Protocol Title:	The effect of intradialytic resistance exercises using resistance bands with exercise physiologist consultation on the physical function of people undergoing hemodialysis: a proof of concept study
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1. Background and Significance

Patients with end-stage renal disease (ESRD) receiving in-center hemodialysis (HD) suffer from high rates of frailty, physical inactivity and mortality. While the prevalence of frailty in older adults (>65 years of age) in the community dwelling population has been measured around 7%,[1] in those undergoing in center hemodialysis the prevalence has been found to be as high as 73%.[2] Even the rate of frailty in the younger (<65) HD population has been measured as high as 36%.[3] In a study that defined frailty using the Fried Frailty Index (FFI) for the hemodialysis population, frailty was associated with a 40.2% 3 year mortality compared to the rate of 16.2% in the same non-frail ESRD population.[3] Overall, this correlated with 2.7 times greater risk of death (95% CI 1.02-7.07, p=0.046) independent of age, sex, comorbidity and disability. Another study examined the various components of frailty (weight loss, exhaustion, low physical activity, weak grip strength and slow gait speed) finding that over a 3.8-year time period, one component of frailty was associated with a hazard ratio of 2.73. This hazard ratio increased to 10 for patients with all 5 components.[4] Exercise has been promoted as a way to combat or slow the progression of frailty across many disciples and age groups. However, exercise in the ESRD patient population remains challenging.

Intradialytic exercise has been a subject of several investigative studies for the past several decades. A Cochrane systematic review in 2011 found there to be significant benefit in patient's aerobic capacity, resting blood pressure, and health-related quality of life from exercising three times per week for greater than 30 minutes per HD session.[5] There have been several examples in the literature of exercise studies and subsequent meta-analysis that have shown improvement in many of the physical fitness tests used to measure frailty such as the 6 minute walk test (6MWT), Timed Get up and Go Test (TUG), Maximum Walking Speed Test, Sit to Stand Test (STS) and overall metabolic equivalents achieved.[6,7,8,9] These exercise routines usually involve either aerobic exercise, resistance exercise or a combination of the two for at least 30 minutes during the 1st two hours of

each HD session. The use of resistance exercises via elastic bands alone has been shown to improve the patient's 30 second STS test and 8-foot TUG test.[10]

Despite the known benefits of exercise, there are no formal intradialytic exercise protocols in the United States. The main barriers in the US are thought to be interference with the workflow of an outpatient dialysis center as well as high rates of patient non-adherence and drop out. A German single-center long term study employing exercise professionals measured 1 and 5-year adherence at 78% and 43% respectively.[11] Unfortunately the data on adherence and efficacy in the United States is lacking. This remains a challenge across the world as nephrologists and dialysis center staff are thought to lack the personnel and resources needed to advise dialysis patients on individualized exercise regimens.[12]

A test of the feasibility and efficacy of an intradialytic exercise (IDEx) strategy will be the primary intent of this project. This IDEx study will consist of an exercise physiologist consultation with HD patients once a week during their 3 times weekly in-center HD sessions over a 3-month period. At these consultations, exercise physiologists will perform physical assessments and develop individualized resistance exercise plans using elastic bands. The exercise physiologist will continue to visit with the patient once weekly after the initial consultation over the 3-month period. The effects of the resistance exercise regimens on physical function will be measured.

2. Study Aims

The primary objective of this study will be to test the feasibility and efficacy of a 3 month exercise physiologist consultation program. Specifically, our aims will be to:

a. Test the feasibility of a 3-month exercise physiologist led program
b. Measure the effect of an exercise physiologist collaboration and intradialytic exercise on the physical function of HD patients using the 30 second STS test,

handgrip strength test [required for frailty scale], 8-foot TUG test and patient physical activity based off of the Low Physical Activity Questionnaire.

3. Administrative Organization

The study will be administered from Satellite Healthcare, Inc., 300 Santana Row, Suite 300, San Jose, CA, 95128. The study site will be Satellite Healthcare Milpitas. 1860 Milmont Dr, Milpitas, CA, 95035.

