Research Protocol and Study Design

*Virtual models for delivery of exercise training in CF: an evaluation of patient engagement and feasibility*

Title:  
Virtual models for delivery of exercise training in CF: an evaluation of patient engagement and feasibility.

Aim:  
Pulmonary rehab is already a well-established treatment modality for patients with chronic respiratory disease. Traditionally, it has been offered in a face-to-face class environment however due to the risk of cross infection, this cannot occur in a CF population. While there is research supporting the benefits of a pulmonary rehabilitation program virtually, this has not been explored with this demographic of patients.  
  
Subsequently, the aim of this study is to evaluate the feasibly and patient engagement with two models of interactive online exercise classes to deliver and promote exercise in adults with Cystic Fibrosis, and patient perceptions of this intervention.  
  
Key Question:  
Are virtual modes of pulmonary rehabilitation effective for patient engagement in the CF population at The Prince Charles Hospital?  
  
Is the level of engagement achieved different for a standard pulmonary rehabilitation model as compared to a self-paced package?  
  
Background:

Physical activity is recognised as an essential component of maintenance of respiratory health in cystic fibrosis (CF), and delivery of exercise education is a critical component of physiotherapy care. 1,2,3. Reduced exercise capacity is associated with a decline in respiratory function and survival in people with CF 4,5. In both short and long-term studies, regular exercise has been demonstrated to decrease the annual decline in lung function in people with CF 6, 7,8, 9. Continued innovative approaches to prompt both exercise and activity participation and adherence at home for adults with cystic fibrosis is required. Group based exercise training is established as the gold standard in people with COPD resulting in reduced symptoms, improved quality of life outcomes, increased exercise capacity, reduced exacerbations and the prevention of hospital exacerbations 10,11 The current COVID-19 pandemic has already prompted a shift to ‘virtual’ models of care delivery within CF centres. People with CF are currently, and for the foreseeable future, receiving decreased routine face to face outpatient appointments at hospitals. This current change to care delivery minimises opportunities to offer exercise training for this cohort of patients.

Home based tele-rehabilitation group exercise programs have been shown to improve exercise capacity in patients with COPD 14, 15 and other chronic diseases 16. A systematic review of telehealth in cystic fibrosis highlighted the potential to provide both physical activity and exercise programmes 18. Exercise sessions of 30 minutes, three times a week over six weeks offered via a virtual platform to children with CF demonstrated participation rates of 85% 17. The program was found to be a convenient and accessible method of encouraging physical activity and participants reported positive feedback regarding joining a group supervised class. 17 Tomlenson et al ( 2019) examined the feasibility and acceptability of online exercise sessions using telehealth in nine adults with CF to engage patients in individualised exercise programs 2 -3 times a week 20. The participants successfully participated in the classes, rating satisfaction with the virtual training at 9/10, while compliance with sessions was 68%.20, 21 Whilst these studies suggest that online training is feasible, questions remain regarding the applicability of the outcomes to the cohort of patients provided with care by TPCH Adult Cystic Fibrosis centre (ACFC). The large number of patients receiving care by this centre (over 300) is prohibitive to offering all patients individualised exercise classes.

Delivery of 1-on-1 exercise training is labour intensive and expensive. Rapid improvements in survival of people with CF is expected to result in increased demand on physiotherapy services, which will outstrip service capacity. Consequently, alternate, scalable models of delivering exercise training are required. In establishing the effectiveness of these models, use of these exercise templates and resources can be used to facilitate a shared-care model and best clinical care across regional and rural CF centres that are less resourced.

The Adult Cystic Fibrosis centre (ACFC) at TPCH provides care to the most geographically dispersed CF population across Australia. Patients serviced by this centre live across Queensland, the Northern Territory and Northern New South Wales. This geographical dispersal imposes a significant challenge to our ability to provide equitable care to regional patients compared to individuals in South East Queensland. Developing tele-based exercise classes enhances accessibility for all patients and may address inequity of care delivery.

