



Home-Based Rehabilitation Interventions To Improve Functional Recovery After TAVR (REHAB-TAVR Study)

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Specific aims

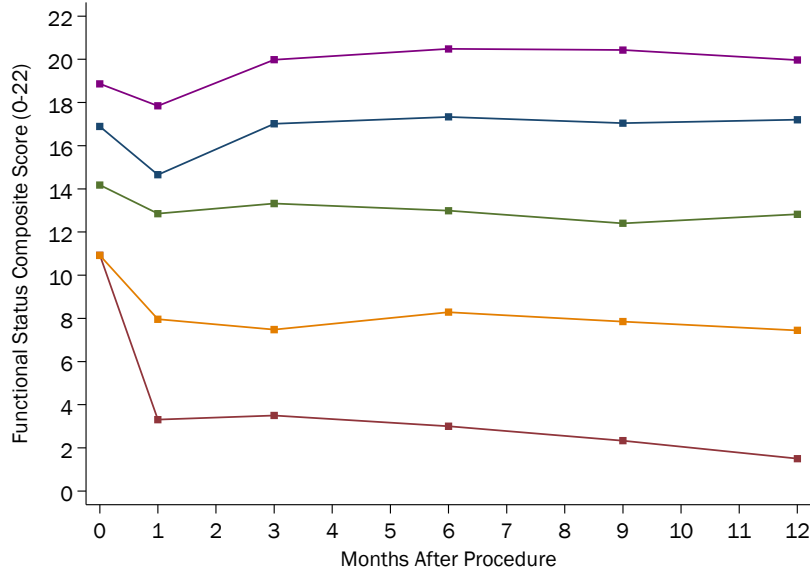
- **Aim 1:** To determine **the effect of a home-based exercise program vs. an attention control educational intervention** on physical function and disability during the 8-week period after TAVR.
- **Aim 2:** To determine **the effect of cognitive behavioral intervention** on the adherence and the change in physical function and disability among the participants in the home-based exercise program.



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Functional decline is common after TAVR

- Transcatheter aortic valve replacement (TAVR) reduces symptoms and mortality in patients with aortic stenosis (AS)
- Offer limited or no meaningful benefit in some patients



Functional Trajectory	SAVR	TAVR
Excellent	37%	14%
Good	38%	23%
Fair	19%	38%
Poor	3%	15%
Very poor	1%	8%

* In-hospital mortality was 2% in SAVR and TAVR.