4. Study Design

a. Experimental design of the study

Randomized controlled trial (RCT) proof of concept study design

b. Study population

Convenience sample from prevalent HD patients from Satellite Milpitas Hemodialysis center in Northern California.

c. Sample size

n=50 (25 intervention - 25 control)

d. Study Outcomes

Feasibility outcomes

- Adherence calculated as the total number of self-reported exercise sessions attempted by the patient when EP not present divided by the total number of hemodialysis sessions. This information will be collected from the patient at the weekly meeting with the EPs.
- Adverse events defined as any injury, impairment or medical condition that was directly or suspected to be due to performing the prescribed exercise.

Efficacy Outcomes

- Change in physical function as measured by the 30 second sit to stand test (STS), handgrip strength test (HGST) and the 8 foot timed up and go test (TUG). Performed prior to initiation of dialysis at their mid-week dialysis session.

5. Study Procedures

a. Subject selection procedures

The Principal Investigator is responsible for screening subjects for the study, ensuring subjects meet all inclusion criteria.

b. Inclusion criteria

- Age 18 years or greater
- Ability to understand and communicate English
- Diagnosis of ESRD and currently undergoing in-center hemodialysis
- On HD for longer than 6 weeks
- Approved by the Satellite Milpitas Medical Director and/or referring physician

c. Exclusion criteria

- Previous major amputations
- Inability to independently ambulate
- Known to be pregnant

d. Recruitment procedures

- The Satellite Healthcare database will be used to identify all in-center hemodialysis patients at the Satellite Milpitas Dialysis Center
- This list of potential subjects will be approved by the Satellite Milpitas Medical Director who will screen to ensure they meet inclusion criteria.
- The study research associate (RA) and PI (Dr. Diskin) will meet with the potential screened subjects in the dialysis center at the patient's weekly dialysis sessions
- The RA and PI will describe the study using a one-page information sheet and consent form as approved by the IRB.
- The RA and PI will offer the patient to take the information home and discuss with their relatives and significant others
- The RA and PI will then approach eligible participants again to consent to participate in the study. After consent is obtained, participants will be randomized into two groups using sequentially numbered opaque sealed envelopes.

e. Study Intervention

- 12 exercise physiologist consultations over 12 weeks
- Up to 3 exercise physiologists will implement an individualized resistance exercise program using elastic bands

f. Study Measures and Activities

- Subjects will meet with an exercise physiologist once weekly during one of their usual in-center HD sessions over a 3-month period.
- At the initial visit, the following physical function tests will be performed on the patient by EP: STS, HGST and TUG.
- At subsequent consultations, exercise physiologists will provide exercise plans and collect feedback on the exercises from the patients.
- EPs will tailor exercise routines to the individual patients based on a combined aerobic and resistance exercise program.

  Aerobic Exercise

  Participants will be asked to commence at a minimum of walking 3 times per week commencing at 20 minutes, and increasing both intensity and time up to 30 minutes x 3 times per week.

  Resistance Exercise

  Participants will be instructed to initially exercise various upper, core and lower body muscle groups using resistance bands for 1 set of 10 repetitions twice weekly. Intensity and repetitions of exercises will be adapted to participants' abilities throughout the 12 weeks. Warm up and warm down exercises will be included where relevant.
- Weekly progress notes and exercise checklists will be employed to monitor the types of exercises used. (see attachments f-h)
- The estimated duration for the appointments will be 30 minutes
- A modified version of the Fried Frailty Index Score will be used to assess for the presence of frailty in both groups at the start of the study. The modification will be the replacement of the Minnesota Leisure Time Activity Questionnaire (MLTAQ) used to measure the low physical activity portion of the FFI with the Low Physical Activity Questionnaire

(LoPAQ). This was previously compared to the MLTAQ in a study of dialysis patients[14].

- Exercise physiologist will encourage patients to complete their individualized exercise routines during their dialysis sessions for which the EP is not present but also at home at their convenience.
- Adverse events can be reported directly to the center manager or the PI. The EP will ask directly about adverse events at every meeting.

6. Data Analysis Plan

Demographic data: age, gender, ethnicity, weight, BMI, end stage kidney disease cause, co-morbid conditions, vintage on dialysis, dialysis treatment details and biochemical indices will be collected. Paired t-test or Wilcoxon-sign-rank will be used to compare the pre and post intervention STS, Hand Grip Test, TUG and modified FFI results depending on the distribution of the data. Patients who drop out or withdraw from the study will be included in the final outcomes with intention-to-treat analysis.