Exercise and physical activity are essential components of cystic fibrosis physiotherapy care. The provision of Tele-exercise classes has the potential to deliver supervised group exercise while mitigating the problem of cross-infection. The opportunity exists to examine different delivery methods using the virtual platform to determine feasibility and patient preference and guide long term implementation of virtual exercise training for adults in a large adult CF centre. If this mode of intervention is deemed feasible and successful, the exercise template may be disseminated to regional centres for a shared care model and replication.  
  
Study Method: *Design*Observation, cohort study.  
  
*Participants*Recruitment to occur through direct approach during clinical consultation and advertisements through TPCH ACFC Facebook page.  
  
As this is a pilot study, a convenience sample size of 12 patients to each exercise group will be recruited.  *Consent*The principal investigators will review the cohort of patients serviced by *The Adult Cystic Fibrosis Centre* and discuss with medical staff where necessary for identification of patients to be included in the study. Eligibility will be ascertained, and patients will be provided with information about the research study. Patients deemed as capable of consent and agreeable to be involved in the study will be consented. If the patient is unable to, the next of kin will be asked to provide consent on their behalf, should they meet criteria for inclusion.  
  
If at any time, the patient wishes to withdraw from the study, data collection and involvement in the program will be ceased.   
  
Consent forms have been attached.

*Inclusion criteria*- Patients >18 years of age serviced by the ACFC at The Prince Charles Hospital with a diagnosis of gene confirmed cystic fibrosis.  
- RFT’s 30-70% predicted FEV1  
  
*Exclusion criteria*  
- Patients <18 years of age  
- Severe pulmonary disease (RFT’s <30% FEV1)  
- Mild pulmonary disease (RFT’s >70% predicted FEV1 )  
- Use of domiciliary oxygen therapy  
- Unable to perform exercise as determined by the medical and/or physiotherapy team  
- Death is deemed imminent or the patient is actively being palliated  
- Patients/NOK on patients behalf do not consent to participate

*Study Design*Timeline:

Eight weeks of study intervention.

Week 1: Pre exercise demographics and baseline measures (via video calls)

Week 2 -7: Training/attendance  
Week 8: Post exercise demographics and outcome measures (via video calls)

Additional feedback Questionnaire (developed with local research and development team - Metro North Engage Team). Focus of feedback will be to assess demand, implementation (study and session completion), practicality (technical issues) and acceptability of training modes and the virtual platform (participant feedback).

2x week 40-minute exercise class.

All participants encouraged to complete a **minimum** of a third session independently.

Sessions will follow the format:   
- Warmup  
- Interval based aerobic and body weight strength exercises  
- Cool down/stretching

*Group A*

Streamed real-time class format (maximum 6 participants per class, 2 classes)

\*Cisco Jabber platform currently available to TPCH (Telehealth Virtual Clinic -latest version/multiple users) allows live interaction between the instructors and participants

*Group B*

2 x pre-recorded video classes per week to be used at home by participants. Titrated up to increase intensity each week  
  
Outcome Measures:  
  
*Primary*- Number of exercise sessions completed   
- Patient satisfaction   
  
• Survey developed with local research and Metro North Engage Team.   
• Focus of feedback will be to assess demand, implementation (study and session completion), practicality (technical issues) and acceptability of training modes and the virtual platform (participant feedback).   
• Combination of Likert scales and open-ended questions. Example questions may include: What was your most/least favourite part of the program and why? Would you participate in a similar program again? What type of changes have you seen because of the program, if any? How has the program helped you?

*Secondary*- Survey a/a  
- Modified BORG scale  
  
*Statistical Analyses*The key statistics are differences in patient engagement correlated with the model of virtual pulmonary rehab in which they are allocated. Data will undergo analysis and interpretation by the principal investigators and statistician using parametric/non-parametric statistics as appropriate. Between-group comparison of categorical data will be performed using Chi square or logistical regression and comparisons of the data will be made. Descriptive statistics will quantify all outcomes pre and post the exercise intervention. Pairwise comparisons will be made for all measures (3min step test, RFT, HR-QoL) pre and post the exercise intervention. Results will be accepted as statistically significant at p< 0.05.