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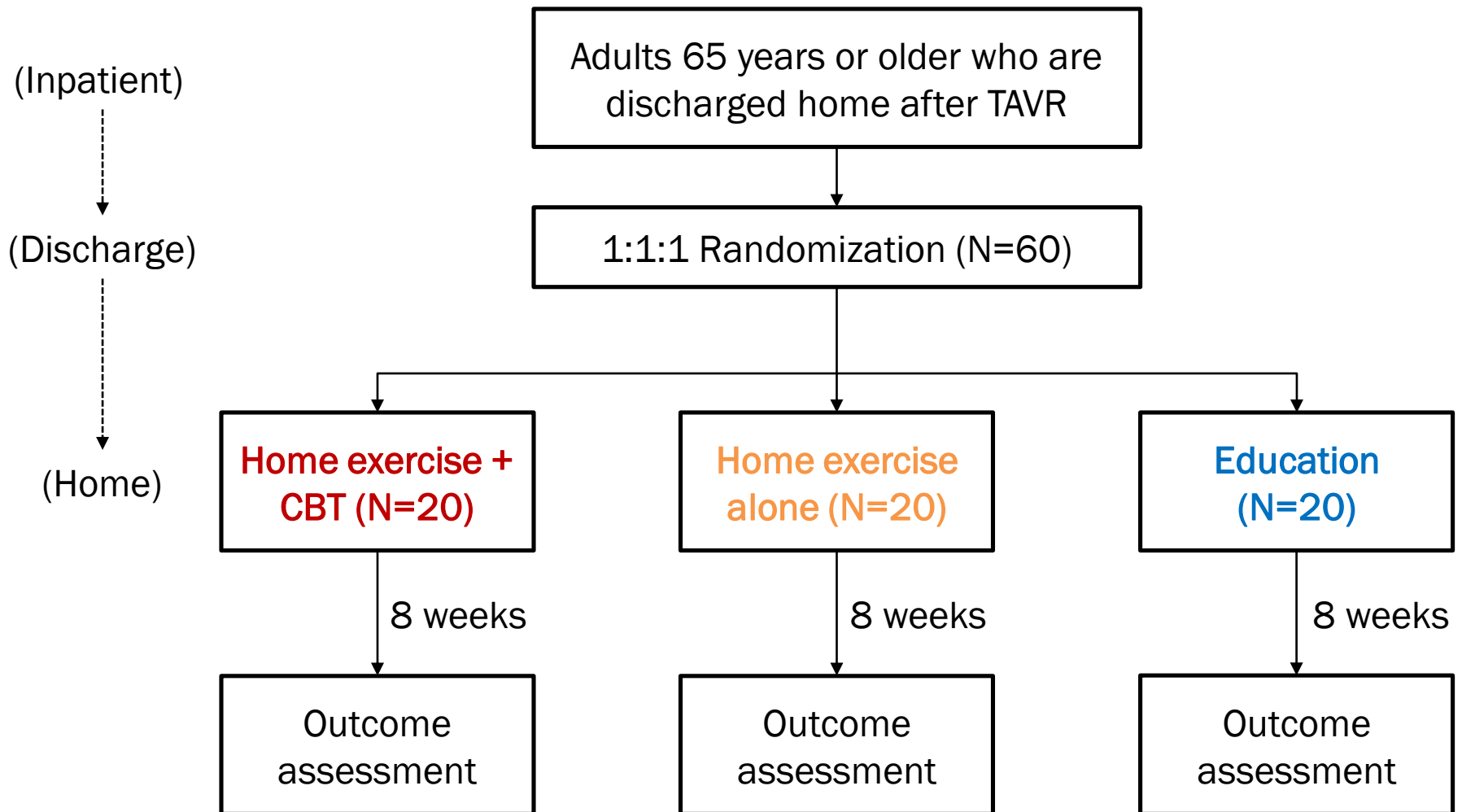
Rationale

- Cardiac rehabilitation benefits patients with MI or heart failure, but it is underused for TAVR patients.
 - This requires outpatient rehabilitation center visits.
- Poor adherence is a major barrier.
 - Home-based program may be as effective as center-based program and with better adherence.
- Cognitive behavioral interventions can improve negative expectations about exercise and low self-efficacy.
 - Combining exercise with CBT may be necessary.



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REHAB-TAVR randomized controlled trial



Selection criteria

- Target enrollment: 60 (20 in each group)

Inclusion criteria

- Age ≥ 65 years old
- Underwent TAVR
- Live within a 20-mile radius of the recruitment site
- Plan to be discharged home
- Provide informed consent

Exclusion criteria

- Stroke or any medical conditions that preclude participation in the exercise intervention
- Severe cognitive impairment (MMSE < 15)
- Enrollment in another clinical trial



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Study interventions

Home exercise + CBT

- Individualized exercise by home PT (40 mins):

- Balance
- Flexibility
- Strength
- Endurance

- CBT (20 mins):

- Enhance positive attitude and beliefs
- Discuss barriers
- Detailed exercise plan
- Goal and monitor progress
- \$10 gift cards per week

8 sessions / 8 weeks

Home exercise

- Individualized exercise by home PT (40 mins):

- Balance
- Flexibility
- Strength
- Endurance

8 sessions / 8 weeks

Health education

- Telephone call by health professional (30 mins):

- Review of activities
- Healthy eating
- General tips for exercise (mainly walking)