7. Timeline

Timeline (months)	1	2	3	4	5	6	7
Refine protocol							
Staff in-services							
Patient recruitment							
Exercise physiology intervention							
Evaluation interviews							
Data cleaning							
Data analysis							
Papers/Report write up							

IDEx Data Collection Plan

Test	Initial Assessment	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12
Demographic • Name/MR No. • DOB/Age • Gender • Racial Origin • Height • Smoker • Dialysis Vintage (months) • Renal Disease	x												
Comorbidities • Lung • PVD • Cerebral • Diabetes • Hypertension • Heart Failure	x												
Dialysis Info • Weight (dry) • BMI • KtV • Hb, PO4, K • Blood Pressure	x												
Physical Function Tests • Sit to Stand	x												x
• Timed up and go	x												x
• Hand Grip	x												x
Modified Fried Frailty Index	x												
EP Meeting Record	x	x	x	x	x	x	x	x	x	x	x	x	x

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8. Attachments

a. **30 Second Sit to Stand**
b. **Handgrip Strength Test**
c. **8 Foot Timed Up and Go**
d. **Modified Fried Frailty Index**
e. **Low Physical Activity Questionnaire**
f. **EP Weekly Progress Note**
g. **EP Exercise Plan**
h. **EP Weekly Checklist**
i. **Pre and Post Intervention Assessment**

a. 30 Second Sit to Stand

Method
Use a straight back chair with a solid seat that is 16" high. Ask participant to sit on the chair with arms folded across their chest.

Instructions
"Stand up and sit down as quickly as possible, keeping your arms folded across your chest. Do this for 30 seconds."

Measurement
The person testing counts the times the client comes to a full standing position in 30 seconds.

Reference: (Jones, Rikli, & Beam, 1999)

b. Handgrip Strength Test

Materials Needed:

- Handgrip strength Dynamometer
- Paper, pen/pencil (to record scores)

Instructions:

1. Illustrate the use of the instrument to the patient prior to testing
2. The patient should be in a standing position, arms to their side, not touching their body. Elbow slightly bent.
3. Ask the patient to squeeze the dynamometer with as much force as possible, being careful to squeeze only once for each measurement.
4. Three trials should be made with a pause of about 10-20 seconds between each trial to avoid muscle fatigue
5. Record the result of each trial to the nearest kilogram. If the difference of the score is > 3 kgs, then repeat the test once more after a rest period. Use the average of 3 measurements.
6. For dialysis patients the non-fistula dialysis arm will be used. If both arms have a fistula, then the arm with the inactive fistula will be used. If no fistula is present, then the non-dominant arm will be used.

Reference: (Handgrip Strength Protocol. Tufts University Nutrition Collaborative, 2003)

c. 8 Foot Timed Up and Go

Equipment/set-up
Place a chair (approximately 17 inches in height) against a wall or firm object for safety to prevent it from sliding backwards. Place a cone on the floor exactly 8 ft away (distance measured is from the front edge of the chair to the back edge of the cone). Ensure a minimum of 4 ft of clearance beyond the cone to allow for turning room. A stopwatch is also required.

Starting Position
Patient is seated in the chair with hands on thighs and feet flat on the floor.

Protocol
Patient is instructed that on the signal "go," they are to rise from the chair (pushing off of thighs or chair is permitted), walk "as quickly as possible" around the cone and return to a seated position in the chair. The participant is told that they will be timed and should therefore walk as quickly as possible but not to run. Following a demonstration, the patient is allowed one practice trial followed by two test trials.

Scoring
The clinician begins the timer when the "go" signal is given (even if the patient has not begun to move) and stops the time at the exact instant that the participant's buttocks contacts the chair following the walk segment. Note the scores of both test trials to the 1/10th second yet the faster of the two times is recorded on the assessment form for evaluation purposes. Results obtained with this test may be compared to age-related normative values.

Adaptation
Use of an assistive device is permitted if required (remember to mark what type of device the patient used on the evaluation form) yet does not allow for comparison with age related, normative values from the Senior Fitness Test. Be sure to retest the patient using the same device on following visits. Additional trials can be administered without a device or a different type of device if appropriate.

Score > 8.5 seconds is associated with high fall-risk in community-dwelling older adults.

