intervention to 1) improve or maintain physical function in patients with MIBC undergoing NAC followed by RC, and 2) globally characterize the impact of the (P)REHAB intervention with respect to patient-reported feasibility and acceptability, health-related quality of life, body-composition, frailty, treatment-associated and clinical outcomes. **Methods:** We will recruit and randomize 102 patients in a 1:1 ratio to the (P)REHAB or SC arms. The (P)REHAB arm will be prescribed a personalized, home exercise program (~20-minutes, 4x weekly) via the ExerciseRx app, during NAC, prior to RC and for 90-days post-RC as well as graded progression in step count. SC participants will receive printed guideline-based recommendations for physical activity during standard perioperative care. ExerciseRx comprises of 1) a provider dashboard integrated into the electronic health record for prescribing exercises and monitoring patient progress, and 2) a patient app, that administers exercise plans and tracks exercise repetitions using sensors in commodity smart devices. Step count in the (P)REHAB and SC arm will be tracked with Fitbit trackers. In the (P)REHAB arm, step count data from the Fitbit will be reviewable in the ExerciseRx provider dashboard and patient app. Eligibility criteria: English-speaking adults (>18 years) with AJCC pT2-4 N0-1 M0 MIBC planning to undergo NAC followed by RC who are willing and able to participate in the trial. Primary outcome: Change in the Short Physical Performance Battery. Secondary outcomes: FitBit-assessed step count and sedentary time, ExerciseRx adherence and usability, patient-reported quality of life (EORTC-QLQ-C30, -BLM30), change in body composition (fat-mass, fat-free mass), frailty (Cancer and Aging Resilience Evaluation), treatment-associated adverse events between baseline and following NAC, and 3 months following RC. Trial enrollment will commence 10/2023. Clinical trial information: NCT06040762. Research Sponsor: Bladder Cancer Advocacy Network.