8 sessions / 8 weeks

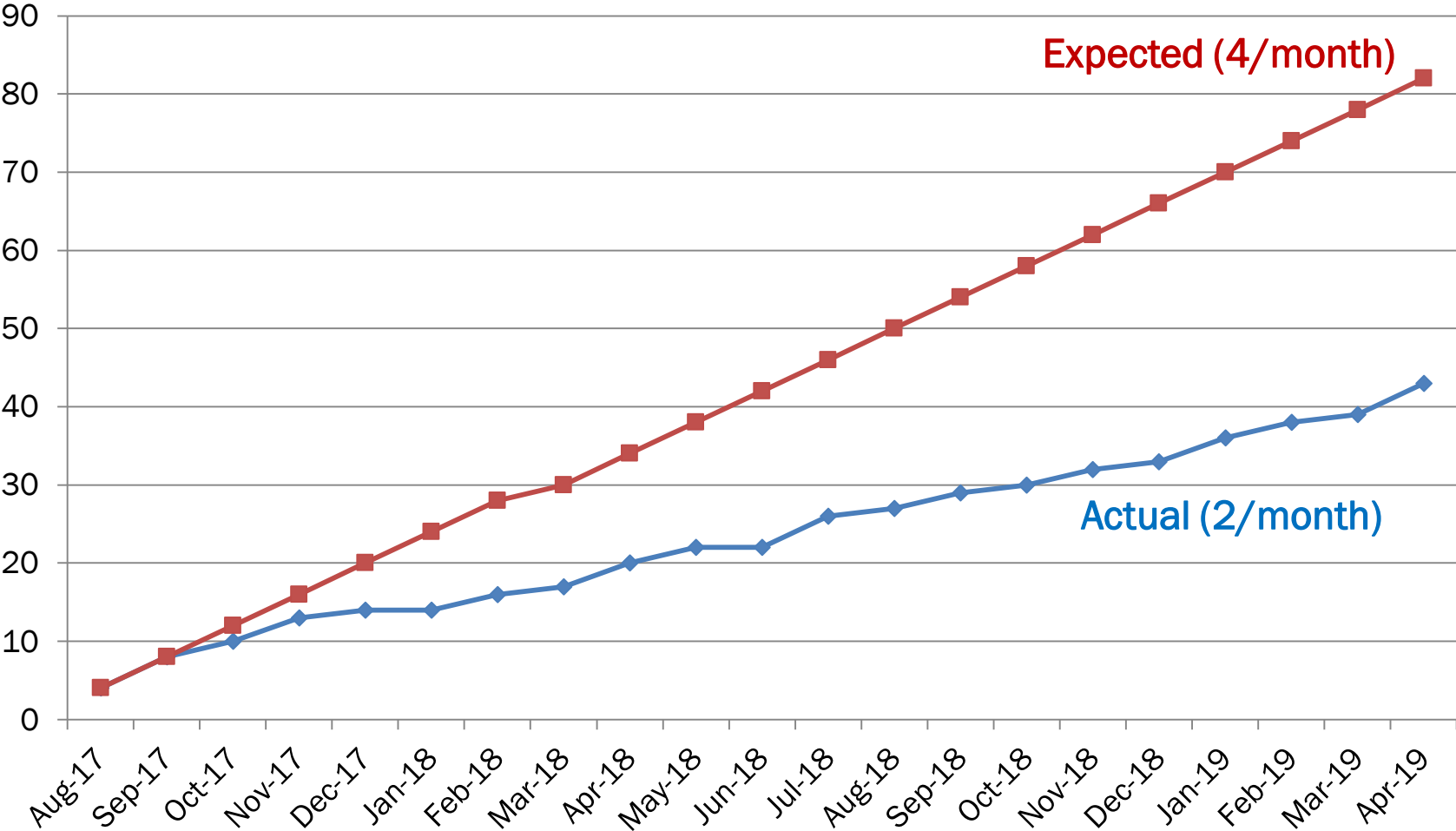
Study outcomes

- **Primary outcome:** Late-Life Function and Disability Instrument-Computer Adaptive Test (LLFDI-CAT)
- **Secondary outcomes:**
 - Short Physical Performance Battery
 - 2-minute walk distance
 - Dominant handgrip strength
 - Adherence (only for home exercise +/- CBT group)
 - Adverse events
 - Self-efficacy / outcome expectation
- Evaluation by an independent assessor at week 4 and 8

