Recruitment and retention rates in a randomized controlled trial of virtual rehabilitation for individuals with long COVID

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Introduction

- After COVID-19 infection, many patients suffer from persistent disabling symptoms including mobility problems, dyspnea, and fatigue.
- Preliminary data from our group shows that at 12-months post- discharge, 46% of patients post COVID-19 report clinically important deficits in mobility compared to baseline as measured by the Activity Measure for Post-Acute Care (AM-PAC).
- This emerging data suggests that these patients will likely benefit from a rehabilitation intervention, also recommended by many international respiratory societies but there is a paucity of evidence to support the effects of rehabilitation in this population.

Objectives:

To describe the recruitment and retention rates in an ongoing randomized controlled trial of virtual rehabilitation for individuals with long COVID.

Methodology

- Study design: Data extracted from an ongoing assessor-blind randomized controlled trail (RCT), people living with long COVID in the provinces of Quebec and Ontario.

Inclusion Criteria	Exclusion Criteria
1. Individuals with confirmed/ probable COVID-19 infection 2. Persisting symptoms of either reduced mobility, muscle weakness, dyspnea, or fatigue; 3. Technologically capable of connecting with an online videoconferencing platform	1. Pre-existing or newly identified severe cognitive impairment; 2. Inability to comprehend English or French 3. Known or self-reported acute and/or uncontrolled cardiac, musculoskeletal, or neurological condition that might render rehabilitation participation unsafe

- Consent and assessments are executed on an online videoconferencing platform and Research Electronic Data Capture system (REDCap: for filling the questionnaires). After pre-assessment, participants were randomized in a 1:1 allocation ratio to either:
  1. Intervention group: 8-week virtual home-based physical rehabilitation + usual care

     Before and after every session, participants are assessed for Post-exertional malaise (PEM), considering which the exercise session is designed. We are also considering the Adverse events occurring during the intervention period.

  2. Control group: Usual care (a set of written generic instructions that guides them on how to manage their symptoms and engage in physical activity)

Table 1: Phase-out design of the exercise sessions, followed for the intervention group

Week	Supervised session (40 minutes each)	Independent session	Educational	Exercises
Week 1-2	3 sessions/ week	0 session	10 minutes in first session	Aerobic, UE*+ LE# strengthening, Balance, Flexibility
Week 3-4	2 sessions/ week	1 session/ week		
Week 5-8	1 session/ week	2 sessions/ week		

*upper extremity (UE) #lower extremity (LE)

Outcome measures of the RCT:

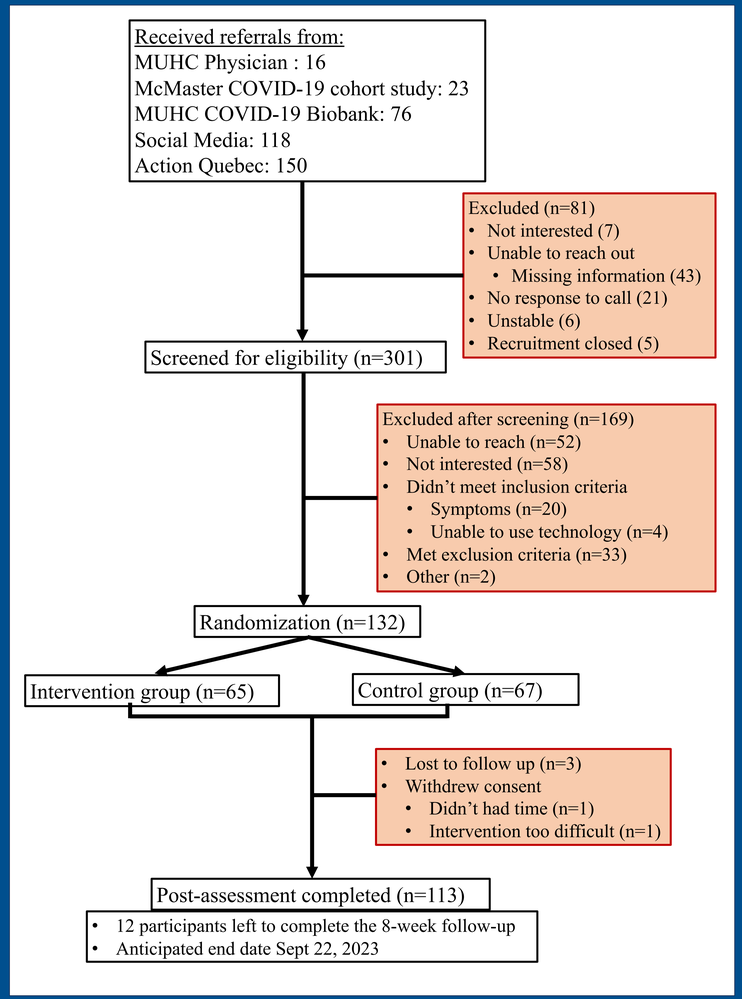
Primary outcome: Activity measure for Post acute care(AM-PAC) mobility scale.

Secondary outcome: One minute Sit-to-Stand, fast Time-up and go, Fatigue scale, Transition dyspnea index, Quality of life questionnaire, Hospital anxiety and depression scale, AM-PAC cognition scale, Post-traumatic stress disorder, and use of health services.

Recruitment Strategies

Study participants from the ongoing RCT on "Virtual physical rehabilitation for patients living with long COVID", sourced from:

- McGill University Health Center (including COVID-19 clinic)
- Québec Action for Post-COVID Study
- McGill University Health Center COVID-19 Biobank
- McMaster COVID-19 cohort study
- Social Media (Sharing templates on Twitter, Facebook, LinkedIn, Radio)



Results

- In a period of 12 months, 301 individuals living with long COVID symptoms presented interest and were screened for eligibility for the RCT.
- The desired sample size of 132 subjects were recruited and randomized to the intervention (n=65) or to the control group (n= 67).

Table 2: Recruitment and the retention rates

	Rate (n%)
Recruitment Rate*	69.47%
Retention Rate**	95.83% (5 drop-outs) (12 participants under the intervention period)

Table 3: Drop-outs and loss to follow up

	N=5
Loss to follow up	3
Drop-out	
1. Intervention was too difficult	1
2. Not enough time	1

**Recruitment rate was calculated as the proportion of people randomized/proportion of people eligible.*

***Retention rate was calculated as the proportion of people providing the outcomes of interest/proportion randomized.*

Conclusion

In our study, 7 in 10 eligible people with long COVID were randomised to our rehabilitation RCT, of which 9 out of 10 (12 still within the 8-week study period) provided end of treatment outcomes. This proposed study is a crucial component of our ongoing longitudinal randomized clinical trial.

Partners

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