Descriptive analysis of the post quantitative questions will be performed. Responses to open ended questions will be coded and organised, and a thematic analysis will be conducted to identify themes about the feasibility and acceptability of the programs to the participants.  
  
As this is a pilot, feasibility study, it is difficult to calculate an appropriate sample side required to effectively power it. Therefore, this proposal is using a convenience sample of 12 patients assigned to each virtual mode that are likely to be recruited during the study period.   
  
*Risk*  
It is acknowledged this patient cohort regularly engages in physical activity and exercise independently at home, without monitoring being undertaken. Patients that may be moderate-high risk of an adverse event occurring will fulfil the exclusion criteria and will not be considered for participation in the study.   
  
All patients that meet the inclusion criteria are considered to be low risk.   
  
Slight discomfort is the only anticipated risk due to an increase in work of breathing or transient dyspnoea during exercise. This risk will be minimised by providing the patient with the option to cease assessment if brief shortness of breath is distressing and to self-pace throughout the exercise session. This will also be monitored using the Modified BORG scale.  
  
As the patients are exercising at home, the external environment will be uncontrolled. Patients will be advised to clear an appropriate space for the exercise session and to remove any trip/slip hazards from the area that may pose a risk. Standard safety instructions will also be provided. Below is an excerpt of the script used at the beginning of each workout.   
  
*“ Hi and welcome to our online pulmonary rehab program. Before we get started with the workout today, if you have had any significant changes to your ongoing CF management or usual symptoms, please contact and discuss with the CF physiotherapists prior to completing this workout.   
– This workout will not require any equipment, however you may want to use a pilates mat or towel during the exercises. In doing this, please check your surroundings and the environment that you are doing the workout in to ensure there are no trip or slip hazards and you have adequate space to complete the exercises.   
– During the workout, we will also go through modifications to some of the exercises. Please choose an appropriate level for your ability. If at any time you are unable to continue due to shortness of breath or fatigue, please stop, rest and re-join as you are able. These exercises should be self-paced, using the team members in the video as a guide for pacing only. The workout is also available to you to be printed off if you would like a hardcopy to follow along with.   
– Before starting the workout, please ensure you have a water bottle to remain hydrated throughout and after the exercise session. You can use Glucolyte in 600mLs or Gastrolyte in 250mLs or as specified by your CF dietician or pharmacist to aid in your hydration.****–*** *Please participate in the workout in its entirety, including stretching in the warm-up and cool down to reduce the risk of any injuries occurring. In the event of a medical emergency, dial 000”*  
  
*Benefit*Hospitals with a CF patient cohort would benefit from introducing virtual telehealth classes as it may aid reducing the number of pulmonary exacerbations and subsequent hospital admissions as a result. Consequently, this would result in reduced heath care costs and burden on the health care system, as well as freeing up relevant, valuable resources. Ultimately it will benefit the patient by reducing complications and morbidity rates, and improving quality of life and reducing the number of admissions. In establishing the effectiveness of these models, use of these exercise templates and resources can be used to facilitate a shared-care model and best clinical care across regional and rural CF centres that are less resourced.  
  
*Limitations*The study is reliant on participants providing accurate feedback in response to survey data collected which cannot be objectively assessed. It therefore can be considered a limitation of the study.

Outcomes and Significance:  
  
Physical exercise and exercise prescription remains an essential component of maintenance therapy for patients with cystic fibrosis. Infection control is a significant factor in limiting class participation by this patient cohort. By establishing the level of engagement in virtual modes of exercise delivery, treatment can be provided to these patients with increased efficiency and efficacy. Continuum of care will be enhanced and engagement with physiotherapists maintained to optimise lung health. Consequently, this may reduce the number of exacerbations experienced by patients, improving quality of life and potentially avoiding the need for a hospital admission.   
  
Successful completion of this project will inform the development of a virtual exercise program, which will then be evaluated for its ability to improve physical conditioning in people with CF and influence disease trajectory.   
  
If this mode of intervention is deemed feasible and successful, the exercise template may be disseminated to regional centres for a shared care model and replication.

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