Study Protocol

Title of the Study: The effectiveness of Azerbaijani National Dances on Cardiorespiratory Fitness and Quality of Life of Older Adults with Chronic Heart Failure Diagnosis

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Background. According to the Global Burden of Disease Study (2017) 64 million people worldwide are living with Heart Failure (HF). Risk factors of HF include age, history of coronary heart disease, atrial fibrillation, hypertension, diabetes mellitus, smoking and low physical activity. Physical Activity and exercise training is considered as one of the components cardiovascular disease prevention and rehabilitation program. Despite of strong evidence of the positive effects of exercise training in Chronic HF patients, the adherence to the exercise component of CR is still not at the level recommended by the international physical activity guidelines. World Health Organisation defines dance as a type of physical activity and recommends its implementation to develop physical skills, especially in the least active population groups. However, use of traditional dancing in general, and Azerbaijani dances particularly, as an intervention in CR programs has not been well established. More research on the use of the cultural dancing as an alternative to traditional exercise programs as a part of CR could provide clearer evidence about the role and effectiveness of traditional dance in CR. The aim of this research is to investigate the impact of Azerbaijani Cultural Dances on cardiorespiratory fitness and quality of life of patients with chronic HF.

Methodology. The study is going to be designed as a randomized-controlled trial. Participants will be randomized using studyrandomizer.com program which is recommended to use for small studies with up to few hundred participants. Three arm design will be undertaken with experimental 1 (dancing, DG), experimental 2 (exercising, EG) and control (CG) groups.

Inclusion Criteria

- Minimum Age: 65 Years
- Maximum Age: 85 Years
- Sex: All

Key Inclusion Criteria:

- Echocardiography detected ejection fraction - 40-49% to justify the heart failure

- Age between 65-85.

Exclusion Criteria:

- Age below 65
- Ejection fraction less than 40% and higher than 49%
- Structural changes of the myocardium (aneurysms, scars, valvular diseases).
- Signs of pleural or pericardial effusions
- Clinically manifested comorbidities (unstable angina)
- Uncontrolled Cardiac Arrhythmias

Intervention Design.

Dancing. Dance sessions will be delivered by the professional dance instructor who trained to work with older adults. Exercise session – by physiotherapist who is trained and has a bachelor's degree in Sport and Exercise Science. Considering that sessions are going to be conducted with one MD and one Nurse on site, 5-7 participants per each session are permitted for the easy observation and help in case of necessity. Only one dance/exercise instructor will attend the session. Certified MD and nurse will observe the whole session. They both BLS and AED application trained. There is an EAD on site. Lab staff is instructed about contact details of Ambulance and Emergency services. The nearest Ambulance station is in 3 minutes driving distance. Each dancing session will consist of three phases: 15 min warm-up, 30 min dance/exercise session, 15 minutes cooldown period.

Exercising. Exercise sessions are going to be designed based on the 2020 ESC Guidelines on sports cardiology and exercise in patients with cardiovascular disease. According to the exercise recommendations in individuals with chronic heart failure, session will consist of aerobic/endurance exercises with low intensity about 40% of VO2 peak. This will continue for about 2 weeks. After 2 weeks the intensity will be gradually increased to 50-65% if tolerated with aiming to reach 70-75% by the end of the 12th week. In addition to the aerobic/endurance training, resistance training exercises will also be added to the structure of the sessions (the intensity level will be kept the same as with aerobic). Warm-up is going to start with very low intensity aerobic/endurance training. Cool-down is stretching exercises and respiratory exercises (10-15 minutes).

Before and after each session blood pressure, resting HR and oxygen saturation will be measured. HR will be monitored during intervention sessions using the Polar belts. In addition, Rate of Perceived Exertion (RPE) will also be used to observe the level of participants' exertion. MD and Registered nurse will take all measurements before and after each session.

Control group participants will be asked to maintain their normal lifestyle during the 12-week period, including physical activity and social interaction patterns. Participants in the control group will undergo the same pre- and post-intervention procedures at T-0 and T-12.

Primary Outcomes:

1. VO2max (CPET, https://pmc.ncbi.nlm.nih.gov/articles/PMC8319417/)

2. QoL (MLHFQ, https://pmc.ncbi.nlm.nih.gov/articles/PMC4756518/).

Secondary Outcomes:

1. Fall risk (Biodex Balance, https://pmc.ncbi.nlm.nih.gov/articles/PMC4998885/)

2. Muscle strength (Handheld Dynamometer, https://pubmed.ncbi.nlm.nih.gov/37060020/).

Statistical Analysis Plan (preliminary)

1. Tests to determine assumptions that data meets parametric status
2. Two Factor Analysis of Variance (ANOVA)

- Factor 1 = Within-participant differences between pre and post CR
- Factor 2 = Between Groups Difference for changes in CRF measures pre to post CR

3. If there is a significant difference between the 3 Groups, a Post-Hoc test to see where the significance lies (e.g

a. between control & exercise,

b. between control and dance, and

c. between exercise and dance)

- This may require an adjustment in reducing the level for setting statistical significance (normally $p < .05$ is used) but because we will have had to perform 3 post-hoc tests this means the level for significance threshold would need to be re-set to $p < .02$ (=.05/3)

Ethical approval

Research is approved by the Ethics Committee of Azerbaijan Sports Academy (ASA) Research Ethics Committee Protocol N: 3-19-14/ 2-818-R-02/2024.
UCL Research Ethics Committee Approval ID Number: 1382