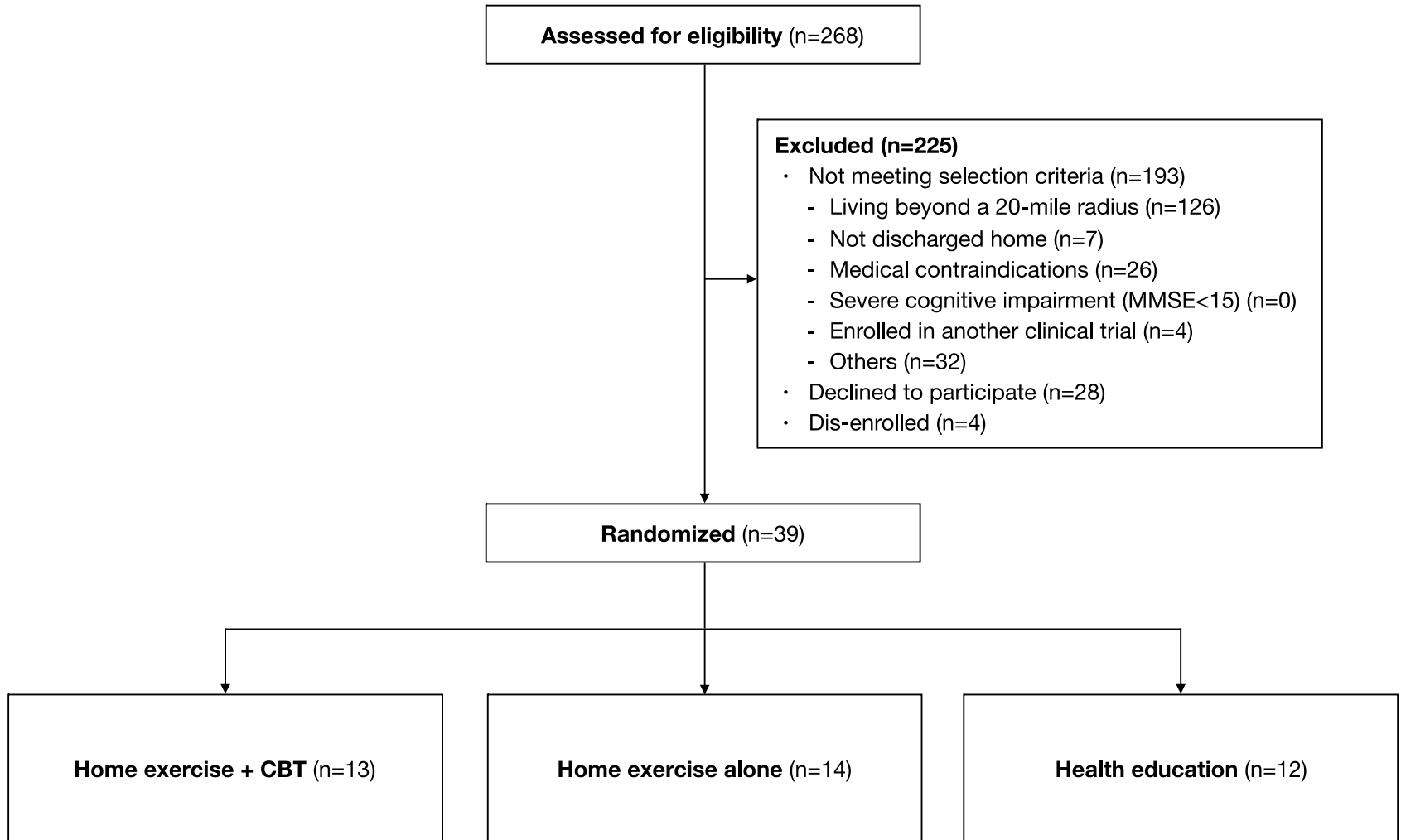


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Recruitment start: August 1, 2017



CONSORT diagram



Baseline characteristics

- Mean age: 84 years (maximum: 97 years)
- Female: 37%
- White: 93%
- Mean MMSE score: 26.4 points
- Mean gait speed: 0.43 m/sec
- Mean LLFDI score:
 - Activity limitation: 53.6
 - Participation restriction domain: 47.8



