

**The study protocol of APP rehabilitation management and evaluations of cardiopulmonary function and motor development in infants with congenital heart disease**

**August 13<sup>th</sup>, 2022**

## • Participants

Home-based rehabilitation of CHD patients was a randomized controlled trial conducted at Beijing Children's Hospital in the year of 2021-2022, aimed at evaluating the prognosis of growth developmental and cardiopulmonary function in CHD infants (aged 4-8 months) with atrial septum defect (ASD) or ventricular septum defect (VSD). Patients with chromosomal abnormalities and family history of mental retardation; small for gestational age and prematurity; history of perinatal asphyxia and hyperbilirubinemia; history of central nervous system disease or imaging suggestive of brain dysplasia were excluded. This pilot study protocol was approved by Capital Medical University; Beijing Children's Hospital. All study volunteers provided written informed consent.

## • Study design

Eligible participants were randomized by a 1:1 allocation ratio by computer either to the recovery group or control group. Upon initial enrollment, weight, height, body mass index (BMI), LVEF was counted, and the developmental evaluation was conducted in both groups before surgery. We recorded their Alberta and Developmental quotient (DQ) including 5 scale zones, changes of real-time HR during tests. To be specific, resting HR, HR in 1,3,5,10min (Max HR) during exercise was captured, and also being recorded 3,5,7min after the assessing test. By simplifying the data of HR, we calculated their rHRI at 3,5,10min; while rHRR at 3,5,7min after exercise and define the mean value as their final indicators<sup>11</sup>:  $rHRI_{(x)min}=(HR_{xmin}-HR_{resting})/X$ ;  $rHRR_{(x)min}=(HR_{xmin}-HR_{Max})/X$ . In contrast to rHRR, rHRI is negatively correlated with VO<sub>2</sub>max. A fast rHRI and slow rHRR represent poor aerobic endurance<sup>11</sup>. All assessments were repeated at 1, 3 and 6 months after the surgery.

## • Procedures

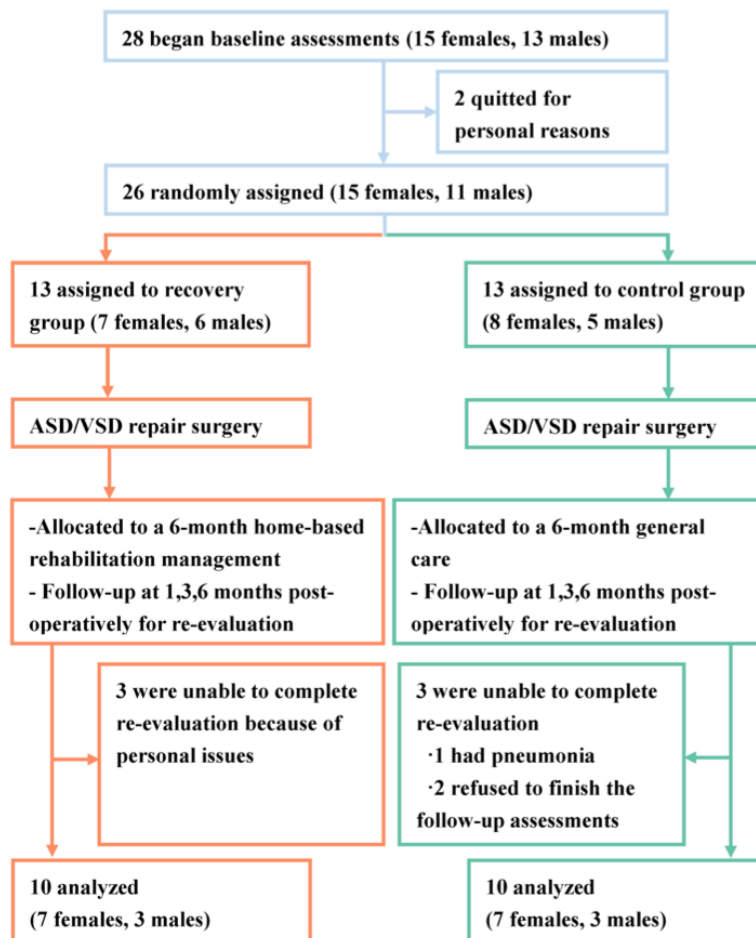
LVEF were recorded according to preoperative cardiac ultrasound results. Alberta test and Neuro-intelligence Scale were performed by doctors from

healthcare department before surgery. While exercising, the patients' resting HR, rHRI and rHRR were monitored by a wearable device in real time. For the recovery group, parents were told to keep this device to connect with our

Rehabilitation Management APP on their cellphones, signed up and created a file for their children. This application, which developed by Wenxin Technology, provided a platform for two-way feedback between patients and physicians. Parents were instructed to upload children's information of each-time training at home. Remote data transmitted the ultrasound result, Alberta and DQ, customized advice for exercising to each patient's account. At the same time, doctors could also monitor the training status individually. The inner page includes home care guidance for CHD children, feeding recommendations, exercise instructions, immunization advice, etc. One month after surgery, there were no specific training plans for all patients. Different training regimens were created for each of patients in recovery group between 1-3 months and 3-6 months following the procedure in accordance with the findings of the developmental evaluation and cardiac ultrasound. Parents were told to assist their children with certain exercises and complete a set amount of training time. Adverse events like sweating, cyanosis and dyspnea were noted. Training motions included sitting balance, hand support, crawling and squatting training<sup>12-14</sup> were scheduled for 1 to 3 months postoperatively, moreover, climbing over obstacles was for 3 to 6 months. Defining that primary endpoint as the baseline-to-six-month difference in cardiopulmonary capacity and physical fitness between the recovery and control group.

## **Statistical analysis**

Student *t* and Wilcoxon tests were used to evaluate between-group differences with respect to baseline characteristics. A *p* value of 0.05 was considered significant for all tests. Repeated measures ANCOVA was applied with change from baseline as the dependent variable, and recovery intervention, time, the rehabilitation multiplied by time interaction as independent variables. Moreover, Spearman test was also applied to find out the correlations between LVEF and rHRI, rHRR respectively. All analyses were performed by using the R language (Version 3.6.3).



Flow diagram of study participants