Reference: (Rose, Jones, & Lucchese, 2002)

d. Modified Fried Frailty Index (Frailty = ≥ 3 of the below criteria)

Fried Frailty Index **V2.0**	
Category	Criteria
Weight Loss If yes, give one point towards frailty.	Self-reported weight loss ≥ 10 lbs/year based off dry weight. (Yes or No)
Physical endurance/energy If No to #1 OR if every day/every week given as #2 give one point towards frailty.	1. Do you feel full of energy? (Yes or No?) 2. During the last month, how often have you rested in bed during the day? (every day, every week, not at all)
Low Physical Activity If no as an answer for very energetic physical activity OR moderately energetic physical activity give one point towards frailty.	Frequency of mildly energetic, moderately energetic and very energetic physical activity using LoPAQ (see attachment e)
Weakness If grip strength is below the 20% cutoff for gender and BMI listed, then give one point towards frailty.	Hand grip strength in kg, dominant hand, average of 3 measurements Frailty: cutoff point Grip strength lowest 20% Men BMI < 24: < 29 kg BMI 24-26: < 30 kg BMI 26-28: < 30 kg BMI > 28: < 32 kg Women BMI < 23: < 17 kg BMI 23-26: < 17.3 kg BMI 26-29: < 18 kg BMI > 29: < 21 kg
Slow Walking Speed If TUG test takes ≥19 seconds then give one point towards frailty.	Timed Up and Go ≥ 19 seconds
If total points towards frailty is ≥ 3 then patient meets criteria for frailty by Fried Frailty Index	

Reference: (Fried et al. Frailty in older adults: evidence for a phenotype. Journal of Gerontology. 2001;56:M146-156);

e. Low Physical Activity Questionnaire

Low Physical Activity Questionnaire (LoPAQ)

1. Please check all of the statements that describe your walking in the last week
   ☐I walked around the neighborhood
   I walked_____times during the week.
   I walked for approximately_____minutes per session.
   ☐I walked for transportation (i.e., to the store, etc.)
   I walked_____times during the week.
   I walked approximately_____minutes per session.
   ☐I walked for the purpose of improving my fitness or for pleasure (above and beyond daily necessities)
   I walked_____times during the week.
   I walked approximately_____minutes per session.
   ☐I did not walk.
2. In the past 7 days, did you participate in other activities that would be described as "light" activities? These are activities that make your heart beat a bit faster than usual—you could talk and sing while doing them. Examples would be: light yard or gardening work, bowling, golfing, boating (motor), leisure bicycling, stretching, yoga, chair exercises or light housework such as folding laundry or washing dishes?
   ☐no ☐yes
   if yes, I participated in these light activities_____times during the week for an average of_____minutes per session.
3. In the past 7 days, did you participate in activities (other than walking) that would be described as "moderate" activities? These activities would make your heart beat faster than usual, and you could talk, but not sing while doing them. Examples of moderate activities would be: aerobics class, swimming (the side stroke or breast stroke), bicycling in the neighborhood, playing badminton or table tennis, softball, downhill skiing or moderate housework such as vacuuming or making beds.
   ☐no ☐yes
   if yes, I participated in these moderate activities_____times during the week for an average of_____minutes per session.
4. In the past 7 days, did you participate in activities (other than walking) that would be described as "vigorous" activities? These would make your heart beat lots faster, make you breathe heavily, making your talking broken up by large breaths. Examples of vigorous activities would be: jogging or running, playing tennis or racquetball, playing soccer, basketball, cross- country skiing, using stepping machines or other equipment at the gym.
   ☐no ☐yes
   if yes, I participated in these vigorous activities_____times during the week for an average of_____minutes per session.
5. In the past 7 days, did you do specific exercises for strengthening muscles?
   ☐no ☐yes
   if yes, I participated in these strengthening exercises_____times during the week.
6. In the past 7 days, did you do exercises for stretching your muscles (flexibility exercises)?
   ☐no ☐yes
   if yes, I participated in these stretching or flexibility exercises_____times during the week.
7. In terms of physical activity and walking, was this a typical week for you?
   ☐no ☐yes
8. In the past 7 days, how much time did you spend sitting, watching television, reading or in front of a computer?
   _____hours/day (average)
9. In the past 7 days, did you nap at home during the day?
   ☐no ☐yes
   if yes, I napped_____times.
   when you nap, how long do you nap?
   _____minutes
10. In the past 7 days, how many hours were you in bed at night?_____hours/night (average)

11. Do you work outside the home?	☐no	☐yes
if yes, does your job require you to do walking?	☐no	☐yes
if yes, your job require you to do physical exertion such as lifting?	☐no	☐yes

(Johanson et al, Characterization of Physical Activity and sitting time among patients on Hemodialysis using a new physical activity instrument. Journal of Renal Nutrition 25:1, 2015 25-30)

f. EP Weekly Progress Note

How did the exercises go in the last week? At how many of your other sessions last week did you attempt to complete your exercises? How many of your aerobic exercises did you complete last week?