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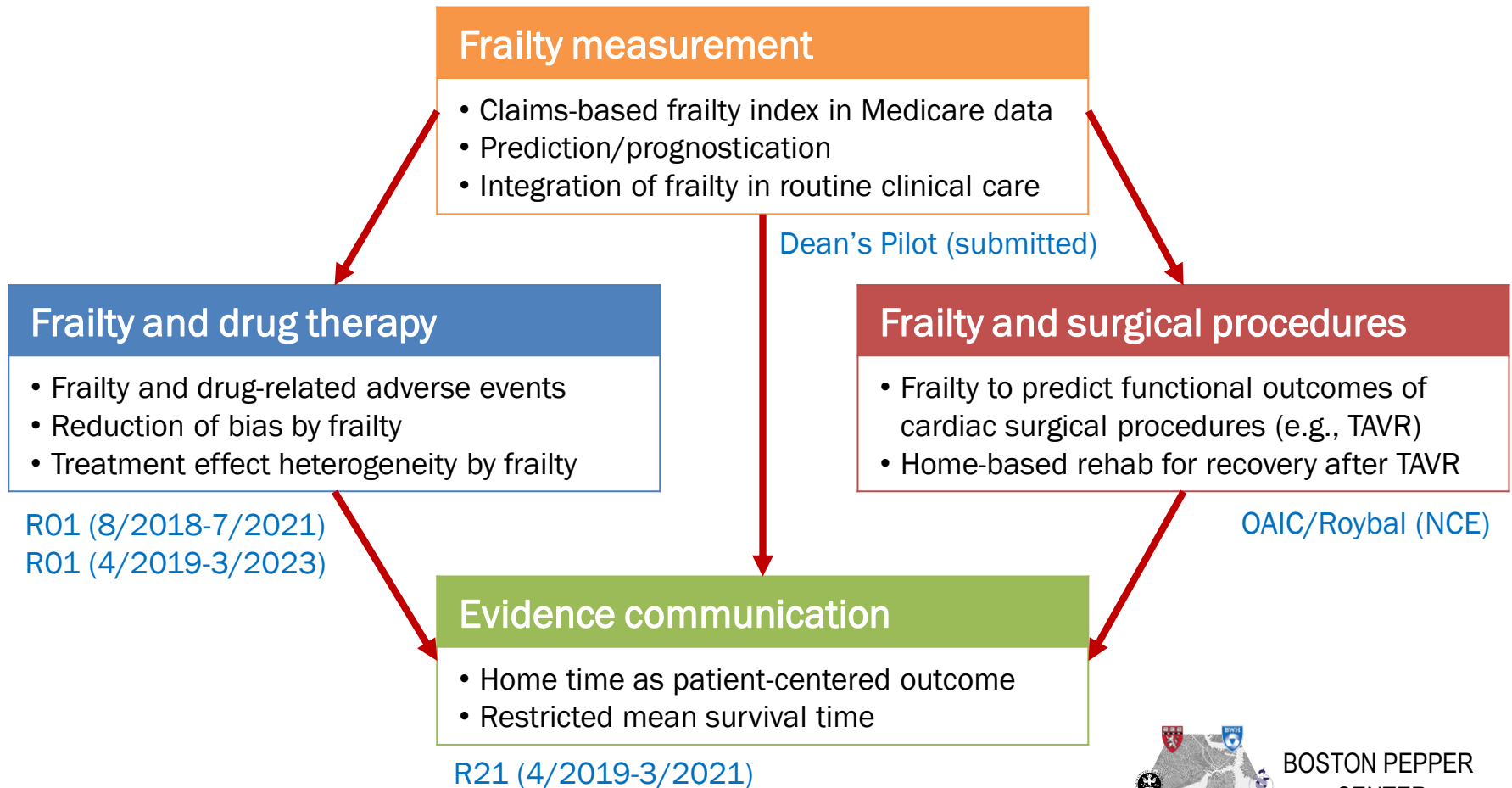
Next steps for REHAB-TAVR study

- Enrollment: 2 per month (half of the expected rate)
 - BWH cardiac surgery was added as another site.
 - IRB approved in April 2019
 - Expected date of enrollment in May 2019
- Drop-out: 29 of 39 randomized participants completed
 - 7 withdrew consent and 3 discontinued from the study due to AE.
 - May need to extend enrollment to 75 total (from 60 planned)
- Expected completion: December 2019
 - R01 in June 2020 (?)



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Career goal: frailty and outcomes research



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Career trajectory

- Research grants
 - 2 R01s and 1 R21 from NIA
 - HMS Dean's pilot (submitted): incorporating functional assessment in routine primary care
- Leadership in professional societies
 - AGS/ACC geriatric cardiology collaboration
 - ISPE geriatric pharmacoepidemiology
- Clinical expertise: Pre-TAVR geriatric assessment
- Mentoring



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