Have there been any noticeable changes that you have observed from our last meeting?

Is there anything that you are able to do now that you could not do before (endurance, strength, or flexibility)?

Have you experienced any symptoms or side effects from your exercise? If yes, what were they? (e.g., pain during any of the exercises? Any dizziness or light-headedness during or post-exercise?)

How can we modify the exercises from our last meeting?

Frequency **I**ntensity **T**ype **T**ime

What new exercises should we add or change for this upcoming week? (Document additional exercises for the new week and changes in prescription)

What are your exercise goals for the next week?

g. EP Exercise Plan

WARM UP						
ACTIVITY	SETS	REPS	TIME	DIST	INTENSITY**	NOTES

Aerobic Exercises		
Number of Attempts	Average Time	Average Distance

CORE BODY – STRENGTH TRAINING					
EXERCISES	SETS	REPS	WEIGHT/BANDS	REST TIME	NOTES

UPPER BODY – STRENGTH TRAINING					
EXERCISES	SETS	REPS	WEIGHT/BANDS	REST TIME	NOTES

LOWER BODY – STRENGTH TRAINING					
EXERCISES	SETS	REPS	WEIGHT/BANDS	REST TIME	NOTES

h. EP Weekly Checklist

IDEX VISIT CHECKLIST

1. Initial Intake visit

- ☐ Complete the PRE-Study Assessment form for both control and intervention patients.
- ☐ Provide intervention patient with an initial Exercise Plan form.
- ☐ Make a copy of the Exercise Plan form. Provide one to the patient and place one in the Patient Information binder.
- ☐ Scan the PRE-Assessment forms for all patients and email to Dyer Diskin at diskinc@satellitehealth.com

2. Weekly visit #1-11

- ☐ Complete the Progress Note form.
- ☐ If any alterations are made to the exercise plan, complete a new Exercise Plan form.
- ☐ Make a copy of the updated Exercise Plan form. Provide one to the patient and place one in the Patient Information binder.

3. Weekly visit #12

- ☐ Complete the POST-Study Assessment form for both control and intervention patients.
- ☐ Complete the Progress Note form.
- ☐ Scan the POST-Study Assessment form for all patients and email to Dyer Diskin at diskinc@satellitehealth.com

4. Reminders

- ☐ Report any adverse events (side effects from exercise) to the Center Manager and email Dyer Diskin at diskinc@satellitehealth.com
- ☐ At any point, a patient may choose to leave the study. If this happens, notify the Center Manager Alan Rex Gil Cepe and email to Dyer Diskin at diskinc@satellitehealth.com

Pre and Post Intervention Assessment

Hand Grip Strength Measurements: Using the Handgrip strength dynamometer take the best of three measurements for the non-fistula arm. If both arms have fistulas, use the arm that is not currently being accessed. If no fistula is present, use the non-dominant arm. Chart whether the left or right arm is used for the test. For the post-assessment make sure it is the same hand used in the pre-assessment. Pause 10-20 seconds between each test.

Handgrip Strength		
Test 1:	Test 2:	Test 3:
Average:	Hand Used:	

Timed Up and GO (TUG): Record time in seconds for the patient to walk 8 feet in a straight line and return to a seated position. Patient is allowed one practice run. Two are counted. Note the average of the two. Chart if an assistance device such as a walker or cane is needed and note the type of assistance device.

Timed Up and Go (TUG) (seconds)	
Trial #1:	Trial #2:
Average:	Assistance Device:

Sit-to-Stand: Have the patient sit with arms crossed over the chest stand up and sit down as quickly as possible. Record the number of times they can go from sitting to standing in 30 seconds.

Sit-to-Stand (Repetitions/ Time)	
# of repetitions:	Repetitions/Time:

Low Physical Activity Questionnaire: Administer the questionnaire on the following page as instructed. Scan and email back results of this and the above physical function tests to diskinc@satellitehealth.com. [see attachment e]